



Empirica™

The Comprehensive Answer for Today's Safety Challenges

The Empirica Suite:

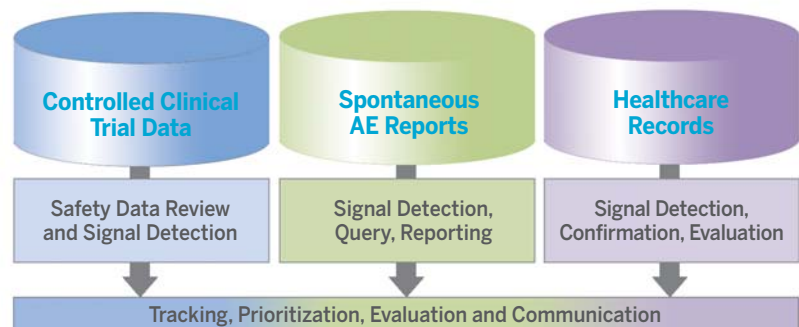
- Designed to meet the increased regulatory and business demands facing today's safety professionals to make product decisions based on a full range of empirical data
- A comprehensive suite of advanced tools for pharmacovigilance and proactive risk management throughout the product life cycle
- Addresses immediate safety reporting and exploratory analysis needs as well as longer-term risk management expectations
- Built to leverage a wide range of safety data sources, from clinical trials to spontaneous reports to healthcare data
- Intuitive user experience for unrivaled access to all available data sources
- Flexible, visual, Web-based applications
- Easy navigation with multiple levels of drill down from summary and aggregate data displays to micro view of individual patient data
- Topic Tracker for managing information about important safety issues
- Integration with Phase Forward's InForm™ GTM electronic data capture platform and Waban Statistical Computing Environment (SCE)

Phase Forward's Portfolio of Solutions for Life-cycle Product Safety and Risk Management

Phase Forward's Empirica™ Suite of innovative pharmacovigilance and risk management solutions provides Adverse Event Reporting, Data Mining, Signal Detection, Evaluation and Management capabilities that help companies identify potential safety problems and manage risk effectively across the full product life cycle. The Empirica Suite was designed to help companies manage their pharmacovigilance activities strategically over the long term. Use of the Empirica Suite can help transform uncertainty into knowledge and improve visibility into all of the available data sources.

The Importance of Life-cycle Product Safety

Heightened political and regulatory oversight together with pragmatic business requirements have magnified the need to improve patient safety and manage risk more proactively from product development through post approval. Sponsors are compelled to have a thorough knowledge of a product's safety profile using all of the resources available to them, including clinical trials, spontaneous reports and, increasingly, healthcare data.



Each of these data sources has its own advantages and disadvantages, but all are important to the thorough life-cycle management of product safety and risk. A signal may be detected from any source, such as spontaneous report data, which may trigger the need to go back to see if early indicators could be found in clinical trials data, and then explored in healthcare data to see if the signal can be strengthened, confirmed or explained. To effectively manage the challenges of identifying, evaluating and responding to signals that could originate from many empirical data sources, today's safety experts need an extraordinarily powerful and flexible suite of tools. This is the rationale behind Phase Forward's Empirica Suite.

Empirica™ Trace

Adverse Event Management

Phase Forward's **Empirica Trace** product is designed to provide control over adverse event tracking and reporting requirements for drugs, devices, biologics and vaccines, providing required documentation for regulatory agencies in the US, Europe and Japan. Core capabilities include automated global report distribution based on pre-defined rules to ensure you get the right report to the right recipient on time. Empirica Trace covers the entire end-to-end process including triage entry, duplicate checking, advanced search and report distribution. It also includes the Reporting Workspace—a feature-rich, visual ad hoc reporting environment. The Empirica Trace product includes advanced automation functionality designed to help you gain control over the complexity of your adverse event reporting requirements.

Empirica™ Gateway

E-Submissions

The **Empirica Gateway** electronic case submission product automates the submission of safety reports to regulators, affiliates and trading partners, adhering to specifications established by ICH, EMEA, PMDA and FDA, including the FDA's latest Electronic Submission Gateway (ESG) standards.

The Empirica Gateway software is a centralized, Web-based application that enables secure business-to-business (B2B) communications for sending, receiving and tracking the electronic submission of individual case safety reports (ICSRs) for an organization.

Empirica™ Study

Clinical Trials Signal Detection

Empirica Study, the latest release of the award-winning CTSD Clinical Trials Signal Detection product developed by Phase Forward's Lincoln Safety Group, provides a dynamic, visual data safety review environment for detecting signals in clinical trials data in CDISC SDTM format. The Empirica Study product helps sponsor safety reviewers explore and improve their understanding of the most critical fundamental safety concerns that drive regulatory reviewers when examining product licensing applications.

Empirica™ Signal

Data Mining and Signal Detection

Empirica Signal, formerly known as WebVDME, is Phase Forward's award-winning tool for quantitative signal detection and signal management for use with spontaneous report data. The Empirica Signal product provides a dynamic, visual data mining environment for detecting signals, uncovering patterns and recognizing emerging trends. Empirica Signal's Topic Tracker and workflow facility allow safety experts to create records including analyses and documentation of relevant topics—both internal and external to the Empirica Signal environment.

Signal Management

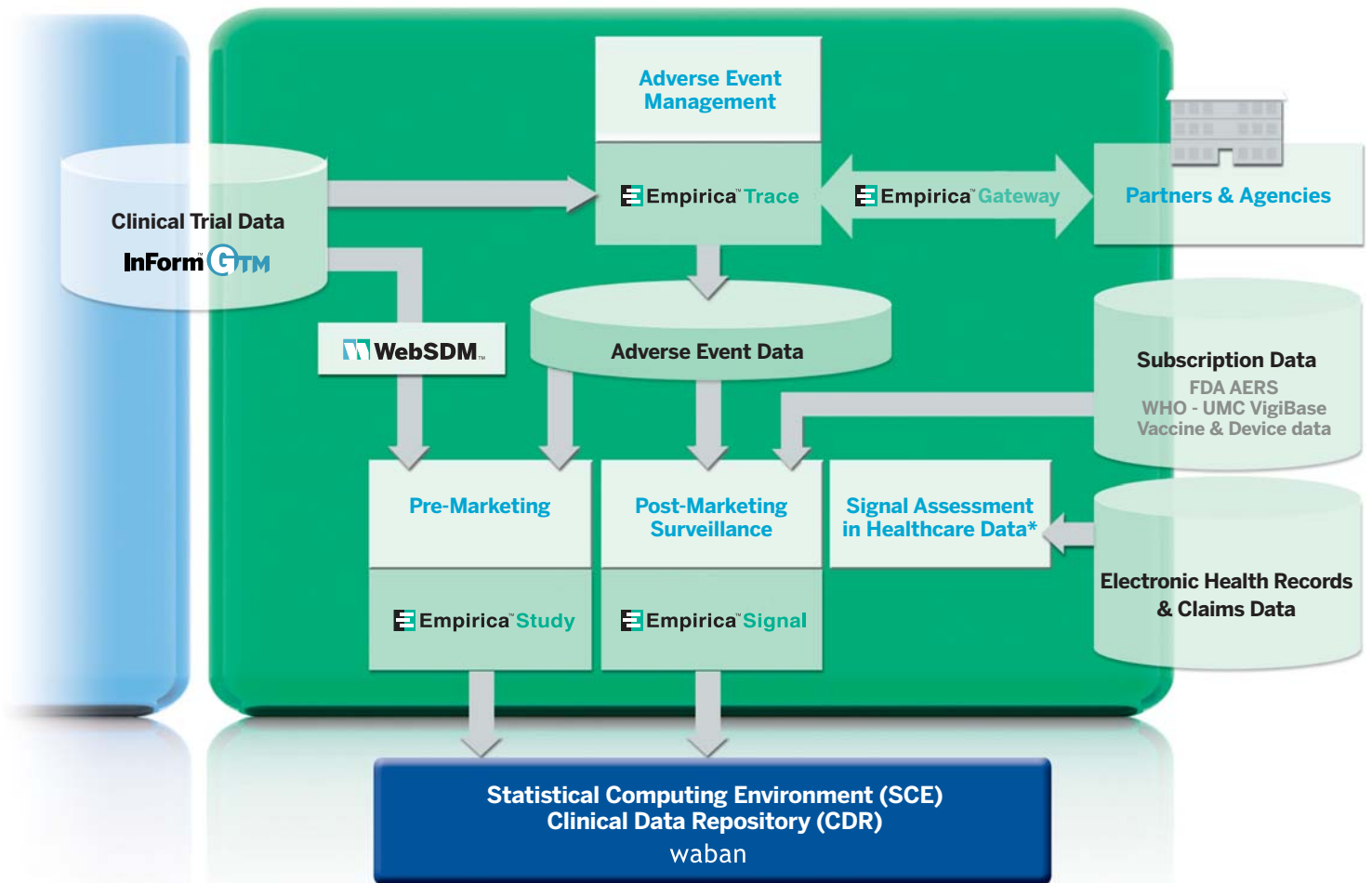
Empirica Signal's Signal Management function integrates the product's powerful features into an organization's routine safety review processes, so they can better manage safety information as it accumulates and changes over time.

*Signal Assessment in Healthcare Data

A pilot is in use by the US FDA and Department of Defense using DoD healthcare data for approximately 12 million patients. This pilot is designed to apply many of the tools and techniques developed for other Empirica products in the vast arena of longitudinal electronic healthcare records and claims databases. It has also been designed to work with a variety of publicly available medical records and claims databases.

The Empirica Suite: A Complete Technology Solution for Today's Safety Professionals

Phase Forward's complete solution for pharmacovigilance and risk management includes Empirica Study for signal detection in clinical trials, the Empirica Trace adverse event management system with Empirica Gateway for case reporting of expedited and spontaneous reports, and the Empirica Signal product with Signal Management to identify, explore, visualize, manage and track the evolution of safety signals in public and proprietary spontaneous report databases.



Using the Empirica Suite with Waban SCE/CDR

The Empirica Suite provides robust facilities for transferring data extracts, metadata and documentation to Phase Forward's Waban Statistical Computing Environment and Clinical Data Repository (SCE/CDR) for further in-depth statistical analysis. SCE/CDR enables integration of data and metadata from multiple sources and provides automation, traceability and control of the key activities involved in the integration, analysis and reporting of clinical trial and safety-related data. SCE/CDR also integrates with traditional third-party analytical tools used by biostatistics groups, such as SAS.

Comprehensive Services & Support:

- Expert training available with custom configuration to meet your safety review team's needs
- Data provisioning for publicly available data sources
- Expert advisory statistical consulting to explain underlying statistical screening methodologies
- Integration with the InForm™ GTM electronic data capture platform and in-house applications
- Expert consulting on data conversion from legacy systems or for transforming clinical trials data into CDISC SDTM format
- Installation services or application hosting available

Why Empirica?

To build a proactive practice of pharmacovigilance and risk management to dramatically improve product safety, you need solutions that provide the right level of functionality, access to all available sources of evidence and expert services to help you manage the volume and complexity of safety information with confidence.

Life-cycle Approach to Risk Management

Managing safety risk requires accurate, timely and complete data about adverse events collected during clinical trials, and continues through post-marketing and the real-world use of approved products. The Empirica Suite provides key capabilities from signal observance to case level verification, including comparisons to public regulatory data sources such as the FDA's Adverse Event Reporting System (AERS) and the World Health Organization – Uppsala Monitoring Center's (WHO-UMC) VigiBase global database of spontaneous reports.

Transform Uncertainty into Knowledge

The ability to easily navigate and drill down to access stored safety-related data is a key business requirement satisfied by the Empirica Suite. Our solutions allow you to streamline your workflow and reduce dependence required by supporting organizations outside of the safety domain. The Empirica Suite also provides an intuitive user experience, which allows for greater freedom to explore resources and become more proactive and confident in your business decisions.

The Phase Forward Advantage

Phase Forward's Lincoln Safety Group, one of the most experienced and respected teams in the industry, provides an array of product and service offerings to commercial, government and regulatory sectors. Our team has extensive domain expertise to more effectively meet your requirements and help you build a proactive pharmacovigilance practice. Only Phase Forward can offer such highly skilled and experienced professionals with a proven track record of working with safety experts globally.

Contact Us for More Information

For more information about the Empirica Suite and Phase Forward's Lincoln Safety Group, please e-mail us at info@phaseforward.com.

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