

PHASE•FORWARD™



Empirica Gateway:

Submission capabilities for secure exchange of safety case information stored in the Empirica Trace adverse event reporting system

Empirica Gateway Features:

- **New** – Personalized installation
- Supports E2B format
- Both send and receive electronic ICSRs and acknowledgements
- Exchange data with regulatory authorities as well as affiliate offices and trading partners
- Simultaneously transmit safety reports to multiple regulatory agencies
- **New** – Support for the asynchronous MDN message format required by EMEA
- Easily transition from paper-based to electronic reporting
- Track the status of submissions from within Empirica Trace
- Maintain a comprehensive audit trail of the electronic submissions process
- Update the case information within Empirica Trace with the relevant reporting status
- Administer Empirica Gateway from within Empirica Trace
- Secure environment
- **New** – Support for Microsoft® Windows® Authentication

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Empirica™ Gateway

Submission Report Automation

Automate the submission of safety reports to regulatory agencies and trading partners

Regulatory agencies on a global basis are mandating electronic submission of Individual Case Safety Reports (ICSRs) to fulfill safety reporting requirements. Many companies are also using the data interchange standard developed for electronic case safety report submission to share safety case information internally and between affiliates and trading partners. Empirica Gateway works with the Empirica Trace adverse event reporting system to provide an electronic case submission and receipt environment for all safety departments.

End-to-End Solution

With Empirica Trace as a building block for an end-to-end safety solution, Empirica Gateway adds a vital capability for the electronic exchange of safety case data. Transmission can be tracked and monitored closely, and all information may be easily accessed from within the Empirica Trace system. Empirica Gateway is a centralized, Web-based application for processing, sending, receiving and tracking the electronic submission of individual case safety reports.

Meet Regulatory Requirements

Empirica Gateway can be used in a 21 CFR Part 11-compliant environment and has been designed to be deployed as part of a validated Empirica Trace system. Empirica Gateway has been designed and tested to enable companies to comply with the E2B specification. Empirica Gateway enables compliance to ICH requirements and submission requirements for the Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), including the FDA's Electronic Submissions Gateway (ESG). Empirica Gateway includes support for the asynchronous MDN message format required by EMA.

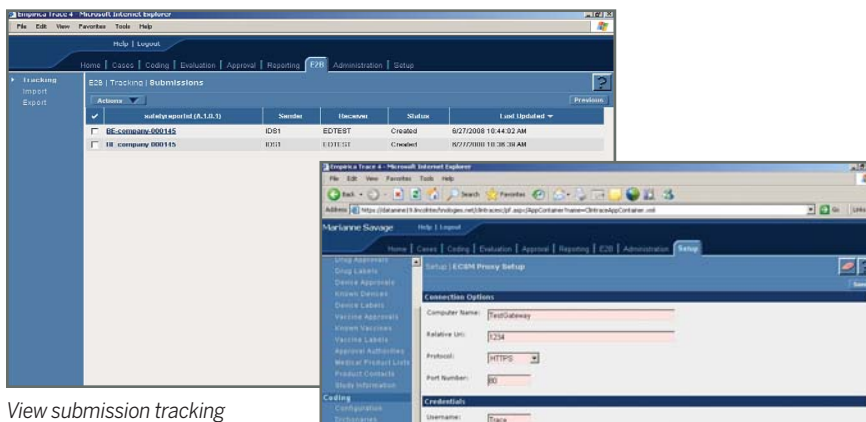
Phase Forward employs a full-time quality and regulatory affairs team that continuously monitors all applicable global regulations for changes and additions, and both Empirica Trace and Empirica Gateway are regularly audited and updated to ensure compliance. Adding Empirica Gateway to Empirica Trace helps to enable users to comply with additional regulations and guidelines for electronic reporting in the US, Europe and Japan.

Secure Messaging Environment

When automating submission of ICSRs, companies are faced with the challenges and concerns of moving from a familiar paper-based submission format to a new electronic format. Empirica Gateway uses the proven E2B standard in a highly secure environment that is integrated with Empirica Trace, easing these concerns. At the same time, users can benefit by eliminating redundant tasks such as duplicate data entry, thereby reducing risk of transcription errors. Empirica Gateway enables companies to safely and efficiently send and receive cases, as well as import cases to the safety database, complete with acknowledgments.

The Benefits of Empirica Gateway

- Efficient and secure exchange of data with regulatory agencies, affiliates and trading partners
- Fully integrated with Empirica Trace to allow access to adverse event reporting and electronic submission data from within a single user interface
- Expert consulting services support the implementation and configuration of both Empirica Gateway and Empirica Trace



View submission tracking

Drill down into electronic message

Technology Advantages

Like the Empirica Trace application, Empirica Gateway is Web-based to support the global management of electronic safety reporting. Empirica Gateway automatically retrieves the E2B files created by Empirica Trace and electronically transmits them to the appropriate regulatory agency. Once transmitted, users can easily and effectively monitor the status of their transactions through a detailed tracking mechanism from within Empirica Trace. Each step of the process is recorded to maintain a complete audit trail and to ensure the successful delivery and receipt of case information by the designated recipients.

Capability to Send and Receive ICSRs

The ability to send ICSRs to regulatory agencies is fast becoming a requirement for biopharma companies. While meeting regulatory requirements is first priority, additional data interoperability benefits arise as a result of implementing the E2B standard in your organization. The E2B standard can be used to receive case data as well as send and exchange ICSRs among affiliate offices and trading partners. Specialized functionality for importing case data allows for review of information in a staging area prior to importing the data into Empirica Trace.

Enhanced Architecture and Security Features

The movement of sensitive safety data outside of company walls needs to be managed carefully. Empirica Gateway has built-in functionality to help protect against submission failures, misdirection and loss of data. User authentication, file encryption, transmission protocols AS1 and AS2 and the E2B standard are implemented as specified by regulatory agencies. Multiple Empirica Gateway servers can be installed on a single machine with each being dedicated to one company or trading partner. Conversely, multiple Empirica Trace servers can be integrated with a single Empirica Gateway server.

Integrated Safety Tools

Empirica Gateway helps unlock additional value from your existing Empirica Trace system. A tight, out-of-the-box integration with Empirica Trace allows users to access the time and efficiency gains of electronic ICSR submissions while maintaining existing workflows. Empirica Trace and Empirica Gateway are part of an end-to-end solution for safety reporting, data management, signal detection and analysis.

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 working with safety experts in the government and commercial sectors.

System Requirements:

- Microsoft® Internet Explorer® 6.0x SP1 or SP2, or 7.x
- Infrastructure requirements are shared with Empirica Trace
- Operating system requirement is Microsoft® Windows® 2003 Server R2
- Database client requirement is Oracle® 10g™
- Empirica™ Trace 4.2 or above is required

Related Data Sheets

- Empirica™ Trace
- Empirica™ Signal
- Empirica™ Study

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