



## Empirica™ Trace

### Electronic Case Submission Module (ECSM)

#### ECSM Features:

- Support E2B format
- 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
- Ease 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 ECSM from within Empirica Trace
- Secure, regulatory-compliant environment

#### ECSM Electronic Case Submission:

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

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

Regulatory agencies on a global basis mandate electronic submission of Individual Case Safety Reports (ICSRs) to fulfill safety reporting requirements. Using the Empirica Trace system as a platform for end-to-end safety management, the ECSM adds a vital capability for exchange of safety case data with regulators and between affiliates and trading partners. Many companies find the E2B standard that was developed to support electronic submissions to be valuable for exchange with partners and contractors as well as its original purpose for regulatory submission. The Electronic Case Submissions Module (ECSM) works with the Empirica Trace adverse event reporting system to provide an electronic case submission and receipt environment for safety departments, both for mandatory submissions and for business use.

#### Meet Regulatory Requirements

The ECSM can be used in a 21 CFR 11-compliant environment and has been designed to be deployed as part of a validated Empirica Trace system. ECSM has been developed and tested to enable companies to comply with the E2B specification. ECSM enables compliance to ICH requirements and submission requirements for the FDA, EMEA and PMDA (formerly MHLW), including the FDA's Electronic Submissions Gateway (ESG).

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

#### Secure Messaging Environment

When automating submission of ICSRs, companies are faced with the challenges and concerns of moving to a new electronic format. The ECSM uses the proven E2B standard. The ECSM is integrated with the Empirica Trace system and features tracking functions that give real-time visibility to the status and disposition of submissions so that you can become comfortable with this electronic submission format. At the same time, the added efficiencies of the ECSM will be seen immediately – in reducing time delays, eliminating redundancy of work effort such as duplicate data entry, and reducing the risk of transcription errors. The ECSM 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 ECMS:

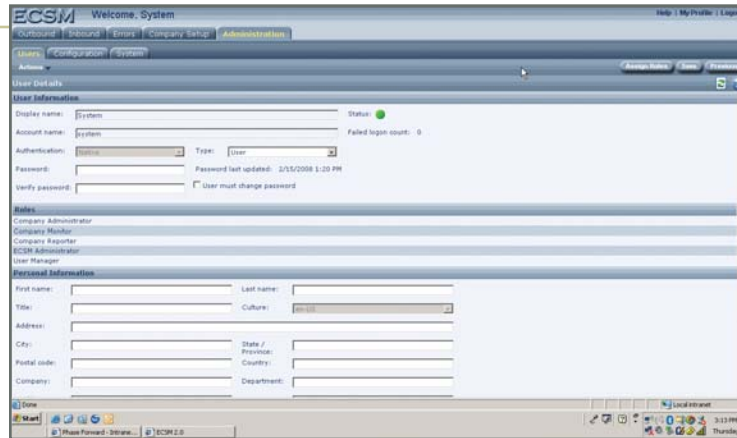
- Efficient and secure exchange of data with regulatory agencies, affiliates and trading partners
- Fully-integrated with Empirica Trace to allow access to adverse event reporting and electronic submission data from within a single user interface
- Expert consulting services support the implementation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

### System Requirements:

Please visit [www.phaseforward.com/products](http://www.phaseforward.com/products) for the latest requirements

### Related Data Sheets:

Empirica™ Trace



Empirica Trace users can easily track and monitor the status of cases and electronic submission on a single screen.

### Technology Advantages

Like the Empirica Trace application, the ECMS is Web-architected to support the global management of electronic safety reporting. The ECMS 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 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 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 office 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.

### Enhance Architecture & Security Features

The movement of sensitive safety data outside of company walls needs to be managed carefully. The ECMS 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.

### Integrated Safety Tools

The ECMS 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 the ECMS 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.

The Empirica Trace system supports a 21 CFR 11-compliant environment. Phase Forward's research and development program actively provides continuous enhancements to the safety solution suite.

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