

ORACLE HEALTH SCIENCES EMPIRICA TOPICS

KEY FEATURES

- Creates a record defining safety topics
- Allows evidence to be collected during investigations
- Provides a collaborative, knowledge-sharing work team environment
- Supports multiple attachment types (including documents, URLs, and direct links to Oracle Health Sciences Empirica data results)
- Provides a complete archive/dossier of actions in a 21 CFR Part 11-compliant environment
- Flexible licensing and services options

KEY BENEFITS

- Facilitates collaboration among work teams
- Improves senior management visibility
- Increases ability to respond rapidly to regulatory inquiries
- Supports proactive lifecycle risk management
- Streamlined implementation
- A foundational component of Oracle Health Sciences pharmacovigilance and risk management solutions

Providing a practical tool for managing the information and activities relevant to drug safety processes, Oracle Health Sciences Empirica Topics helps safety professionals take a proactive, whole-lifecycle approach to product safety. Web-based and easy to use, Oracle Health Sciences Empirica Topics serves as a centralized repository and collaborative workspace for information and actions related to safety issues—replacing the ad hoc solutions organizations have relied on in the past.

Track and Manage

With regulatory authorities continually implementing new tools to scrutinize data—ranging from pre-clinical to clinical and observational as well as spontaneous report data—sponsors need to be proactive about product safety.

While sophisticated case processing and data mining software provide solutions for many of the mandatory safety requirements, some routine everyday tasks require a simpler approach. In fast-paced and increasingly stressful environments, safety professionals need a trusted tool to help them track and manage relevant information and record their actions and responses in a regulatory-compliant manner.

Record and Respond

Despite the vast quantities of information that must be reviewed by safety scientists, the tracking of basic issues and actions is often primarily a manual process. Many safety experts resort to ad hoc solutions such as custom PC databases, spreadsheets, to-do lists, or even the ubiquitous sticky note. And because information is typically contained in documents or Web pages, version control difficulties often arise.

Once an issue has been identified and tagged for action, it must be assigned for research or resolution—a task made much more difficult when workflows are unclear. It also becomes difficult for management to gain an executive-level view of what needs to be done and whether critical tasks are being completed on time. Meanwhile, sponsors must be certain that they can provide a complete, auditable record of what they knew and how they responded—in the event of a significant safety occurrence.

Collect and Refine

As a Web-based application designed to track information and actions related to safety issues, Oracle Health Sciences Empirica Topics helps safety professionals absorb and act on vital safety signals. At the program's core are *topics*, or collections of information relevant to the drug safety investigations. Once topics are created, they may be assigned to team members for actions (for example, literature searches, data mining runs, meetings, or other research activities), and their completion (or the progression to another set of actions) can be recorded.

Attachments such as documents, graphics, data mining results, URLs, and outputs from Oracle Health Sciences Empirica Signal product can be added to a topic or action as part of this accumulating dossier of knowledge.

RELATED PRODUCTS

A foundational component of Oracle Health Sciences pharmacovigilance and risk management solutions, Oracle Health Sciences Empirica Topics is included with **Oracle Health Sciences Empirica Signal** and **Oracle Health Sciences Signal Management**. It can also be integrated with other Oracle Health Sciences safety solutions, including

- **Oracle Health Sciences Empirica Study On Demand.** Signal detection from clinical trials data.
- **Oracle Health Sciences WebSDM On Demand.** Data standards.
- **Oracle Argus Safety.** Case capture and processing.
- **Oracle Argus Safety Japan.** Case capture and processing specific to Japan's PMDA requirements
- **Oracle Argus Interchange**

THE OWNERSHIP EXPERIENCE

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry that can scale to the demands of the smallest to the largest companies. With Oracle Health Sciences, clients enjoy lifecycle project management, study design and implementation, site and user provisioning, out-of-the-box integrations, hosting and application management, user training, and 24x7 global support. Clients looking to bring applications directly into their enterprise can also leverage Oracle Health Sciences full range of mentoring programs, training offerings and implementation services to transfer knowledge in-house for additional flexibility.



Oracle is committed to developing practices and products that help protect the environment

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Hardware and Software, Engineered to Work Together

Work teams can be defined within the product, and configurations allow companies to customize the system to adapt to their individual business processes.

The screenshot displays the Oracle Health Sciences Empirica Topics web interface. It shows a topic detail view for 'Diazepam co-prescribed with antidepressants - Suicidality'. The interface includes sections for 'Topic General Information', 'Topic Links', 'Topic Comments', 'Topic Attachments', and 'Topic Actions'. The 'Topic Attachments' section contains two rows of data:

Attachment name	Attachment description	Source	Created By	Comments
Docket for 2004 FDA Proceedings	This document analyzes and evaluates data submitted by sponsors of several psychotropic drugs in response to FDA requests regarding data pertinent to pediatric suicidality.	URL	Mark Oneil	2
FDA black box warning letter	FDA letter requesting a labeling change for antidepressants to include a black box warning about suicidality in children and adolescents.	File	Sara Evans	2

Figure 1. Through its easy-to-use, Web-based interface, Oracle Health Sciences Empirica Topics lets safety professionals create topics to track relevant information about recorded safety issues.

Using Oracle Health Sciences Empirica Topics

Oracle Health Sciences Empirica Topics is often used to respond to safety issues that have been identified through routine pharmacovigilance review, signal detection software, assertions in literature, or direct regulatory requests. For example, a record of the topic is created, and relevant information is attached. (This information can include a copy of the case, data mining results, the regulatory communication, a URL to literature, and so on.) Next, all members of the previously designated safety work team who subscribe to this category receive e-mail notification. The topic may be assigned to an individual for action, and amended or edited (with a Part 11-compliant audit trail) as new information is discovered. At any point, the topic may be routed to other members of the work team for further action or approval (often as part of a predefined workflow process); links to other topics, actions, or records and comments may be also be added. When used with Oracle Health Sciences Empirica, data mining results and graphics can be explored. At any time a topic can be viewed, printed, or downloaded in PDF format by authorized users. Once a topic has been resolved, it can be locked but later reopened by an authorized user.

Contact Us

For more information about Oracle Health Sciences Empirica Topics, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.