

ORACLE HEALTH SCIENCES EMPIRICA TOPICS

KEY FEATURES

- Provides a collaborative, knowledge-sharing work team environment
- Integrates seamlessly with Oracle Health Sciences Empirica Signal for end-to-end signal management
- Allows evidence to be collected during investigations
- Customizable templates simplify topic creation
- Supports multiple attachment types (including documents, URLs, and direct links to Oracle Health Sciences Empirica Signal data results)
- Provides a complete archive/dossier of actions in a 21 CFR Part 11-compliant environment
- Allows alerts to warn when due date is approaching for pending actions
- Self-documenting workflow configuration
- Web services interface to support cross-application integration
- Oracle Business Intelligence (OBIEE) reporting support
- Flexible licensing and services options

KEY BENEFITS

- Supports proactive lifecycle risk management and regulatory compliance (EU GVP Module IX and CIOMS VIII)
- Helps manage regulatory inspections successfully
- Facilitates collaboration among work teams
- Improves senior management visibility
- Increases ability to respond rapidly to regulatory inquiries
- Streamlined implementation

Providing a practical tool for managing the information and activities relevant to drug safety processes, Oracle Health Sciences Empirica Topics enables safety organizations to comply with signal management regulations including GVP Module IX and CIOMS VIII, and helps them to successfully manage and pass regulatory inspections. 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 provides 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 or regulatory inspection.

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 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 can be added to a topic or action as part of this accumulating dossier of knowledge.

RELATED PRODUCTS

A key component of the Oracle Health Sciences Safety Suite, Oracle Health Sciences Empirica Topics is integrated with Oracle Health Sciences Empirica Signal to provide signal management capabilities. It can also be used to track information from other Oracle Health Sciences Safety Suite components, including:

- **Oracle Health Sciences Empirica Study.** Signal detection in clinical trials data.
- **Oracle Health Sciences Empirica Healthcare.** Signal evaluation in EHR and claims databases.
- **Oracle Argus Standard Edition.** Case capture, processing and reporting.
- **Oracle Argus Enterprise Edition.** Case management with advanced analytics and business intelligence.
- **Oracle Argus Safety Japan.** Case capture, processing and reporting specific to Japan's PMDA requirements.

THE OWNERSHIP EXPERIENCE

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud application 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 features a 'Topic General Information' section with fields for 'Topic name', 'Topic description', 'Current state', 'Reason for change', 'Assigned to user', 'Keywords', and 'Project'. Below this is a 'Topic Links' section with filters for 'Project', 'Current state', 'Assigned to user', and 'Keywords'. A table lists one topic: 'Diazepam and antidepressants - Suicidality' with columns for 'Topic name', 'Topic description', 'Current state', 'Work teams', 'Assigned to user', 'Created By', 'Modified By', and 'Modified'. Below the table is a 'Topic Attachments' section with filters and a table listing two attachments: 'Docket for 2004 FDA Proceedings' and 'FDA black box warning letter', with columns for 'Attachment name', 'Attachment description', 'Source', 'Created By', and 'Comments'.

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 21 CFR 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 also be added. When used with Oracle Health Sciences Empirica Signal, 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.