

The Oracle Health Sciences Safety Suite

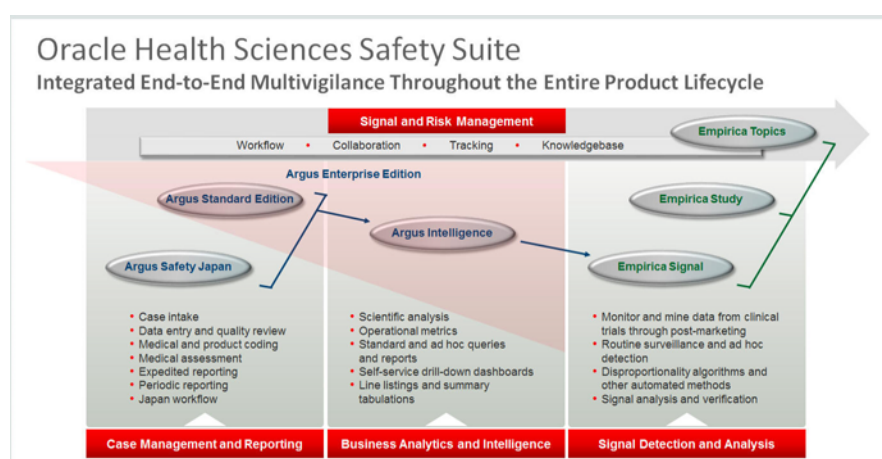
Suite Information

Release 8.1.1

E90672-02

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The Oracle Health Sciences Safety Suite is an integrated solution for end-to-end vigilance from adverse event management to signal management, through the entire lifecycle of a medicinal product from clinical trials to post-marketing surveillance.



The Oracle Health Sciences Safety Suite consists of the following components:

- **Oracle Argus Standard Edition:** Manage and report adverse events through a workflow including case intake, data entry, coding, quality review, medical review, expedited reporting, and periodic reporting. Modules include Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, and Oracle Argus Unblinding.
- **Oracle Argus Enterprise Edition:** In addition to managing the adverse event workflow and reporting, employ a powerful and flexible business analytics and intelligence platform for both scientific analysis and operational metrics. Modules include Oracle Argus Analytics, Oracle Argus Insight, Oracle Argus Mart, Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, and Oracle Argus Unblinding.
- **Oracle Argus Safety Japan:** Manage and report adverse events in Japan, and connect the global and local workflows using a single database.
- **Oracle Health Sciences Empirica Topics:** Manage and document safety signals through a workflow including validation, prioritization, assessment, confirmation/refutation, and resulting actions.

- **Oracle Health Sciences Empirica Study:** Detect and analyze safety signals in clinical trial data including adverse events, clinically significant labs, electrocardiograms, vital signs, and shifts from baseline.
- **Oracle Health Sciences Empirica Signal:** Detect and analyze safety signals in post-marketing spontaneous adverse reaction data including public health authority databases and/or private inhouse databases such as Oracle Argus.

For more information on Argus Safety, visit the Oracle Health Sciences Safety suite page at:

<http://www.oracle.com/goto/pharmacovigilance.html>

Documentation Accessibility

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