

ORACLE HEALTH SCIENCES EMPIRICA STUDY ON DEMAND

KEY BENEFITS

- Provides a scientific framework for proactive review of the safety profile of emerging products
- Supports a more active and transparent safety review process consistent with FDA and CIOMS VI guidance documents
- Provides easily navigable access to clinical trials safety data
- Supports analysis of both single studies and pooled studies
- Allows exploration of demographics, adverse events, concomitant medications, labs, ECG, vital signs, study completion, and other study data through interactive visual displays
- Provides advanced graphical and visualization tools
- Enables rapid navigation from aggregate data displays to individual patient profiles
- Facilitates review data by age, gender, or race
- Provides a broad library of standard analysis types and tabular displays

With a Web-based architecture built on the Oracle Health Sciences WebSDM On Demand data repository platform and a wealth of graphical, tabular, and statistical tools for examining, analyzing, and classifying potential signals prior to drug approval, Oracle Health Sciences Empirica Study On Demand provides a revolutionary tool for detecting potential safety problems early in the pre-marketing clinical trial stage. Using the data it provides, safety reviewers can improve their understanding of the key safety concerns regulatory reviewers are looking out for when examining applications for product licenses.

Improving Product Safety During Clinical Development

With the costs of developing new therapeutic products constantly on the rise, pharmaceutical companies can ill afford to develop products that fail to gain approval—or worse still, remove products from market *after* they've been approved because a safety defect was not identified earlier in the process.

Today's regulatory reviewers are using sophisticated new analytical tools to delve deeper into clinical data, thanks to the advantages provided by the standardized data format of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM), which enables the use of standard statistical screening methods. In addition, the Food and Drug Administration (through published guidance documents) and the Council for International Organizations of Medical Sciences (CIOMS) VI have provided insight into the fundamental areas of safety review for any new drug application.

Drug makers and sponsors need to capitalize on these insights and take advantage of all available technological resources to better understand the emerging safety profile of their products during development. Exploring and analyzing safety issues early in the development process can help users make actionable decisions sooner. Oracle Health Sciences pharmacovigilance and risk management solutions delivers adverse event reporting, data mining, signal detection, and signal management capabilities. Designed to help companies strategically manage their pharmacovigilance activities, Oracle Health Sciences safety solutions enable pharmaceutical companies to identify potential safety problems and manage risk effectively across the full product life cycle.

Unleashing the Potential of Standardized Clinical Data

Providing a dynamic, visual data review environment, Oracle Health Sciences Empirica Study On Demand allows companies to review safety data and detect signals in clinical trials data in CDISC SDTM format. The standard SDTM data structures enable the reuse of advanced statistical analysis algorithms and simplify data pooling, bringing a new degree of visibility and understanding into clinical data.

KEY FEATURES

- Analyze individual or pooled study data
- Uncover safety issues specific to age groups, genders, and races
- Browse aggregate values, trends, and outliers in blinded study data
- Evaluate safety effects across drug dose groups in unblinded study data
- Drill-down from visual, aggregate data displays to subject lists and individual, time-aligned patient profiles
- Improved navigation between patient profiles for sets of patients
- Improved, streamlined process for handling in-stream data loading
- MedDRA browser, data browser, report builder, and subset list query wizard
- Document, manage, and track signals as clinical data accumulates
- Compare a new product's safety profile to comparators on the market as displayed by Oracle Health Sciences Empirica Signal
- Built on the same platform—Oracle Health Sciences WebSDM On Demand—used by the FDA to validate and review study submissions,
- Supported by Microsoft Windows 2003 Advanced Server and can be integrated with other applications such as clinical safety systems.

Review Safety Data from Completed Studies

The safety review interface of Oracle Health Sciences Empirica Study On Demand is designed to support the workflow outlined in the FDA 2005 Safety Review Guidance.¹ A first step in reviewing any study is to get a demographic overview of the study population by treatment group and a summary of some critical enrollment parameters. From this interface, you can also get a Kaplan Meier plot or exposure summary graph to gain a high-level overview of the study data. In addition, Oracle Health Sciences Empirica Study On Demand now supports nonparallel study design.

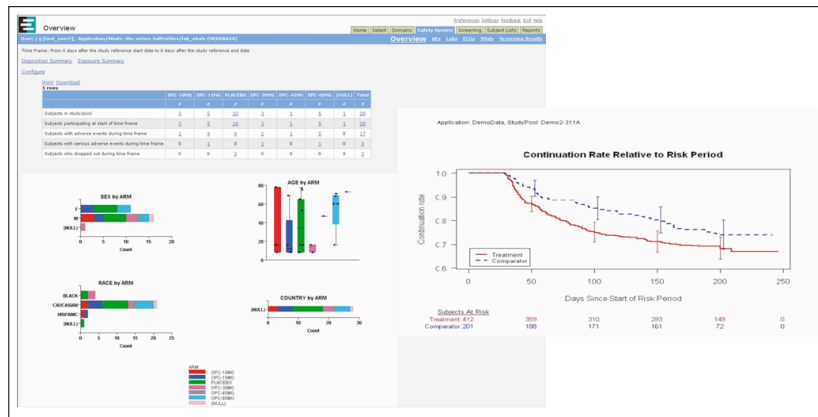


Figure 1. Oracle Health Sciences Empirica Study On Demand provides a variety of views of clinical data.

Explore Safety Data for In-Stream Blinded Trials

Oracle Health Sciences Empirica Study On Demand provides a rich portfolio of graphical displays to help users understand overall safety trends and outliers while a study is active and treatment is blinded. For example, one can see several outliers in the liver function test shift display below (Figure 2), and then drill down to examine the individual patterns for each patient.

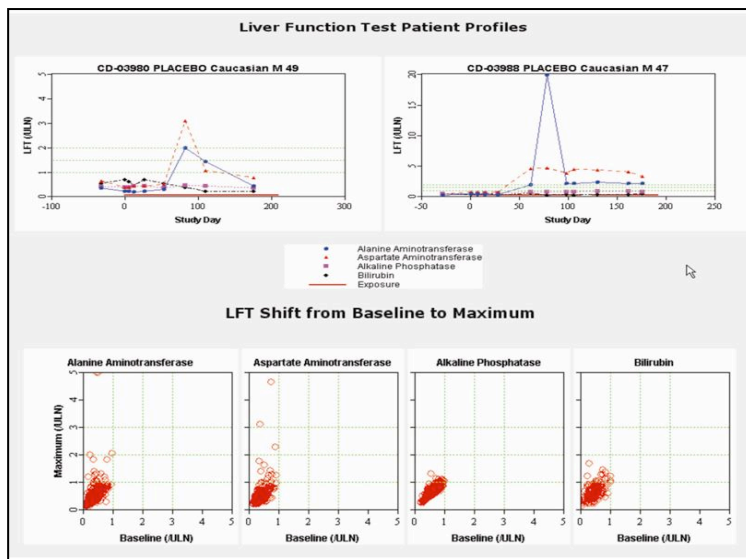


Figure 2. A graphical interface allows users to drill down to individual patient profiles.

¹ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Reviewer Guidance, Good Review Practices, February 2005

RELATED PRODUCTS

Oracle Health Sciences pharmacovigilance and risk management solutions also include:

- **Oracle Health Sciences Empirica Topics.** Lifecycle signal tracking and resolution.
- **Oracle Argus Safety.** Case capture and processing.
- **Oracle Argus Safety Japan.** Case capture and processing specific to Japan’s PMDA requirements
- **Oracle Argus Interchange**
- **Oracle Health Sciences WebSDM On Demand.** Data standards.
- **Oracle Health Sciences Empirica Signal with Oracle Health Sciences Empirica Signal Management.** System for identifying, managing, and tracking the evolution of safety signals in public and proprietary spontaneous report databases

Explore Adverse Event Data

By taking advantage of the signal scores, tabular displays, and graphical tools provided by Oracle Health Sciences Empirica Study On Demand, companies can compare reported adverse events and serious adverse events across treatment groups and at all MedDRA levels (including Standardized MedDRA Queries and custom event lists).

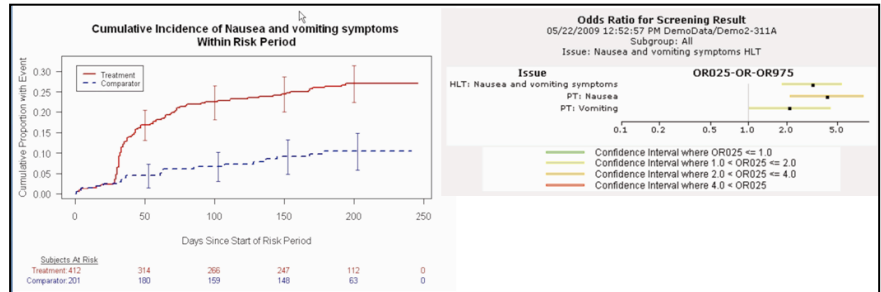


Figure 3. The above example shows a cumulative incidence display for nausea and vomiting, together with a display of the odds ratio screening result with confidence intervals.

Explore Lab Data

Oracle Health Sciences Empirica Study On Demand provides a wide variety of lab data visualizations, including those charting clinical significance and change from baseline, as well as specialized displays for hemotoxicity and liver functioning (including Hy’s law). Using Oracle Health Sciences Empirica Study On Demand’s expanded and improved lab graphs, users can explore emerging safety signals such as change from baseline, lab shifts, normal range outliers, scatter plots, and more.

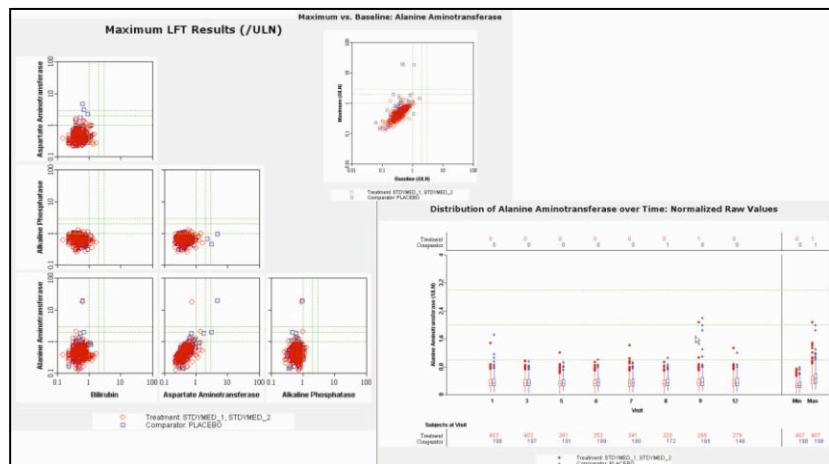


Figure 4. Oracle Health Sciences Empirica Study On Demand offers a variety of lab graphs that allow users to explore emerging safety signals.

Review Screening Results for Signals Affecting Sub-Populations

Oracle Health Sciences Empirica Study On Demand computes signal screening scores for the full study population or for subgroups by age group, gender, or race—allowing safety reviewers to see if stronger signals are associated with particular sub-populations.

The library in Oracle Health Sciences Empirica Study On Demand includes denominator-based screening tests to detect highly disproportional incidence of events among subjects and population subgroups across treatment groups:

- Adverse events at MedDRA Preferred Term, High Level Term, High Level Group Term, and System Organ Class levels

- Significant difference from lab or vitals baseline
- Standardized MedDRA Queries (SMQs) and custom event lists
- Clinically significant lab test results
- Hy’s law test for hepatotoxicity
- Clinically significant QT prolongation
- Premature study discontinuation
- Advanced Bayesian logistic regression techniques



Figure 5. This adverse event display in Oracle Health Sciences Empirica Study On Demand shows event terms differentiated by subgroup.

Identify Safety Signals

To highlight safety signals, Oracle Health Sciences Empirica Study On Demand employs simple statistical methods for identifying and tracking disproportionalities between treatment groups. Integrated tracking tools assure that signals can be monitored through to resolution, providing the basis for a more comprehensive statistical, medical, and management review.

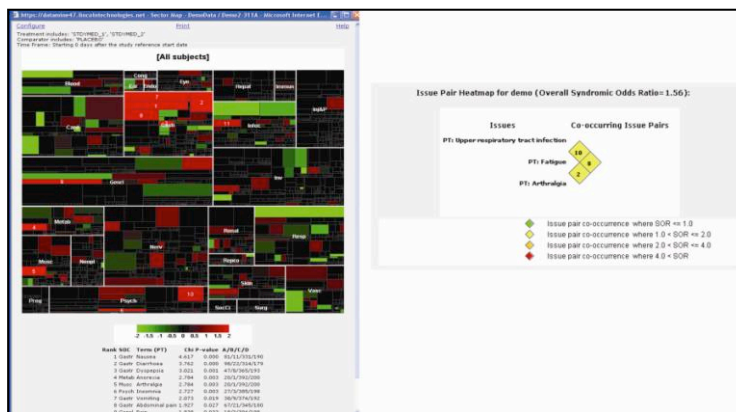


Figure 6. In the Sector Map graph above, adverse events that appear more frequently in treatment than comparator are shaded red according to signal strength; those that appear more often in comparator or placebo are shaded green.

Visualize and Drill Down to Explore Data

Designed to unleash the power of standardized clinical trials data for nontechnical safety experts, Oracle Health Sciences Empirica Study On Demand provides a rich, intuitive set of advanced graphical visualizations that describe the clinical study populations and a drug safety profile from a variety of angles. When a user clicks on any of these aggregate graphical displays, they are presented with a menu of options for further graphical and tabular displays of data, including lists of all the subjects included.

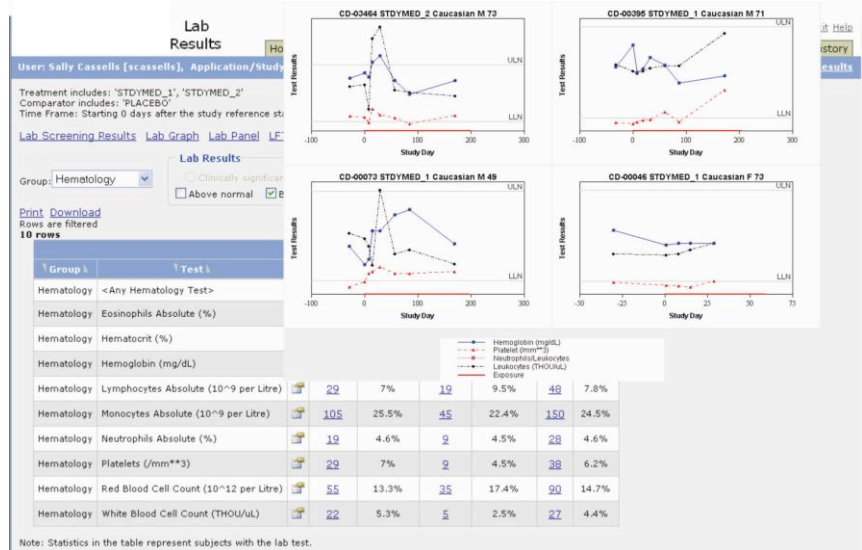


Figure 7. A rich, intuitive set of advanced graphical visualizations describe the clinical study populations and drug safety profile from a variety of perspectives.

From a list of subjects, a user can display a tabular patient profile showing all of the critical safety data for each subject. And from there, they can display graphical patient profiles that depict this data for a patient over time. In addition to these overall patient profiles, Oracle Health Sciences Empirica Study On Demand includes specialized patient profiles to display measures such as hepatotoxicity and vital signs, along with easy navigation tools to browse through sets of patient profiles for a group of subjects at a time.

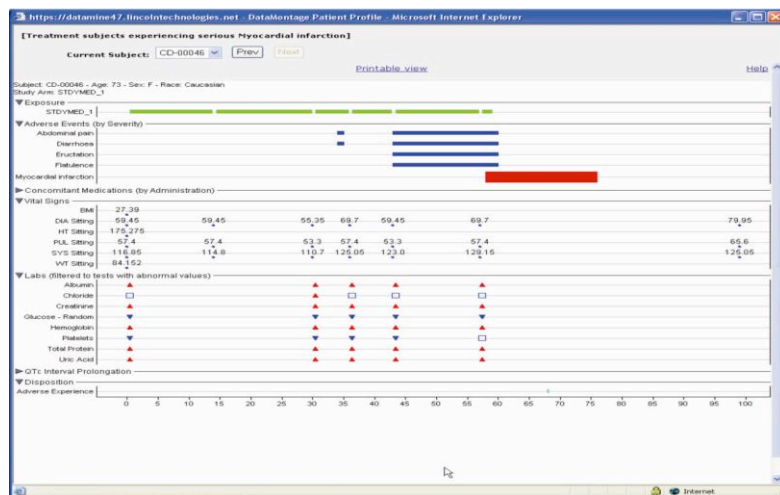


Figure 8. Oracle Health Sciences Empirica Study On Demand includes a variety of specialized patient profiles

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.

Comprehensive Services and Support

From implementation and validation to training, data integration, safety monitoring, and more, you can rely on Oracle's expert service and support team to ensure a successful deployment.

Included among Oracle Health Sciences Empirica Study On Demand's service and support offerings are:

- Web-based and on-site training with custom configuration to meet your safety review team's needs
- Implementation consulting for process development and integration with in-house clinical trials data feeds and for data provisioning strategies on active trials
- Expert advisory statistical consulting to explain the underlying statistical screening techniques used to identify safety signals
- Expert consulting on the conversion of clinical trials data into CDISC SDTM format
- Validation support services
- Installation services
- Application hosting
- 24x7 help desk support

Contact Us

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



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

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