

Oracle Health Sciences Empirica Study



With a wealth of graphical, tabular, and statistical tools for discovering, analyzing, and classifying safety signals prior to market approval, Oracle Health Sciences Empirica Study provides a revolutionary tool for detecting potential safety problems early during clinical development of medicinal products. Using this solution, safety reviewers and medical monitors can improve their understanding of the key safety concerns regulatory reviewers search for when examining applications for market authorization.

Improve Product Safety During Clinical Development

With the costs of developing new therapeutic products constantly on the rise, life sciences 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 delving deeper into clinical data to attain insight into the fundamental areas of safety review for any new product application. Sponsors and manufacturers need to capitalize on these insights and take advantage of all available technological resources to better understand the emerging safety profiles of their products during development. Exploring and analyzing safety issues in clinical studies can help safety reviewers and medical monitors make actionable decisions sooner. As an organization moves toward risk-based monitoring, it's critical that subject safety is maintained. Oracle Health Sciences Empirica Study enables the discovery of safety issues early in the development process, helping to avoid further investments into unsafe products.

HEALTH AUTHORITY PUBLICATIONS

Oracle Health Sciences Empirica Study helps you comply with multiple health authority guidelines:

- Report of CIOMS Working Group VI: Management of Safety Information from Clinical Trials
- FDA Reviewer Guidance: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review
- FDA Draft Guidance for Industry: Safety Assessment for IND Safety Reporting

FDA's own use of Oracle Health Sciences Empirica Study and Oracle Health Sciences Empirica Signal is described in this document:

- Data Mining at FDA White Paper

Comply with Health Authority Guidelines

The safety review interface of Oracle Health Sciences Empirica Study is designed to support multiple FDA and CIOMS guidelines (see sidebar on left). Using it to review your clinical trials will aid you in finding safety problems before the regulators do.

Review Safety Data from Completed Studies

Providing a dynamic, visual data review environment, Oracle Health Sciences Empirica Study allows you to review safety data and detect signals in clinical trial data in CDISC SDTM format. The standard SDTM data structures allow the solution to use advanced statistical analysis algorithms and simplify data pooling, bringing a new degree of visibility and understanding into clinical data. In addition, non-parallel study design is supported. A first step in reviewing any study is to get a demographic overview of the study population by treatment group, a summary of critical enrollment parameters, and an exposure summary in order to gain a high-level overview of the study data.



Figure 1. The solution provides a variety of views of clinical data.

KEY BUSINESS BENEFITS

- Provides a scientific framework for proactive review of the safety profiles 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 trial safety data
- Supports analysis of both single studies and pooled studies
- Allows exploration of demographics, adverse events, concomitant medications, labs, ECGs, vital signs, study completion, and other study data through interactive visual displays
- Provides advanced graphical and visualization tools
- Enables rapid drill-down from aggregate data displays to individual patient profiles
- Facilitates review of data by age, gender, or race
- Provides a broad library of standard analysis types and tabular displays

Explore Safety Data for In-Stream Blinded Trials

Oracle Health Sciences Empirica Study 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, you can find several outliers in the liver function test shift display below (Figure 2), and then drill down to examine the individual patterns for each subject.

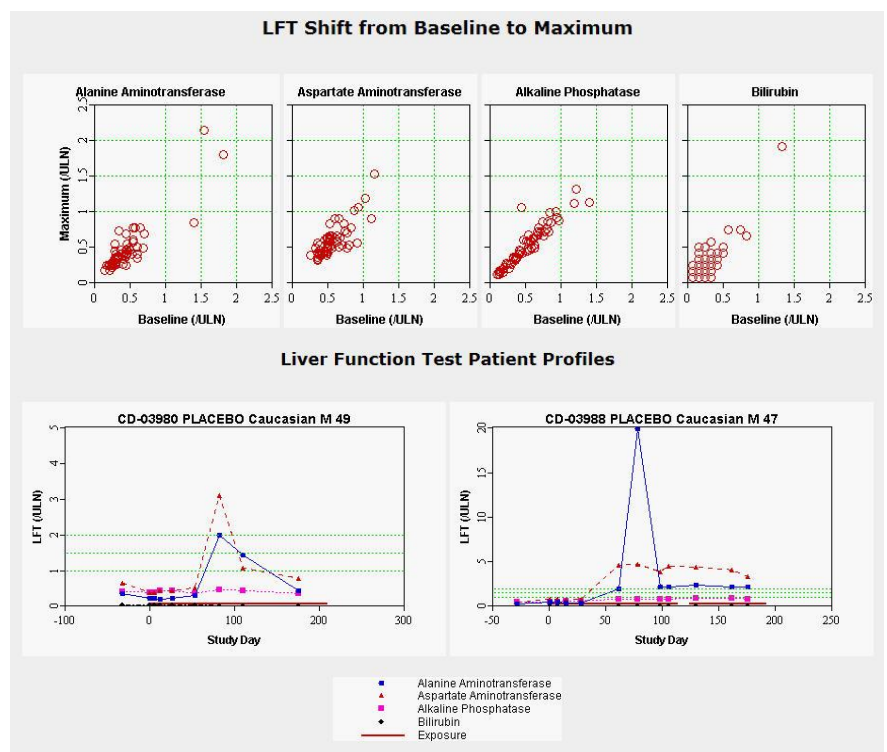


Figure 2. A graphical interface allows users to drill down to individual patient profiles.

Explore Adverse Event Data

By taking advantage of the signal scores, tabular displays, and graphical tools provided by Oracle Health Sciences Empirica Study, you 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).

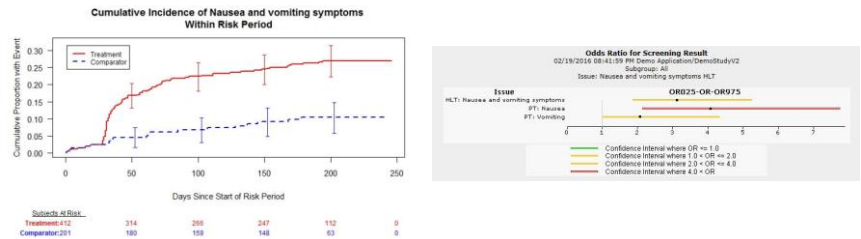


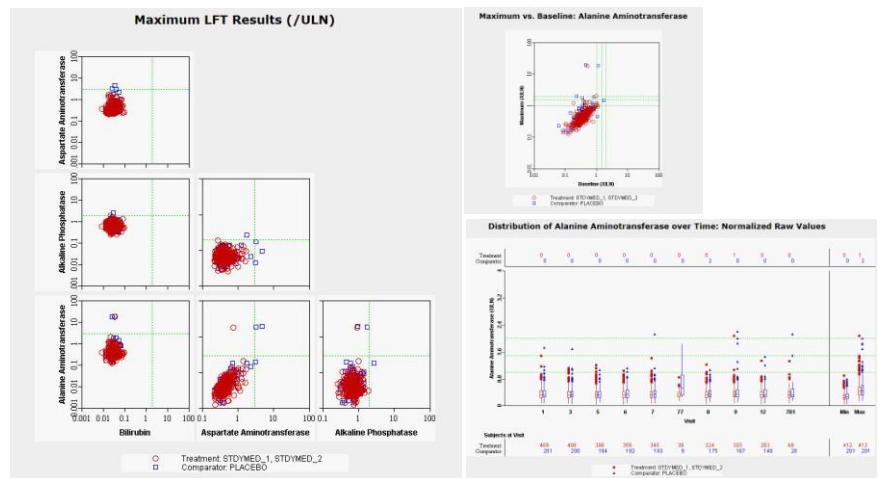
Figure 3. Cumulative incidence display together with a display of the odds ratio screening result with confidence intervals.

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 dosage 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
- Compare a new product's safety profile to comparators on the market as displayed by Oracle Health Sciences Empirica Signal
- Use Oracle Health Sciences Empirica Study for analysis of CDISC SDTM clinical data housed in Oracle Life Sciences Hub

Explore Lab Data

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



- Adverse events at MedDRA Preferred Term, High Level Term, High Level Group Term, and System Organ Class levels
- Standardized MedDRA Queries (SMQs) and custom event lists
- Clinically significant lab test results
- Significant difference from lab or vitals baseline
- Hy's Law test for hepatotoxicity
- Clinically significant QT prolongation
- Premature study discontinuation
- Advanced Bayesian logistic regression techniques

RELATED PRODUCTS

Oracle Health Sciences Empirica Study is part of the Oracle Health Sciences Safety Suite, which also includes:

- Oracle Health Sciences Empirica Topics for lifecycle signal tracking and resolution
- Oracle Health Sciences Empirica Signal for post-marketing surveillance of spontaneous adverse reactions
- Oracle Health Sciences Empirica Healthcare Analysis for signal evaluation in EHR and claims databases
- Oracle Argus Standard Edition for adverse event capture, processing and reporting
- Oracle Argus Enterprise Edition for adverse event management with advanced analytics and business intelligence
- Oracle Argus Safety Japan for adverse event capture, processing and reporting specific to Japan's PMDA requirements

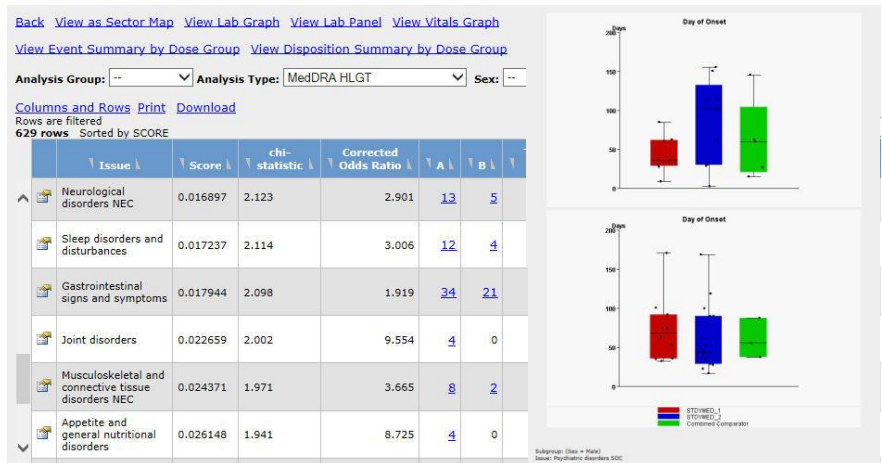


Figure 5. This adverse event display shows event terms differentiated by sub-group.

Identify Safety Signals

To highlight safety signals, Oracle Health Sciences Empirica Study employs advanced 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.

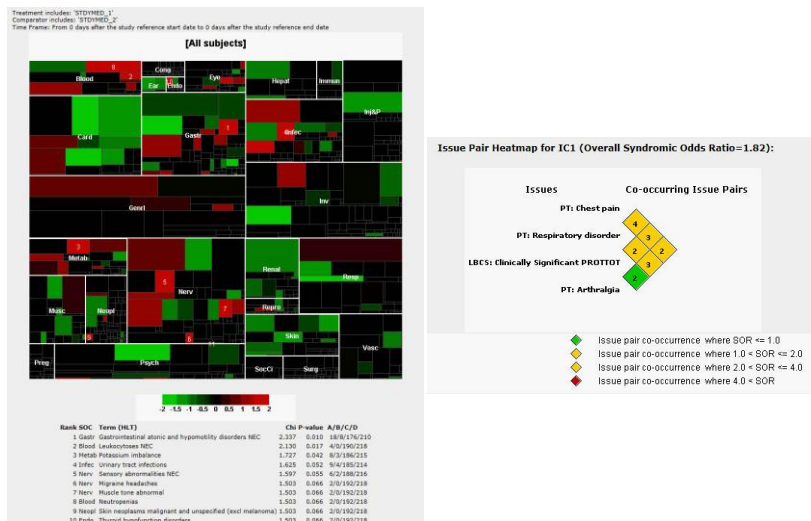


Figure 6. Two innovative visualizations: the Sector Map and the Issue Pair Heatmap.

Visualize and Drill Down to Explore Data

Designed to unleash the power of standardized clinical trial data for safety experts, Oracle Health Sciences Empirica Study provides a rich, intuitive set of advanced graphical visualizations that describe the clinical study populations and product safety profiles 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.

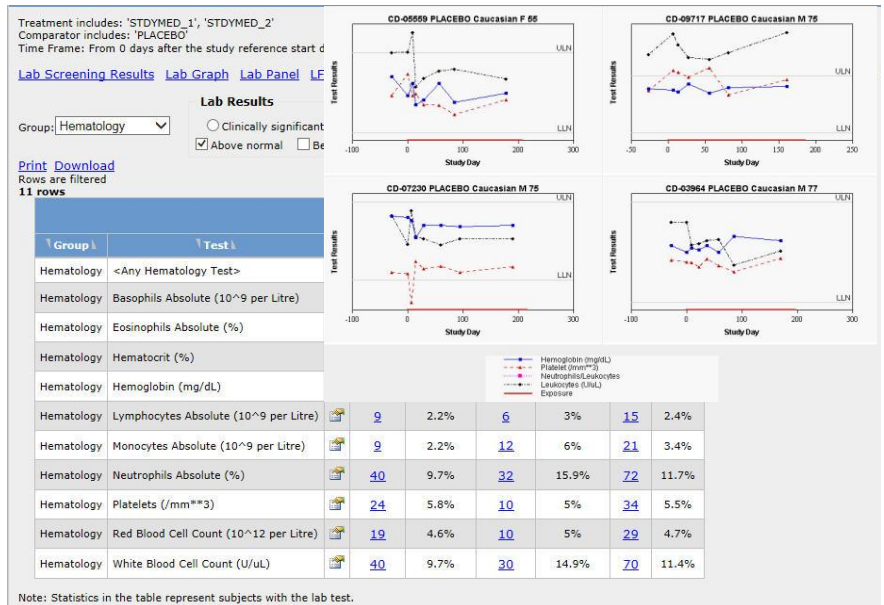


Figure 7. Multiple visualizations describe the study populations and product safety profiles from a variety of perspectives.

From a list of subjects, display a tabular patient profile showing all of the critical safety data for each subject. From there, display graphical patient profiles that depict this data for a subject over time. Oracle Health Sciences Empirica Study 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.

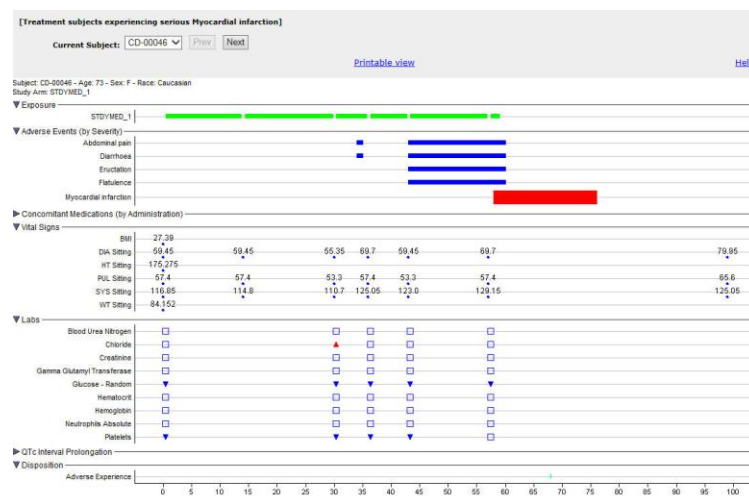


Figure 8. The solution includes a variety of specialized patient profiles.

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's service and support offerings are:

- Software as a Service (SaaS) in the Oracle Health Sciences Cloud
- Web-based and on-site training with custom configuration to meet your safety review team's needs
- Implementation consulting for process development, data provisioning strategies, and integration with in-house clinical trial data feeds
- Expert advisory statistical consulting to explain the underlying statistical screening techniques used to identify safety signals
- Expert consulting on the conversion of clinical trial data into CDISC SDTM format
- Validation support services
- Installation services
- 24x7 help desk support

CONTACT US

For more information about Oracle Health Sciences Empirica Study, visit oracle.com/healthsciences or call +1.800.633.0643 to speak to an Oracle Health Sciences representative.



CONNECT WITH US



blogs.oracle.com/health-sciences



facebook.com/oraclehealthsciences



twitter.com/oraclehealthsci



oracle.com/healthsciences

Integrated Cloud Applications & Platform Services

Copyright © 2016, Oracle and/or its affiliates. All rights reserved. This document is provided for information purposes only, and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. We specifically disclaim any liability with respect to this document, and no contractual obligations are formed either directly or indirectly by this document. This document may not be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without our prior written permission.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group. 0216

