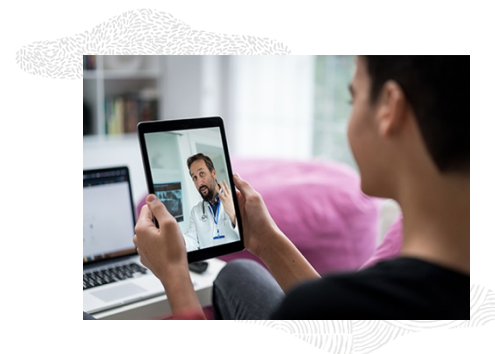ORACLE

Empirica
Smarter safety signal management

More than 90% of life science companies are looking for safety signals in multiple big data sets, which makes management difficult. What if safety and pharmacovigilance teams could process all that data more efficiently while gleaning risk insights earlier?

Protect patients and the company

Safety signal management is first and foremost an activity that safeguards patients and study subjects, but it is also important for protecting the company. Oracle Health Sciences Empirica Cloud Service (Empirica) can help halt wasted investment in the development of unsafe products while also helping companies avoid penalty fees, product recalls, and negative press. Empirica can help you comply with signal management regulations around the world and reduce findings in regulatory inspections. Developed in collaboration with—and used by— multiple health authorities, Empirica lets you see what the regulators see.

End-to-end signal management

Empirica fully supports the complete signal management process including detection, validation, prioritization, assessment, confirmation or refutation, and the tracking of any risk mitigation and minimization actions. A signal may also change its status, for example becoming more important as new evidence is collected. Over time, Empirica becomes a knowledge base—a central repository of product risk information that grows smarter as you gather more information.

"The pharmaceutical industry, as well as the regulators, will increasingly depend on big data solutions due to the increase in volume and variety of data to be analyzed in order to make the most informed decisions about the benefit-risk profiles of drugs."

ADDRESSING THE DATA CHALLENGES OF PHARMACOVIGILANCE, INFORMA BUSINESS INTELLIGENCE RESEARCH REPORT

Empirica / is the market-leading solution for detecting, analyzing, and managing safety signals for investigational and authorized medicinal products.

Casting a wider net

Traditionally, signal detection focused solely on the spontaneous reports in your own safety database, but modern approaches widen the search to public spontaneous data (WHO, FDA, PMDA, etc.), clinical study data, electronic health records, administrative claims, social media, and more. This explosion in data can provide valuable insights but can also overwhelm signal evaluators. Empirica is outfitted with specialized algorithms optimized for specific kinds of data, and after detection, it can help you aggregate and make sense of the signals from multiple sources, so you can make better decisions.

Better insight, efficiency, and accuracy

By enabling detection of signals with a longer lead time, Empirica provides risk insights earlier. And, with visual elements like graphs and colors that quickly alert users to work that needs attention, safety evaluators are able to drill-down into detailed data and manage safety issues more efficiently. In addition, Empirica lowers the number of false positive results, through sophisticated algorithms, which reduces the work of reviewers. Taken together, these powerful capabilities optimize your team's time and budget. Empirica truly delivers smarter signal detection and management for the modern world of safety.

"We're committed to advancing the science of safety and bringing the benefits of that research to our Empirica customers. Throughout the product's history, our team of world-class statisticians and data scientists has continuously enhanced Empirica's signal detection methods, which have evolved into industry-leading algorithms in wide use today."

BRUCE PALSULICH
VICE PRESIDENT,
PRODUCT STRATEGY
ORACLE HEALTH SCIENCES

Connect with us

Call +**1.800.633.0643** or visit **oracle.com/healthsciences** Outside North America, find your local office at: **oracle.com/contact**.

B blogs.oracle.com/health-sciences   in linkedin.com/showcase/oracle-health-sciences/   f facebook.com/oraclehealthsciences

About Oracle Health Sciences

As a leader in Life Sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the Life Sciences industry to improve patient outcomes. Oracle Health Sciences. For life.