

THE EVOLVING DRUG SAFETY LANDSCAPE: A Conversation with Chan Russell



Overview

With continued focus on effective and safe drug therapies, both regulatory agencies and the pharmaceutical industry are making efforts to improve the safety of the drug development process with advanced technology.

The result is an evolving drug safety landscape. Chan Russell is Vice President of Safety Product Strategy, and drives information technology strategies for Oracle Health Sciences lifecycle safety management and pharmacovigilance solutions.

Mr. Russell possesses more than 20 years of experience developing computer systems for biomedical applications and has led the development of major pharmaceutical industry applications related to clinical data management, laboratory data analysis, adverse event tracking and reporting, and safety signal detection. Previously he was President of Phase Forward's Lincoln Safety Group and cofounded Belmont Research, Inc.

Here, Mr. Russell addresses changes in the drug safety landscape. He also discusses the role of Oracle Health Sciences safety solutions in managing these changes.

Frequently Asked Questions

How do you see the current drug safety landscape and how is it evolving?

While companies must still continue to cover the fundamentals of case processing and reporting—often on tighter budgets—they are also expected to do quite a bit more than in the past. At Oracle, we've already seen increased requirements for risk management plans, risk evaluation and mitigation strategies, as well as more requests for post-authorization studies. The FDA is researching new methods to review clinical trials safety data for signals, and there are many initiatives to try to capitalize on observational healthcare records and claims data for improved insights into drug safety, such as the FDA Sentinel system, the Observational Medical Outcomes Partnership (OMOP) and the eHealth Initiative (eHI).

So, there appears to be an increased focus on safety-related issues among regulators. What is at stake, and how is the industry reacting?

Regulators—the FDA in particular—have been under increased public and political pressure to reduce the risk of regulated medical products without delaying the review and approval process for new therapies. This puts regulators in a delicate position in that they are looking for ways to review safety more rigorously, yet also more rapidly. As a result, they're placing a much greater reliance on technological approaches. Most sponsors realize they can't just sit by and watch—they need to have capabilities that are at least comparable to what's being done at the regulating agencies.

How have trial sponsors responded to this more vigilant regulatory environment?

Some sponsors are continuing to seek new efficiencies in the traditional, mandatory, pharmacovigilance processes, and taking a wait-and-see attitude towards some of the new developments. Others are just beginning to realize the benefits of quantitative approaches to spontaneous report data, and some progressive companies have completely reinvented their safety processes. As the industry transitions from passive to active surveillance activities, demand is building for a more thorough, exploratory approach that can use quantitative techniques with all available evidence, ranging from the discovery and preclinical through post-approval stages.

What data sources are feeding this more comprehensive, proactive approach to drug safety?

At Oracle, we believe today's safety experts need expanded access to at least three major sources of data: clinical trial data; spontaneous adverse event reports, and electronic health records. Each data source has its own individual strengths and weaknesses, but when taken together, they can provide a broad range of information to support a life-cycle approach to drug safety.

Could you provide an example of this more proactive drug safety approach?

One example is a collaboration on a novel solution to screen drug candidates for potential adverse medical reactions, which won the Wall Street Journal Technology Innovations Award for Healthcare IT in 2008. The solution made it possible to identify possible relationships between chemical fragments of drug compounds and potential safety issues—which were identified primarily from spontaneous report data through data mining—during the early stages of drug development.

What is Oracle's safety strategy and how does it fit into the expanded regulatory safety paradigm?

The increased regulatory focus on safety issues has crystallized the industry need for an integrated suite of safety tools to access, analyze and relate multiple sources of safety data. As such, Oracle offers the Oracle Health Sciences safety solutions comprehensive pharmacovigilance and risk management product set that provide solutions for adverse event management; pre- and post-market signal detection; and electronic submission of case reports to regulatory authorities.

What other safety initiatives is Oracle pursuing?

We're working to improve integration, both among our full product line of clinical and safety products, as well as with applications developed by sponsors and other companies. The need for integration is one of the reasons why we've been so supportive of industry standards. The CDISC Study Data Tabulation Model (SDTM) standard, for instance, is a fundamental prerequisite for our clinical trials signal detection system feature in Oracle Health Sciences Empirica Study On Demand.

Additionally, Oracle Health Sciences clinical data warehousing solutions provide an enhanced safety data repository that will integrate with our safety and E-clinical products. Oracle also has a significant research and development project focused on signal detection in healthcare databases that is sponsored by the U.S. Department of Defense (DoD) and the FDA. We have begun a pharmaceutical company pilot program to use some of the technologies and experiences gained in the DoD project in conjunction with commercially available healthcare data.

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Hardware and Software, Engineered to Work Together

Could you provide more details about the Department of Defense project?

This project has been a multiyear activity sponsored jointly by the DoD and the FDA. Oracle is using the DoD Tricare data system, which includes approximately 12 million DoD active duty personnel, dependents and retirees. It's a rich and representative database because it includes all age groups and very good representations of patient observations and treatments for both inpatient visits and outpatient claims.

We have been able to transform streams of longitudinal data into a series of artificially-constructed, adverse event reports, and have adapted and expanded our Oracle Health Sciences Empirica Signal both for signal detection (through data mining) and signal evaluation (using cohort selection, query tools, reporting, and visualizations). We've barely scratched the surface of all that can be done with this type of data, but we're fascinated by what we've already seen and the many possibilities still before us.

It sounds like there are some real innovations occurring in the field of drug safety, where will these breakthroughs take us?

As we learn to capitalize on these new sources of knowledge and the methods for using them, we should see a real uptick in the quality of medicines, as well as the confidence of physicians prescribing drugs and the comfort level of patients who are taking them. We've always known that spontaneous reporting systems suffer from underreporting and bias, so the possibilities of learning what's really happening out there using healthcare data is especially provocative. Even our preliminary forays into the data mining of healthcare records have uncovered valuable information that might have previously gone unnoticed.

Safety experts now have more resources at their disposal than ever before. What the industry needs now are the advanced tools and experience to use these resources more effectively to improve the overall public health. We believe Oracle Health Sciences safety solutions can help make this possible, and we are extremely excited about what the future holds.