



## **Opportunistic Growth: Oracle Buys Relsys to Strengthen Its eClinical Position**

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### **IN THIS PERSPECTIVE**

This Health Industry Insights Perspective examines the recently announced acquisition of Relsys International, a leading drug safety and pharmacovigilance solution provider by Oracle Corp. To us as analysts, the acquisition makes perfect sense and reinforces several important trends driving the industry today. In addressing the continuing move toward improved operational efficiency, continued critical importance of drug safety in achieving drug approvals, and growing market share in this increasingly competitive life science IT ecosystem, Oracle's acquisition of Relsys strongly complements its existing health sciences portfolio to provide its pharmaceutical and biotechnology clients with a comprehensive IT suite to advance their clinical trial efforts. While the integration of Relsys into Oracle is expected to require significant effort, the addition of this leading pharmacovigilance solution clearly strengthens Oracle's ability to respond to market needs and provides Oracle with new upsell opportunities into Relsys' substantial client base.

### **Situation Overview**

#### ***The Convergence of eClinical IT***

There is steady movement forward in the transition from paper-based information management in clinical trials to managing information electronically. Each information segment in the clinical development process has grown electronic equivalents, but interoperability was often a latent or nonconsideration. As these solutions have matured, companies developing multiple segment solutions have made efforts to interconnect their product offerings. Within the life science market, drug development companies have typically engaged external systems integrators to custom connect their diverse array of clinical IT solutions, regularly connecting what they consider to be best-of-breed clinical segment IT solutions from different vendors to achieve their eclinical ecosystem goals. When properly implemented, direct benefits can be substantial, ranging from better data quality to faster time to results.

As commercial eclinical product solutions have matured, two major pathways have opened up to expedite the process of clinical trial data interoperability. Lead by the Clinical Data Interchange Standards

Consortium (CDISC), the move to establish global, vendor-neutral, platform-independent data standards across all aspects of clinical research is progressing at a slow but steady pace. In parallel, commercial vendors with multiple clinical IT product offerings have worked to fully connect their products with the goal of promoting the synergistic features enabled by product connectivity.

Bringing Relsys' leading adverse event reporting, risk management, and drug safety analysis solutions into the Oracle clinical product suite can be expected to accelerate electronic information sharing in the critical clinical pharmacovigilance IT niche that is currently held back by the need for human intervention at multiple points in the process.

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### **The Critical Importance of Pharmacovigilance in Drug Development**

While, by definition, pharmacovigilance is the pharmacological science centered around the study of drug adverse events, the term is generally used interchangeably with drug safety. Regardless of the name used, pharmacovigilance is a critical element in the clinical development process, continuing throughout the entire drug life cycle and prominently important during both clinical trials and peri-approval/marketing.

Living in the shadow of highly publicized drug withdrawals and failures such as Vioxx, torcetrapib and, most recently, Raptiva, drug developers have been and remain highly risk averse with respect to issues surrounding drug safety. This concern has raised the importance of monitoring drug safety during clinical trials, with a strong focus on identifying significant adverse event concerns as early as possible with a view toward both preventing exposure of patients and terminating ill-fated trials as early as possible. Although numerous technology products have been commercialized in the pharmacovigilance space, with many developed as an extension of preexisting, commercial, non-industry-specific product solutions, the most successful products in the industry to date have been drug industry-specific solutions developed specifically for the space. Relsys has been a leading example of this approach, and its incorporation into the Oracle product suite is expected to expand Oracle's product capabilities by adding significant new drug safety processing and reporting capabilities and analytics to supplement Oracle's existing AERS drug safety product option.

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### **Fueling Business Growth at Oracle**

While expected to remain intact as a separate product during the initial transition period, Oracle is expected to invest substantial effort during the first 12–18 months to integrate the Relsys drug safety product suite into the much larger Oracle clinical product suite. As a leading drug safety solution in the life science industry today, Relsys possesses a

substantial client base that is of significant value to Oracle. Once integrated (or concurrent with the integration process), Oracle can be expected to pursue significant upselling efforts in hopes of adding other Oracle product offerings to existing Relsys customers. With only one other major eclinical vendor (Phase Forward) capable of providing a comprehensive eclinical solution, the expanded Oracle offering has the potential for significant new traction in the marketplace.

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### **Moving Forward**

The acquisition of a leading drug safety production solution by Oracle is a strong indication of Oracle's commitment to maintain a leadership role in driving the future of clinical information management. While standards-based interoperability will continue to drive progress toward company-independent best-of-breed product selection for many companies, comprehensive eclinical product suites can be expected to retain significant appeal, especially as more and more of the clinical development process is outsourced. Once the primary focus of solutions is targeted toward small and medium-sized pharmaceutical and biotech companies, comprehensive eclinical solutions are receiving increased interest from large pharmaceutical companies as companies look for new opportunities to control costs and replace homegrown legacy eclinical solutions.

To succeed, Oracle must remain diligent in its efforts to fully integrate Relsys into the Oracle eclinical product suite. The effort is not expected to be easy and will require significant investment and commitment from Oracle if it is to be done properly and effectively. With Oracle's recent creation of its Health Sciences Global Business Unit as evidence of its commitment to the industry, we believe that Oracle is up for the challenge.

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### **Essential Guidance**

The acquisition of Relsys by Oracle is an important validation of the industry trend toward comprehensive electronic data/information management in the life science industry. Beyond adding a leading industry drug safety solution to the already multifaceted Oracle product suite, this acquisition brings the additional benefit of an expanded customer base from which it can expect significant upsell opportunities.

Oracle's ability to fully extract value from the Relsys acquisition is not assured. Oracle needs to invest significant time and resources in fully integrating the Relsys product line into the existing Oracle product suite. Full integration can be expected to unleash significant benefits through more timely, transparent sharing of data across the eclinical value chain, accelerated extraction of time sensitive insights, and improved, more informed, overall decision making.

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### Related Research

- *Big Pharma Finds the Path to an Effective CDW* (Health Industry Insights #HI215884, February 2009)
- *U.S. Life Science 2009 Top 10 Predictions* (Health Industry Insights #HI216217, January 2009)
- *U.S. Electronic Data Capture 2007–2012 Spending Forecast and Analysis* (Health Industry Insights #HI215874, December 2008)
- *Medidata Brings Intelligent Design to Clinical Trials* (Health Industry Insights #HI215334, November 2008)
- *The Power of Familiarity: TranSenda Takes on CTMS* (Health Industry Insights #HI213286, July 2008)
- *A Vision for Sustainable Intelligence in Integrated Clinical IT Systems* (Health Industry Insights #HI206165, March 2007)
- *Adverse Event Reporting and Pharmacovigilance: Making Drug Safety Happen* (Health Industry Insights #LSI1011, April 2005)
- *Lincoln Technologies: Strategic Pharmacovigilance* (Health Industry Insights #LSI1001, January 2005)

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