New Emerging Biopharmaceutical Market Solutions from Oracle Health Sciences

Providing hundreds of customers in this sector with industry-leading, affordable, best of breed, clinical R&D cloud solutions.

» Optimizing their clinical development and productivity
» Facilitating their regulatory compliance
» Providing an affordable pricing model and rapid deployment method
» Offering access to the **Oracle CRO Advantage** Program
» Enabling faster delivery of drugs to patients

Emerging biopharmaceutical organizations face a growing number of regulatory requirements and, due to increased competition,[1] acute pressure to speed time to market. **Small CRO's who have adopted the Oracle Health Science platform have decreased clinical trial set-up by more than 50 percent (%), from up to nine (9) weeks, to down to two to four (2 to 4) weeks**.

Oracle Health Sciences suite of industry-leading cloud solutions[2] including: **Oracle Health Sciences InForm**, **Oracle Health Sciences IRT**, **Oracle Argus**, **Oracle's Siebel Clinical Trial Management System**, and **Oracle Health Sciences ClearTrial Plan and Source Enterprise Edition Cloud Service**, provide emerging organizations with the ability to optimize productivity and navigate complex regulatory compliance requirements with ease..

Emerging Biopharma Customer Examples

Biopharmaceutical organizations, including **sponsors** such as Accera and NewLink Genetics and **contract research organizations (CROs)** H2O Clinical, FMD K&L and 4C Pharma Solutions, selected Oracle Health Sciences solutions to manage their end-to-end clinical trial processes, boost clinical development productivity, facilitate compliance, and build scalable, affordable platforms for growth.

"Oracle has long been a trusted partner working alongside smaller, emerging firms by developing innovative solutions to help them grow. Our industry-leading clinical development, management, and safety solutions deploy rapidly and scale on demand, empowering emerging biopharmas to optimize clinical productivity, focus resources on innovation, and manage critical regulatory requirements with confidence."

STEVE ROSENBERG
SENIOR VICE PRESIDENT AND GM
ORACLE HEALTH SCIENCES

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[1] DiMasi JA, Faden LB. "Follow-on Drug R&D: New Data on Trends in Entry Rates and the Timing of Development," Tufts Center for the Study of Drug Development Working Paper, Boston, Mass.: CSDD. September 2009. Accessed March 2015

[2] IDC Health Insights, "Vendor Assessment: 2014 Top 10 Life Science Software Vendors," Eric Newmark and Alan S. Louie, March 2015.

» **H2O Clinical**, a US and Taiwan-based CRO delivering highly cost-effective, focused, clinical data management services, reduced its trial set-up time by over half, using Oracle.

> *"H2O Clinical, a US and Taiwan-based CRO delivering highly cost-effective, focused, clinical data management services, was able to reduce its trial set-up time by more than 50 percent (%), from up to nine (9) weeks down to two to four (2 to 4) weeks, using Oracle Health Sciences InForm."*

» **FMD K&L** adopted Oracle Health Sciences InForm to help ensure data accuracy and efficiencies.

> *"We are dedicated to providing high-quality results to get our clients' drug or medical products approved quickly,"* said Dr. Xin Ke, president, FMD K&L. *"Oracle Health Sciences InForm is a proven, industry-leading clinical data management system that enables us to raise the standard of excellence through accuracy and consistency on a continuous basis. Additionally, the ability to collaborate with Oracle on developing industry standards and implementation of best practices has been invaluable in improving the quality and efficiency of our services."*

» **Accera**, a biotechnology company focused on conditions affecting the central nervous system, uses cloud-based Oracle Health Sciences ClearTrial Plan and Source Enterprise Edition Cloud Service to layout predictable costs and model scenarios for future trials

> The solution helps Accera communicate the implications of different scenarios to investors and other stakeholders. It also gives the company a benchmark for cost comparisons, and helps with financial projections and forecasting for each scenario. This allows Accera personnel to use time and resources more efficiently in the critical planning stages of their clinical development programs.

» **4C Pharma Solutions** and **NewLink Genetics** use Oracle Argus Safety for greater insight into product-safety issues, improved productivity, and streamlined safety reporting.

> *"As the life sciences industry becomes more regulated in reference to drug safety, we believe in providing customized, reliable, cost-effective, and global solutions while building long-lasting relationships to provide a great experience,"* said Yathendra Madineni, M.D., CEO, 4C Pharma Solutions. *"We build with trust, prove with quality, and truly make our partners' requirements our passion. With Oracle Argus Safety solutions, our team can help our partners focus on research and innovation while we take care of the rest."*

» **NewLink Genetics**, developing, and commercializing immuno-oncology products that use the body's own immune system to fight cancer, implemented the centralized database within Siebel Clinical Trial Management System, to manage its clinical trial activities and improve relationships with investigators, from early to late-stage studies.

> *"We develop multifaceted treatment strategies and several immuno-oncology agents through clinical trials enrolling patients at sites worldwide,"* said Eugene P. Kennedy, M.D., vice president of Clinical and Medical Affairs, NewLink Genetics. *"As we push forward to bring much needed treatment options that will revolutionize the way we treat patients with cancer, our team utilizes Oracle Health Sciences solutions for real-time visibility into our operational performance and regulatory compliance requirements."*

Additional Information

*To learn more the Oracle CRO Advantage program:

» Twitter @OracleHealthSci and @OracleCROAdv
» Facebook.com/oraclehealthsciences
» Read our press release here
» Visit about Oracle Health Sciences at www.oracle.com/health-sciences
» Call 1.800.633.0738