



Products Created through LION bioscience and Silicon Genetics Alliance **ACCELERATE LIFE-SCIENCES R&D**

The LION Target Engine and SRS-GeneSpring Connectors are the first products to be created from a multiyear joint-development and marketing collaboration that LION bioscience and Silicon Genetics entered in June 2003. The combination of LION Target Engine and SRS with Silicon Genetics GeneSpring is expected to enable researchers to improve the speed and accuracy of their analysis.

The companies developed the Connectors in response to strong customer demand for integration between the two companies'

biological solutions. The Connectors allow users of GeneSpring, a tool for expression analysis, to easily transfer data to the LION Target Engine and SRS data and analysis tool integration platform. Results displayed in LION Target Engine and SRS can be automatically transferred to GeneSpring for additional analysis.

In addition, the SRS-GeneSpring Connector also provides a page in SRS, which includes predefined queries tailored for gene expression data analysis. The integration of SRS and GeneSpring allows scientists to include biological information from both public and proprietary sources in their gene expression analysis.

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Health Research International **LAUNCHES ONLINE SURVEY CAPABILITY**

Health Research International has launched its real-time, online survey capability. The online format complements the company's existing survey expertise, encompassing design, data acquisition, custom database creation, and statistical analysis.

The online surveys feature professionally designed templates that optimize the quality and quantity of responses, and the confidential administrator section can be tailored to the specific analytical requirements of each client.

"We are especially pleased that the online survey and administrator capabilities allow our customers to monitor the survey results real-time as they come in, enabling them to react almost immediately to important information," says Rick Hallett, director of custom consulting sales. "The online format also is convenient for respondents, and it provides a mechanism for our clients to monitor market developments over time, such as quarterly or even monthly."

Real-Time Online Surveys represent HRI's most recent addition to its portfolio of custom consulting services. In addition to primary data acquisition, these services include pricing sensitivity studies, FDA and international regulatory services, reimbursement analysis and support, physician and end-user interviews and focus groups, economic market modeling and forecasting, and operations analysis.



Rick Hallett

Rick Hallett, director of custom consulting sales at HRI, says the company's new survey capability allows customers to react almost immediately to important information.



Serge Bodart

"The Symfo acoustic PDA diary will add tremendous value to the clinical projects that are suitable for this innovative type of EPD. We are confident that many projects in clinical drug development and disease-management programs will benefit from the Symfo acoustic PDA," says Serge Bodart, CEO of Symfo.

and symptomatology. The PDA solution can accommodate "quality of life" questionnaires and includes visual analogue scales. The color screen interface can be designed to maximize ease of use for the patient, and a validated Web-based platform allows sponsors to develop study questionnaires online with the ability to make modifications during the course of the study if needed.

Symfo Tool **OPTIMIZES USE OF ELECTRONIC PATIENT DIARIES**

Symfo has launched technology designed to simplify the tasks of recording and then transmitting patient self-reported data in the clinical-trial process. The approach used by the Symfo Acoustic PDA Diary optimizes the implementation and utilization of electronic patient diaries.

The Symfo Acoustic PDA Diary transmits patient data without wires using a standard telephone with the company's unique acoustic transmission technology. Data from clinical trials, postmarketing studies, and disease management programs are immediately available to sponsors for review online.

To transmit information, a patient dials a toll-free number and puts the PDA next to the phone to enable wireless, acoustic transmission. This is the first PDA product available with an acoustic transmission. The solution collects validated date- and time-stamped information that can be available for review online in near real time.

The acoustic tool uses mobile technology and allows instantaneous recording of events such as medication intake and symptomatology. The PDA solution can accommodate "quality of life" questionnaires and includes visual analogue scales. The color screen interface can be designed to maximize ease of use for the patient, and a validated Web-based platform allows sponsors to develop study questionnaires online with the ability to make modifications during the course of the study if needed.

invivodata Enhancements Address **KEY REGULATORY REQUIREMENTS FOR CLINICAL-TRIAL DATA INTEGRITY**

invivodata Inc. has launched invivodata eSource Manager v2.0, an update to its eSource management system for electronic Patient Reported Outcomes (ePRO) data.



Dr. Jean Paty

The invivodata eSource Manager provides an online solution that allows investigators to control their patients' ePRO data, while also complying with the clinical-trial protocol.

invivodata eSource Manager v2.0's new features include tools to generate local copies of data at the clinical-research site, the use of 64-bit DES data encryption on the eDiary to provide even tighter security and integrity, and extended investigator-activity reports.

These enhancements allow clinical-trial investigators, monitors, and regulators to easily and efficiently review, maintain, and control the ePRO source

data used to evaluate the safety and efficacy of new treatments.

invivodata eSource Manager's compliance with regulatory requirements has been recently confirmed through approval of a new drug application based on data collected using the invivodata eDiary system and through FDA's permission to proceed with trials after its review of the proposed e-diary methods. The invivodata eSource Manager monitors any changes to the clinical trial data by creating a comprehensive audit trail, which is key to meeting regulatory requirements. The FDA's regulations state that the investigator's primary responsibility is to prepare and maintain case histories on all patients involved in a clinical trial.

"Data integrity is the goal of all clinical studies and can never be compromised," says Dr. Jean Paty, chief quality officer for invivodata. "The invivodata eSource Manager provides an online solution that allows investigators to control their patients' ePRO data, while also complying with the clinical-trial protocol. While our eSource management system has always included functionality that secures ePRO data from willful tampering or accidental changes, we've added several new user enhancements to make the process smoother for both investigators and regulators."

LIQUENT PRODUCT MEETS INDUSTRY NEED for R&D Document Management

The Lipient InSight Foundation is the first product from the Lipient's family of solutions that integrates document, publishing, and submission management technology. The Documentum-based electronic regulatory document-management system is designed from the ground up to optimize document management in support of emerging submission formats such as the common technical document (CTD) and electronic common technical document (eCTD).

InSight Foundation extends a standard Documentum investment by providing a pretailored configuration based on best practices for pharmaceutical research and development documentation.

The InSight Foundation is easily configured, allowing organizations of all sizes to avoid costly investments in software customization.

"Users benefit from well-defined processes that guide organizations toward good content creation, review, security, and assembly without the extended consulting engagements required by other solutions," says Hugh Tamassia, Lipient's chief technology officer.

InSight Foundation is part of Lipient's complementary product suite, Lipient InSight, which integrates enterprise compliance processes, including the creation, publishing, consumption, and management of documents.

"The release of InSight Foundation represents a major milestone in the achievement of our overall product vision," adds Jay Nadler, president and CEO of Lipient. "This product was developed after extensive discussion with Lipient's customers as well as a review of regulatory specifications to provide the best-fit solution for document management optimized for today's regulatory operations. InSight Foundation can also be configured to meet the document management requirements of manufacturing and sales and marketing organizations within the life-sciences enterprise."



Jay Nadler

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Follow up

HEALTH RESEARCH INTERNATIONAL,

Cleveland, Ohio, provides the pharmaceutical and medical-device industries with reliable, comprehensive, and meticulously researched market analysis that incorporates strategic vision and a thorough understanding of competing medical technologies. For more information, visit healthri.com.

INVIVODATA INC., Pittsburgh, integrates science and technology to improve the process for capturing patient self-report data, delivering unmatched patient compliance with study protocols. For more information, visit invivodata.com.

LION BIOSCIENCE AG, Heidelberg, Germany, with U.S. offices in Cambridge, Mass., provides proven information and knowledge-management solutions to significantly improve life-science R&D

performance and productivity. For more information, visit lionbioscience.com.

LIQUENT INC., Fort Washington, Pa., is a provider of content assembly, publishing, and regulatory and intellectual property information solutions for the life-sciences industry, and a part of the Intellectual Property Group of Information Holdings Inc. For more information, visit liquent.com.

SILICON GENETICS, Redwood City, Calif., is a leading provider of expression data analysis and management solutions that accelerate the pace of functional genomics research and drug discovery. For more information, visit silicongenetics.com.

SYMFO, Cambridge, Mass., is a fast-growing international organization specializing in electronic patient diary solutions. For more information, visit symfo.com.