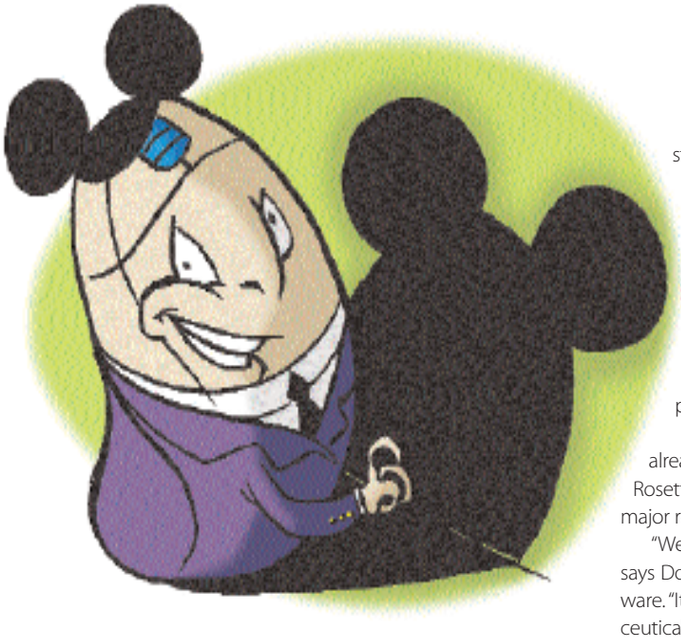

GENE-EXPRESSION DATA ANALYSIS SYSTEM
Is Targeted to Smaller Research Organizations

The Rosetta Luminator system, a client-server bioinformatics system for storing and analyzing microarray data, has been launched by Rosetta Biosoftware and Agilent Technologies Inc. The gene-expression data analysis solution was developed to meet the needs of small- to medium-size pharmaceutical and biotechnology corporations, as well as academic laboratories and core facilities involved in gene-expression research. The system is designed to grow with the needs of the gene-expression researcher, and provides a seamless upgrade path to Rosetta Biosoftware's flagship enterprise gene-expression data analysis product, the Rosetta Resolver system, which is targeted toward large pharmaceutical companies and major research facilities.

Agilent has exclusive distribution rights to the system. The company already has an arrangement with Rosetta Biosoftware to distribute the Rosetta Resolver system, targeted at large pharmaceutical companies and major research facilities.

"We view this new product as a catalyst for gene-expression research," says Douglas E. Bassett Jr., Ph.D., VP and general manager of Rosetta Biosoftware. "It will enable the research efforts of small- to medium-size pharmaceutical and biotechnology companies, as well as many academic institutions, by serving as a powerful solution for gene-expression analysis tailored in capacity and price to meet the needs of these researchers."

The Rosetta Luminator system can analyze ratio and intensity data in one system, negating the need for separate modules or products to analyze various data formats. The system also provides a centralized Oracle database to locally warehouse all microarray data and relevant experiment annotations.

In addition, the system leverages Rosetta Biosoftware's advanced technology-specific error models to assign P-values and error bars to every single gene-expression data point. This facilitates the identification of genes with significant present/absent calls or up/down regulation at a desired confidence level. The quality statistics calculated by these error models automatically take advantage of experimental replicates, and are used by every feature of the system to produce optimal results.

Dr. Douglas Bassett Jr.

"The Rosetta Luminator will enable the research efforts of small- to medium-size companies and institutions by serving as a powerful solution for gene-expression analysis tailored in capacity and price to meet the needs of these researchers," says Douglas E. Bassett Jr., Ph.D., VP and general manager of Rosetta Biosoftware.

MediMedia Introduces Web-based Report Capabilities for TRACKING HMO FORMULARY STATUS

MediMedia Information Technologies is introducing Formulary Access Spectra, a report available on www.formularycompass.com for all major therapeutic classes. Formulary Access Spectra provides easy-to-use summaries of a product's HMO formulary status and allows standardized comparisons between products. Users also can review historical formulary status trends for products in a therapeutic class, which provides insight to the managed-care marketplace for strategy development and monitoring.

Web-based report tracks HMO formulary status for all major therapeutic classes.

Users of the report can assess the trend in formulary status for products and compare data with competitors, monitor trends in overall class coverage, determine HMO responses to new market entrants for specific therapeutic classes, adjust forecasts based on HMO coverage trend data, and determine overall formulary status over time.

The report is available through the Website for Formulary Compass, a database that contains the complete drug formulary for more than 2,800 managed-care organizations. Information contained in the service is collected directly from managed-care pharmacy directors or their designees by MediMedia Information Technologies personnel and entered into the database daily.

Users can develop reports online and e-mail the results directly to their company e-mail account in the form of an Excel spreadsheet, giving clients more flexibility in formatting and printing reports than a traditional Web browser.

WEB-BASED TRIAL MANAGEMENT TOOL
Provides Enhanced Flexibility and Security

Kendle International Inc.'s TrialWeb Version 2 Web-based clinical research solution provides pharmaceutical and biotechnology customers with uninterrupted access to real-time trial status information. The customized Web-based service, accessible via www.kendle.com, connects Kendle associates, customers, and clinical teams worldwide in a collaborative and secure environment to maximize knowledge and information exchange on clinical studies.

Kendle's latest release of TrialWeb features enhancements designed to provide improved flexibility and security. Version 2 is compliant with Federal Regulation 21 CFR Part 11, providing the highest level of security available for clinical-trial data. The system also has been validated according to the FDA's Good Clinical Practice guidelines, which govern the design and conduct of clinical trials. The original version of TrialWeb was released in November 1999.

The system is a "one-stop shop" for drug program and project-related information, making it possible to record and track clinical-trial progress in real time. TrialWeb is similar to a live electronic bulletin board with virtual project rooms, discussion forums, project tools, links to secure project reports, online profiles of project team members, and site search capabilities.

"As the period of exclusivity for new drugs continues to shrink, speed to market has never been more important," says Chris Bergen, Kendle president and chief operating officer. "Internet-based clinical research solutions such as TrialWeb are critical to our customers' ability to expedite trial-critical processes and bring life-changing drugs to market more quickly and efficiently."

Chris Bergen

"Technology continues to play an important role in further compressing clinical development timelines," says Chris Bergen, president and chief operating officer of Kendle.

Online Resource **PROVIDES REGIONAL LIFE-SCIENCE NEWS**

The Central Indiana Life Sciences Initiative has launched www.cilsi.com, which provides news on the area's major life-sciences companies, as well as information about the initiative, and research and funding.

www.cilsi.com provides news on Central Indiana life-sciences companies.

The CILSI is a collaborative effort of Indiana's Health Industry, Central Indiana Corporate Partnership, Indiana University, Purdue University, The Indy Partnership, and the city of Indianapolis. Central Indiana's $13.6 billion life-sciences industry, which includes Eli Lilly & Co., The Cook Group, Guidant, Roche Diagnostics, and Dow AgroSciences, employs more than 82,000 workers in about 900 companies — a 50% greater concentration than the national average.

The CILSI works with corporate, government, economic development, and academic leaders to make Central Indiana a national and international life-sciences center.

IMS Prescriber Profiler Service **DELIVERS ACCESS TO PHYSICIAN-LEVEL MARKET INTELLIGENCE**

A Web-enabled application launched by IMS Health offers clients actionable, integrated insights into prescriber demographics, prescribing activity, and sampling eligibility. IMS Prescriber Profiler tracks and integrates market-size information by therapeutic class, product, prescriber demographics, and physician eligibility to receive drug samples — enabling marketing managers to more effectively identify high-potential prescribers, pinpoint product opportunities, and refine promotional strategies.

"Prescriber Profiler leverages IMS' extensive information assets and organizes them in powerful new ways, so marketing professionals can anticipate and plan rather than react," says Bill Henderson, group director at IMS Marketing. "IMS can help clients focus their market analysis and planning on physician behaviors and more easily identify opportunities."

IMS Prescriber Profiler combines the information power of Xponent, the IMS service that tracks prescribing behavior of more than a million U.S. physicians, with IMS Prescriber Validation Services, which verifies the eligibility of U.S.-based physicians to dispense drug samples. Users can segment prescribers by specialty, location, and licensing information, as well as prescribing activity for specific markets, regions, and products in all therapeutic classes.

Software offers high data **INTEGRITY, SECURITY, AND EFFICIENCY**

Aegis Analytical Corp. has released Discoverant 1.7, an enhanced version of its manufacturing enterprise software application that uses data from multiple sources and quickly translates them into useable intelligence. The release gives pharmaceutical manufacturers the ability to meet the FDA's 21 CFR Part 11 mandate for data-intensive decision-making without replacing existing data gathering and control systems.


Dr. Justin Neway

"The beauty of these new features is that they do more than just help make the manufacturing process FDA compliant, they improve the consistency of product quality, which leads to greater profits and competitive advantage," says Justin Neway, Ph.D., Aegis' executive VP and chief science officer.

Discoverant 1.7's direct, read-only connection to data sources protects original records, while using a virtual subset of data that allows all work to be tracked. By leveraging the data directly, Discoverant 1.7 eliminates potential errors that can occur when manually plugging thousands of values into spreadsheets, as required by other decision-making tools.

Intellisphere Launches **INTERNET RESOURCES FOR MS PATIENTS**

With a goal of providing patients with a collection of Internet resources on general disease information, associations and organizations, and support groups, Intellisphere LLC has published *MS net guide: A Patient's Guide to Multiple Sclerosis Websites*. The guide will be made available to patients in neurologists' waiting rooms across the country.

In conjunction with the patient print piece, a *MS net guide* Website, located at www.msnetguide.com, was developed to provide quick access to all sites listed in the pamphlet, as well as additional links to insurance information, home-care products, clinical trials, nationwide treatment centers, professional journals, and treatment options.

To ensure its reliability and usefulness, all Websites were reviewed by noted neurologists Dr. Richard Blanck, from the New York University School of Medicine, and Dr. Patricia K. Coyle, from Stony Brook Health Science Center.

Teamwork Promotes **ONLINE EDUCATION TOOL FOR HEART PATIENTS**

Health Resource and the American Heart Association are teaming up to promote a free online education tool, Heart Profilers, through the Health Resource Newsletter. The Heart Profilers Website helps patients who have experienced heart failure, angina, atrial fibrillation, and heart attack understand the medical treatments that may be right for their specific condition.

Heart Profilers, available at www.americanheart.org/heartprofilers, details the pros and cons of treatment, relevant research studies, and important considerations for patients to discuss with their doctor. The Website gives heart patients key information needed to take charge of their health and participate in treatment decisions with their healthcare provider.

"We are very pleased to be working with the American Heart Association to help promote Heart Profilers in our pharmacy newsletters," says George Neal, president and chief operating officer of Health Resource. "The program offers helpful information and encourages patients to work with their doctors. We are excited to educate our readers about this credible, valuable resource."

Health Resource will promote the online educational tools through advertisements in the Health Resource Newsletter, which is delivered to more than 17 million pharmacy patients each week as they pick up their prescriptions at more than 17,500 pharmacies nationwide. The newsletter includes information about a patient's prescription, health articles related to the medication or condition being treated, and product advertising or health promotion messages.

Partnership to Deliver **AUTOMATED TOOLS AND SERVICES TO ASSIST WITH FDA REGULATION COMPLIANCE**

PentaSafe Security Technologies Inc. and QinetiQ Trusted Information Management Inc. have teamed up to provide joint sales, consulting services, and ongoing development of best-practice solutions that specifically aid FDA-regulated companies with 21 CFR Part 11 compliance.

As part of this alliance, PentaSafe and QinetiQ have launched the VigilEnt Policy Center FDA Content Module for 21 CFR Part 11, a supplementary policy tool to PentaSafe's VigilEnt Policy Center. The FDA Content Module contains a best-practice policy library, documents, quizzes, and other supporting documentation that facilitate pharmaceutical, biotech, and medical-device companies' compliance with 21 CFR Part 11.

"The power of PentaSafe solutions and QinetiQ Trusted Information Management's years of security expertise has forged a powerful answer to the challenges posed by FDA 21 CFR Part 11," says Michael J. Corby, president of QinetiQ Trusted Information Management.

Using VigilEnt Policy Center, information security personnel and FDA compliance officers can increase end-user awareness of 21 CFR Part 11 by establishing and automating a process to distribute customized content throughout their organization. Additionally, VigilEnt Policy Center and the Content Module combined can ensure and track regulatory compliance with 21 CFR Part 11 by providing: online user acceptance of policies; allowing users to electronically sign a policy acknowledging that they have read and understood the policy; assessment of existing policies and gap analysis to determine adequacy and measure degree of compliance; a quizzing mechanism to test employees' knowledge of policies to ensure they read and understand the policies; a reporting mechanism that gives employees a way to quickly and easily inform management of potential regulatory policy breaches; and numerous management reports to monitor and report on users, policies, quizzes, and policy violations.

Michael J. Corby, president of QinetiQ Trusted Information Management, says with VigilEnt Policy Center, life-science companies can process sensitive and critical information in full, secure, trackable regulatory compliance.

COMPLIANCE STRATEGY FOR FDA'S ELECTRONIC RECORD KEEPING, Signature Rules Released

A white paper has been published to assist pharmaceutical, medical-device, and diagnostic companies achieve compliance with FDA 21 CFR 11, the regulatory agency's rule on electronic records and signatures.

Schneider Electric, the world's largest manufacturer of electrical distribution, industrial control and automation products, and systems, and Stelex-TVG Inc., leading consultants to FDA-regulated industries, partnered to publish the paper to help their customers.

Stelex-TVG's and Schneider Electric's white paper addresses FDA 21 CFR 11 to assist pharmaceutical, medical-device, and diagnostic companies achieve compliance.

"The goal of this white paper is to specifically address these regulations and provide detailed guidance for customers using Schneider Electric's automation hardware and software," says Steven Pogrebivsky, a Stelex principal and one of the paper's authors. "These suggestions will assist customers with existing and future installations to bring their operations into compliance with 21 CFR Part 11 regulations."

The white paper covers Schneider Electric's existing automation hardware and software product lines, which are widely used in pharmaceutical plants and the regulatory requirements of programmable logic controllers and software used to develop PLC programs compliant with the federal regulation.

"As the FDA's interpretation of 21 CFR 11 evolves, we believe that it must eventually get to the real source of plant automation data, the programmable logic controller," says Stephen Larson, global pharmaceutical marketing management for Schneider Electric. "This white paper will help our customers achieve compliance on their legacy systems, as well as drive our product development efforts to create new products that are compliant right out of the box."

HIVresistanceWeb's HIV Drug and Mutation Reference Guide **NOW AVAILABLE FOR HANDHELD DEVICES**

Craig Sterritt

The PDA software provides clinicians with a robust yet portable source of HIV drug resistance information.

HIVresistanceWeb, an online medical community from Vertibrae Inc., has published the HIV Drug and Mutation Reference Guide, available for free download from www.HIVresistanceWeb.com onto Palm handheld devices and other PDAs.

The guide's PDA application represents the handheld digital version of HIVresistanceWeb's Drug and Mutation Data Webpages, which provide at-a-glance and in-depth drug- and mutation-specific information, as well as extensive references and links to research databases.

"With more than 1,000 downloads in the first 30 days, it is clear that HIV clinicians appreciate the ability to have HIV drug resistance information on hand when making treatment decisions based on viral load results, treatment history, and/or genotypic resistance test results and interpretations," says Brian Conway, M.D., co-chair of the HIVresistanceWeb Editorial Board.

"The PDA software provides clinicians with a robust yet portable source of HIV drug resistance information," says Craig Sterritt, HIVresistanceWeb's managing editor. "In terms of richness and depth of information, the handheld software offers a nice midpoint between our online drug and mutation data pages, which are quite comprehensive, and our printed reference guide, which necessarily provides only cursory information on drug resistance mutations."

A printed reference guide, entitled HIV Drug Resistance Information At a Glance, also is published by Vertibrae for HIVresistanceWeb.

HIVresistanceWeb is an independent, educational resource dedicated to the advancement of anti-HIV therapy through information sharing and expert discussion of current issues in antiretroviral drug resistance and clinical HIV virology. HIVresistanceWeb is made possible by an unrestricted educational grant from GlaxoSmithKline.

Follow up

AEGIS ANALYTICAL CORP., Lafayette, Colo., provides manufacturing software and expertise that help pharmaceutical and biotech companies improve compliance, increase profits, and gain competitive advantage. For more information, visit aegiscorp.com.

AGILENT TECHNOLOGIES INC., Palo Alto, Calif., is a global technology leader in communications, electronics, and life sciences. For more information, visit agilent.com.

AMERICAN HEART ASSOCIATION, Dallas, is a national health agency whose mission is to reduce disability and death from cardiovascular diseases and stroke. For more information, visit americanheart.org.

CENTRAL INDIANA LIFE SCIENCES INITIATIVE, Indianapolis, is a collaborative effort of the Indiana's Health Industry, Central Indiana Corporate Partnership, Indiana University, Purdue University, the Indy Partnership, and the City of Indianapolis, to make Central Indiana a national and international life-sciences center. For more information, visit cilsi.com.

HEALTH RESOURCE, St. Louis, is a business unit of Health Marketing Services, the healthcare subsidiary of Catalina Marketing Corp. Health Resource distributes therapeutically targeted healthcare information, including marketing communications. For more information, visit catalinamarketing.com.

IMS HEALTH, Fairfield, Conn., is a provider of information solutions to the healthcare and pharmaceutical industries. For more information, visit imshealth.com.

INTELLISPHERE LLC, Plainsboro, N.J., publishes a series of journals focused on the Internet and technology. For more information, visit mdnetguide.com.

KENDLE INTERNATIONAL INC., Cincinnati, is a full-service contract research organization and global provider of clinical research and development services for the pharmaceutical and biotechnology industries. For more information, visit kendle.com.

MEDIMEDIA INFORMATION TECHNOLOGY, Yardley, Pa., collects, consolidates, and interprets pharmaceutical and healthcare information from health plans and hospitals in the U.S. and aggregates that data creating audits and database tools that serve health plans, hospitals, electronic prescribing software vendors, and pharmaceutical companies with strategic information. For more information, visit mminfotech.com.

PENTASAFE SECURITY TECHNOLOGIES INC., Houston, enables companies to safely grow their business by providing integrated security management solutions that ensure compliance with security policies as well as defend against the latest security threats. For more information, visit pentasafe.com.

QINETIQ TRUSTED INFORMATION MANAGEMENT INC., Worcester, Mass., offers a complete range of security solutions to meet and manage the needs of organizations. For more information, visit qinetiq-tim.com.

ROSETTA BIOSOFTWARE, Kirkland, Wash., is a provider of bioinformatics solutions to aid in drug discovery and the development of pharmaceutical and agricultural products. The company is a business unit of Rosetta Inpharmatics Inc., a wholly owned subsidiary of Merck & Co. For more information, visit rosettabio.com.

SCHNEIDER ELECTRIC, Palatine, Ill., is a leader in electrical distribution, industrial control, and automation products, systems, and services. For more information, visit schneider-electric.com.

STELEX-TVG INC., Bensalem, Pa., provides quality solutions to FDA-regulated companies by assisting corporations with quality auditing services, system development, e-enterprise solutions, system validation services, and training. For more information, visit stelex.com.

VERTIBRAE, New York, a division of Mediaworks Inc., is a growing network of online medical education communities. For more information, visit vertibrae.com.