



MEDIFACTS AND GLENEAGLES CRC ALIGN to Expand Cardiovascular Clinical Research Capabilities

An expanded scope of global cardiovascular clinical-research services is expected to be created through an alliance between Medifacts International and Gleneagles CRC Pte Ltd. (GCRC). The companies' combined expertise offers early-stage drug and device development consulting, regulatory submission assistance, and Phase II to Phase IV clinical-trial execution, including data management and statistical analysis to pharmaceutical companies worldwide.

GCRC has working relationships with more than 40 study sites throughout Asia. Medifacts' alliance with GCRC will provide U.S. and European pharmaceutical, biotech, and device companies with increased access to Asian study sites, patient populations, and experienced investigators thereby facilitating cost effective, global studies.

The alliance is designed to provide a global reach through one point of contact for increased site accessibility, as well as providing an increased investigator pool, increased demographic and geographic scope, advanced IT capability and FDA-compliant data management and clinical capabilities. The alliance also will combine proven global expertise in successful trial conduct and management with a comprehensive "tool kit" specifically designed for cardiovascular studies.

Medifacts will offer non-invasive core laboratory services to its clients as well.

DIA AND CENTERWATCH TEAM UP to Disseminate Clinical Research Information

This collaborative agreement establishes an ongoing process to jointly deliver, throughout the world, a more complete continuum of practical and valuable information for pharmaceutical and research professionals.

The Drug Information Association (DIA), and CenterWatch, a division of Thomson Healthcare, have agreed to disseminate clinical-trial information and resources to industry professionals worldwide. DIA will distribute CenterWatch's news and information services to biopharmaceutical companies, regulatory agencies, and other pharmaceutical and related healthcare industry professionals.

As part of this agreement, CenterWatch will provide its publications, training guides, news reports, clinical research investigator profiles, investigational drug profiles, and career development infor-

mation to DIA members to assist biopharmaceutical companies and other industry professionals to more effectively manage and conduct all aspects of their clinical-research studies. In addition, CenterWatch has agreed to promote DIA membership to more than 35,000 international clinical research investigators.

"DIA has always had a reputation for providing high-quality educational programs for pharmaceutical industry professionals," says Kenneth Getz, president and CEO of CenterWatch. "We are thoroughly delighted to be not only providing our information services to DIA members, but to also be raising awareness of the value of DIA membership among investigative sites."

URAC to Develop HIPAA PRIVACY AND SECURITY Accreditation Programs

URAC has announced plans to create the first-ever accreditation programs addressing both the privacy and security of health information. The comprehensive HIPAA compliance solution is being implemented to aid healthcare organizations in certifying their HIPAA compliance program.

"Healthcare organizations throughout the country have invested significant resources to ensure they are compliant with the new strict HIPAA regulations," says Garry Carneal, URAC president and CEO. "Now, healthcare organizations can certify their HIPAA compliance program and assure customers they have followed good practices to protect patient information."

URAC will offer two new accreditation programs:

HIPAA Privacy Accreditation and HIPAA Security Accreditation. URAC is designing the new accreditation programs to serve all types of healthcare organizations covered by HIPAA, such as health plans, healthcare providers, and health information clearinghouses. The programs also will be applicable to business associates.

"Making the program available to business associates is important as well," says Lisa Gallagher, URAC senior VP of information and technology accreditation.

The accreditation program will review all aspects of an organization's HIPAA compliance program. In addition,

URAC is identifying organizations to serve as beta-sites for the evaluation of the accreditation programs.

HIPAA compliance is one of the great challenges facing healthcare organizations. URAC accreditation will help companies demonstrate to themselves and others that their HIPAA compliance programs are on the right track.

**STEPHEN W. GAMMARINO
CHAIRMAN OF THE URAC BOARD
OF DIRECTORS**

ACCME PREPARES DRAFT SET OF STANDARDS for Commercial Support

The Accreditation Council for Continuing Medical Education has prepared a draft of a new set of ACCME Standards for Commercial Support, which is now being presented for comment.

One of the major changes suggested by the document concerns commercial interest in CME programs. The document states that some of these

relationships may create conflicts of interest that cannot be addressed only by disclosure. ACCME states that if a provider has a commercial interest in a clinical area, then that clinical area should be excluded from the CME developed and presented under the umbrella of their ACCME accreditation statement.

ASTROLABE ANALYTICA'S MESSAGE MAPPING System Guides Commercialization Decisions

Astrolabe Analytica Inc. has launched the Astrolabe Message Mapping System, which is designed to help pharmaceutical, medical-device, and medical diagnostics manufacturers assess the information on their products that is being disseminated in scientific literature and other sources.

The Message Mapping System was created to guide development programs for the healthcare industry and currently is in use at four major pharmaceutical companies.

"The costs for the development of a new pharmaceutical product have been estimated to be as high as \$800 million," says Lawrence Liberti, executive VP for Astrolabe Analytica. "With so much money at risk to bring a new pharmaceutical product from concept to market launch, pharmaceutical company executives have been looking for tools they can use to help them make critically important go/no-go decisions. And, this is precisely what the Astrolabe Message Mapping System is designed to do."

The Astrolabe Message Mapping System provides objective, third-party analyses. Its trend reports have been designed to help executives see the strengths and weaknesses of a product and map messages about a product or service that have appeared in regulatory dossiers and scientific and professional literature. The reports then highlight the key message points that have been either addressed or overlooked. This, in turn, helps executives make high impact, cost-effective decisions.

"The reports from the system provide critical insights that are used for product planning," Mr. Liberti says. "These insights are in the areas of a product's competitive advantages, market positioning, and target audiences for communications. Executives looking at our reports can easily discern when they need to invest in research and development, clinical trials, or marketing programs to capitalize on opportunities that exist. Message Mapping also can be used to guide clinical research budgets and analyze business development and/or licensing opportunities."

Astrolabe Analytica was launched early in 2002 as an offshoot of Pharmaceutical Information Associates.



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New Journal Focuses on EMERGING FIELD OF TOXICOGENOMICS

The National Institute of Environmental Health Sciences, part of the U.S. Department of Health and Human Services, has published the first issue of a new journal focused on the emerging field of toxicogenomics. *EHP Toxicogenomics*, a sister publication of *Environmental Health Perspectives* (EHP), is the first journal dedicated to this growing field.

The peer-reviewed journal will span the breadth of international research on the genomic basis of environmental disease through research articles, commentaries, and news from the field.

"Toxicogenomics is expanding as a field of study with great promise for broadening our understanding of how our genes interact with toxicants and in defining the molecular basis of disease," says Dr. Kenneth S. Ramos, director of the NIEHS Center for Environmental and Rural Health and editor.

The journal also will cover bioinformatics, pharmacogenomics, proteomics, metabonomics, molecular epidemiology, translational aspects of genomic research, and molecular medicine.



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Follow up

THE ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, Chicago, strives to identify, develop, and promote standards for quality continuing medical education used by physicians to improve quality medical care for patients and their communities. For more information, visit accme.org.

ASTROLABE ANALYTICA INC., Philadelphia, an affiliate of Pharmaceutical Information Associates Ltd., was launched in 2002 to support the international pharmaceutical industry's scientific communication needs. For more information, visit astrolabeanalytica.com.

CENTERWATCH, Boston, a business within The Thomson Corp., is a publishing and information services company that focuses on the clinical-trials industry. For more information, visit centerwatch.com.

DRUG INFORMATION ASSOCIATION, Horsham, Pa., is an international organization that annually holds more than 100 meetings, training courses, and symposia for nearly 30,000 members from the pharmaceutical industry, government regulatory agencies, academic institutions, contract service organizations, and other organizations around the world. For more information, visit diahome.org.

GLENEAGLES CRC PTE LTD., Singapore, a wholly owned subsidiary of Parkway Holdings Ltd., is a contract research organization and one of the largest Pan-Asian site management organizations that caters to the needs of clinical research and drug development companies. For more information, visit gleneaglescrc.com.

MEDIFACTS INTERNATIONAL INC., Rockville, Md., is a global contract research organization

focused on cardiovascular, renal, pulmonary, stroke, and metabolic clinical development programs for the pharmaceutical, biotech, and medical-device industries. For more information, visit medifacts.com.

THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, Research Triangle Park, N.C., is part of the National Institutes of Health. The organization's mission is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate. For more information, visit niehs.nih.gov.

URAC, Washington, D.C., is a leader in the accreditation of health and managed care organizations. URAC offers accreditation programs that span a broad spectrum of healthcare services. For more information, visit urac.org.