



Octagon Launches **STRATEGIC CLINICAL OFFERINGS**



Tom Guinter, VP of CDS, is heading up Octagon Research Solutions' new support organization for CDISC standards.

Octagon Research Solutions Inc. has a new service offering to support organizations transitioning to CDISC (Clinical Data Interchange Standards Consortium) standards. The newly formed Clinical Data Strategies (CDS) group is led by Tom Guinter, VP of CDS. The group was formed by realigning Octagon's CIM (Clinical Information Management) group. CDS offers a comprehensive set of consulting, training, and conversion services to support the creation of data that are compliant with CDISC standards and HL7 RCRIM initiatives.

Additionally, the company has appointed Daphne Ewing as VP of Clinical Data Operations (CDO), which is comprised of clinical-data management, programming, statistics, and medical writing functions.

"Strong leadership in both Clinical Data Operations and Clinical Data Strategies is key to the success of our CIM services," says Jim Walker, president and CEO of Octagon. "With CDISC initiatives and electronic submissions such as the eCTD playing a greater role in the industry, effectively managing the life cycle of electronic data is becoming paramount."

inChord Establishes **THE NAVICOR GROUP**

New agency to offer expertise in oncology and immunology.

inChord Communications Inc. has launched The Navicor Group, a new advertising agency focused exclusively on companies marketing oncology and immunology products.

"Today there are more cancer therapies under clinical development than any other therapeutic area," says Blane Walter, chairman and CEO of inChord. "As pharmaceutical companies continue to develop these exciting new products, the demand for marketing experts who understand this complex field will grow. inChord has a long history of working in oncology across several of our divisions. Now we're taking that expertise to the next level by establishing a specialty agency to serve companies whose focus is oncology and immunology."

The Navicor Group is led by Garnett Dezember, who serves as president. Mr. Dezember joined The Navicor Group's sister agency GSW Worldwide three years ago as senior VP to lead several oncology accounts. Before joining GSW Worldwide, Mr. Dezember worked at Bristol-Myers Squibb for 20 years, where he oversaw the marketing efforts for several key oncology and immunology products, including the launches of Taxol and Zerit.

Mr. Dezember is supported by an experienced staff, including an oncologist, an infusion pharmacist, an oncology/immunology medical sales liaison, and strategic marketers and creative professionals who have launched numerous cancer and immunology products. The Navicor Group currently employs 20 associates.

"Having led marketing programs for more than a dozen oncology and immunology products, our team can hit the ground running, immediately providing valuable insights and strategic thinking to guide our clients' marketing efforts," Mr. Dezember says.

The Navicor Group already serves as agency of record for two industry leading products: Rituxan, a treatment from Genentech for non-Hodgkin's lymphoma, and Vidaza, a treatment from Pharmion for myelodysplastic syndromes (MDS).

"With about 100 products on the market and 400 therapies in clinical trials, there are more than enough marketing opportunities in oncology and immunology to keep several agencies busy," Mr. Walter says. "The creation of The Navicor Group gives inChord a specialized resource to address the needs of particular clients and to provide solutions that will lead to growth for their brands."



Our name, Navicor, represents our unique ability to help clients navigate through obstacles and coordinate all of the critical elements for successful product promotion, says Garnett Dezember, President of The Navicor Group.

ClinPro Launches **CENTER FOR ONCOLOGY RESEARCH MANAGEMENT**

Operating under ClinPro Inc., the Center for Oncology Research Management (CORM) is providing clinical-trial services solely for the development, testing, and approval of anticancer drugs, oncology diagnostics, and cancer supportive care modalities. The division is led by Howard G. Goldsweig, M.D., ClinPro VP of medical affairs and a board-certified medical oncologist.

With the formation of CORM, ClinPro is tapping into the needs of the highly specialized discipline of cancer drug/oncology clinical trials. CORM offers pharmaceutical and biotech clients a single-source solution. Using process analysis modeling and adapting the technology platform of its parent company, CORM has developed procedures that expedite many of the tasks involved in initiating, conducting, and analyzing



As an oncologist, leading CORM is an exciting opportunity in what I consider an extremely interesting and challenging area; from a business point of view, CORM offers ClinPro a tremendous growth opportunity, says Dr. Howard Goldsweig, VP of Medical Affairs at ClinPro.

oncology clinical trials. These process initiatives fall into four categories: site management, database engineering, technology, and added-value benefits.

"CORM differentiates itself from other CROs by focusing entirely on cancer product development and optimizing its service offering for managing clinical trials of oncology products," says Richard Purcell, president of ClinPro.

CORM has assembled European and North American networks of prequalified investigator sites, many of which operate using single contracts. Local site personnel are being pretrained in CORM's standard operating procedures.

The site-management initiative markedly reduces the up-front time spent identifying, qualifying, and

negotiating with investigators.



The Ziment Group Launches **NEW** **DIVISION TO** **HANDLE** **MULTICLIENT** **STUDIES**



IMAP solutions deliver powerful understandings about markets that are different from what can be delivered through traditional custom designed market tracking research, says Howard Ziment, CEO of The Ziment Group.

The Ziment Group has launched IMAP (Integrated Marketing and Promotion) Research, a new division specializing in conducting multi-client studies to track brand performance for the pharmaceutical and healthcare industries.

"Our clients are looking more toward multiclient solutions when it comes to having an ongoing understanding of the therapeutic marketplaces in which their products compete," says Howard Ziment, CEO of The Ziment Group. "Powered by WebSurveyResearch and the Ziment Chronic Illness Internet panels, this division has

instant access to more than 75,000 physicians and 400,000 patients from around the globe. This degree of access to all critical influencers enables IMAP to provide fully integrated marketplace understandings and powerful recommendations for clients.

WHAT'S NEW ON THE SHELVES

▶ **INVESTIGATIONS OPERATIONS MANUAL (IOM), 2004-2005 EDITION** is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors.

The manual, published by **FDANews**, discusses exactly how investigators conduct an inspection and how company staff members should conduct themselves during an inspection.

There are significant changes and additions to the 2004-2005 edition, including counterfeit product investigations, import and export instructions, inspection report writing, reports of observations, and revised sample schedule charts. New or changed text is shaded for easy reference as to what's been updated since the last edition.

For more information, visit fdanews.com/wbi/bookstore.

▶ **59TH EDITION OF DRUG FACTS AND COMPARISONS** is a comprehensive drug resource for healthcare professionals that offers an efficient way to access current drug-related information.

Published by **Wolters Kluwer Health**, the book is therapeutically organized in an easy-to-use format that allows for quick comparisons of similar drugs and contains thousands of monographs covering more than 22,000 prescription and 6,000 OTC drugs. Each monograph contains the information that healthcare professionals need to make informed decisions, including generic and trade names, indications, administration and dosage, warnings, interactions, pharmacokinetics, and adverse reactions. Other valuable features of Drug Facts and Comparisons include thousands of comparative charts, manufacturers/distributors index, Canadian trade name index, and an extensive primary index. The 2005 edition includes dozens of new drugs, the latest significant indications, and revised comparative tables. Additionally, Drug Facts and Comparisons includes the new Drug Identifier CD-ROM, which enables searches of more than 5,000 color images by shape, generic or brand name, manufacturer, color, imprint, NDC code, coatings, and scoring. Drug Identifier allows users to locate a specific drug in seconds and is ideal for physicians, other prescribers, and hospital nursing stations.

For more information, visit drugfacts.com.

The Neighborhood Educates **MINORITY** **PATIENTS AND PHYSICIANS**

Four diverse organizations have joined forces to form The Neighborhood, a unique venture that provides pharmaceutical and healthcare companies with the ability to create successful minority healthcare education programs. The Neighborhood's partners include The JL Co., cruz/kravetz/IDEAS, Nakatomi & Associates, and Young Communications Group. Collectively, these organizations have well-established credentials in healthcare marketing and education as well as multicultural advertising and public relations. The organization also has a strategic collaboration with the Association of Academic Health Centers (AHC), which represents more than 100 major university health complexes nationwide.

The Neighborhood's services include multicultural strategy development, continuing medical education (CME) activities sponsored by prominent teaching hospitals, patient/consumer seminars, and

numerous other education and awareness-building efforts that target patients, consumers, and healthcare professionals.

"Nearly one-third of all Americans are of diverse cultural backgrounds, and by 2050 racial and ethnic minorities will comprise the majority of the U.S. population; this is already true in most major urban areas," says Clyde Evans, Ph.D., VP of the AHC and chair of The Neighborhood's health-education board of advisors.

As part of its relationship with the AHC, The Neighborhood collaborates with the AHC's member universities to create healthcare education programming; in turn, the AHC brings The Neighborhood access to the expertise of that membership.

The Neighborhood also has an alliance with the Spanish-language television network Univisión and is led by a health-education board of advisors that includes physicians and academic researchers from

a number of the nation's leading medical schools and teaching hospitals.

"Because health is such a personal matter, culture is an especially important lens through which medical information and advice are understood, perceptions and opinions are formed, and products and services are viewed and evaluated," says Carl Kravetz, CEO of The Neighborhood. "The agency uses its unique resources to create educational programs that respect and honor multiple cultural perspectives, thus directly impacting the quality of healthcare received in diverse communities."



The Neighborhood is uniquely qualified to work with pharmaceutical and healthcare companies to develop culturally appropriate educational programming that maximizes health outcomes for these diverse populations, says Dr. Clyde Evans, VP of the AHC and Chair of The Neighborhood's health-education board of advisors.

CME Enterprise Enhances Educational Portfolio Through **ACQUISITION OF ENABLE HEALTHCARE**



Enable Healthcare and CME Enterprise share a common vision and goal: to deliver the most scientifically rigorous and compliant accredited activities to healthcare practitioners, says Deborah Wood, President and CEO of Deborah Wood Associates.

CME Enterprise, a subsidiary of Deborah Wood Associates, has acquired the business assets of Enable Healthcare. The merging of the two organizations' education and compliance expertise increases the value of services offered by each entity.

Enable brings many strengths and advantages to CME Enterprise, including ACCME accreditation, experience with faculty relationships, and innovative services, such as DriveTimeCME and cmeOn-Call.

"We are enormously pleased to be merging our talents and proprietary products with an organization that has a proven track record of fully understanding compliance and the concrete ability to adapt to changes in regulations. CME Enterprise offers an excellent team of leaders in CME," says Alicia Efesiou, president of Enable Healthcare.

ProCE Announces **INFLIGHT CE**

Medical professionals can gain valuable continuing education credits through Inflight CE, a new program designed for healthcare professionals en route to major medical conferences. Inflight CE materials are included in every seat pocket of major airlines such as American, United, and Delta.

"We are excited by the opportunity to provide this novel approach to continuing medical education," says Richard Lewis of ProCE Inc. "By providing education in flight, Inflight CE is able to effectively reach even the busiest medical professionals. Inflight CE is ideal for companies that want to differentiate their CME offerings."

With Inflight CE, ProCE oversees the writing and publication of a continuing education monograph printed in the magazine of a major airline, offering a complete turnkey operation. Numerous options, including an in-flight TV billboard or ongoing Internet access to the monograph, are available as part of this program.

Amgen Forms **VENTURE CAPITAL FUND** to Assist Early-Stage Companies

Amgen has formed Amgen Ventures, a corporate venture capital fund designed to provide emerging biotechnology companies with resources to develop pioneering discoveries focused on human therapeutics.

"Amgen is driven by a desire to transform science through innovation and, in this way, to develop important new treatments for grievous illness," says Roger M. Perlmutter, M.D., Ph.D., executive VP of research and development of Amgen. "Our internal efforts concentrate on therapeutic areas such as oncology, metabolic disorders, and inflammation. We understand that science is a global and collective endeavor and that many of the scientific breakthroughs of tomorrow will come from early-stage companies. We also understand the challenges that these companies face."

With an initial commitment of \$100 million, Amgen Ventures intends to invest in early-stage companies primarily focused in areas of current therapeutic interest to Amgen, but also will include novel modalities with the potential to address targets in both current and emerging therapeutic areas of interest.

Accelrys Launches **NANOTECHNOLOGY CONSORTIUM**

In a move aimed at enabling companies to bring nanoproducts to market more quickly and with reduced risk, Accelrys Inc. has launched the Accelrys Nanotechnology Consortium. The goal of the Nanotech Consortium is to accelerate the development of software tools that enable the design of nanomaterials and nanodevices. Additionally, the consortium is expected to enhance nanotechnology R&D by fostering collaboration between scientists and engineers. The consortium provides a project framework and a detailed scientific proposal that addresses the challenges of rational nanomaterials and nanodevice design.

Members of the consortium include industrial researchers, academic experts, and Accelrys scientists, who are focused on developing, validating, and applying simulation to a particular research area. Members receive software, the right to provide formal input into Accelrys product plans, access to regular meetings at which experiences and ideas are shared, and dedicated application support. The consortium also offers early access to cutting-edge technology. Charter members include Coming Inc., Fujitsu, e2v Technologies, Imperial College, and Uppsala University.

The consortium is an ongoing program, organized into phases of three years. The first phase runs from July 1, 2004, to August 31, 2007.



This latest initiative is an extension of the Accelrys Consortium model, which has in the past delivered important advancements in areas such as catalysis and combinatorial chemistry, says Mark J. Emkjer, President and CEO of Accelrys.

Torre Lazur McCann Creates **CONSUMER GROUP**

Consumer Communications Group, Torre Lazur McCann's new division, is a reflection of the agency's growth in DTC assignments.

Serving as president of the new group is Jane Ames, who comes to Torre Lazur from Saatchi & Saatchi Healthcare, where she served as executive VP in charge of Prilosec, Nexium, and Entocort. She is credited with developing the "purple pill strategy," which helped make Prilosec one of the top-selling drugs.

The creation of the consumer division allows the agency to fully



Jane Ames joins Torre Lazur McCann as President of its newly created Consumer Communications Group.

integrate its clients' consumer, professional, and managed-care activities, says Beverly Breitenbach, Torre Lazur McCann's CEO in the United States.

"In today's environment, we believe that the best way to serve the client is to provide all aspects of the marketing program under a single agency roof," she says.

In addition to Ms. Ames, members of the Torre Lazur McCann Consumer Group include Matt Leung, VP, management supervisor, and Vanessa Levin and Jennifer Alampy, who lead the creative team.

Manhattan Institute Announces 21ST CENTURY FDA TASK FORCE

The Manhattan Institute has created a 21st Century FDA Task Force with more than 20 members to devise and promote better science-based regulations at the FDA that will decrease the time and cost required for new drug development while increasing the safety and efficacy of the nation's drug supply.

Robert Goldberg, Ph.D., Task Force chairman and director of the Manhattan Institute's Center for Medical Progress, has created a brain trust of leading scientists and stakeholders comprising experts from academia, industry, and the policy community. The Task Force will develop and disseminate proposals to reform the FDA's drug approval and safety monitoring procedures.

"The Task Force will leverage the current crisis to transform the FDA and embrace the promise of 21st century technologies," Dr. Goldberg says.

The Task Force also is chaired by Nobel Prize winner Joshua Lederberg, Ph.D., professor emeritus at Rockefeller University, and includes Frederick Goodwin, M.D., professor of psychiatry and director of The Center on Neuroscience, Medical Progress, and Society at the George Washington University Medical Center, and former head of the National Institute of Mental Health.

In recent years, the creation of new medicines has become increasingly difficult, costly, and time consuming. Currently, it is estimated that it may take up to a decade and cost more than \$800 million to successfully develop a single new medicine for FDA approval. At the same time, recent safety concerns over



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pediatric antidepressants and widely used painkillers, such as Vioxx, have riveted the public's attention on the FDA's inability to identify serious side effects until years after a drug is released onto the market.

The reality is that safety and innovation are two sides of the same coin. Over the past 10 years, computer-assisted technologies have deciphered the human genome and led to a revolution in the basic sciences.

"Today, more than ever, is it possible to personalize medicine to ensure that the right patient gets the right medicine — and avoids the wrong ones — based on his or her genetic profile," Dr. Goldberg says. "But the FDA's regulatory framework for developing, approving, and monitoring the safe use of medicines called the 'critical path' is essentially the same as it was 30 years ago. As a result, the full potential of personalized medicine is frustrated and the FDA is unable to reassure patients that the prescriptions they use are as safe and effective as possible. The solution proposed by our Task Force is a new, flexible, science-driven FDA critical path that will encourage the development of more effective, safer, and less expensive per-

sonalized medicines."

Currently the Task Force is compiling working papers from its members, holding meetings with prominent scientific experts and industry leaders, and preparing a document for release in Spring 2005 with specific recommendations for reform.

BDStrategics Partners with Challenger to **IMPROVE PHYSICIAN RELATIONSHIPS**

BDStrategics Inc. and Challenger Corp. have entered into an agreement to offer strategic, collaborative, and flexible deployment solutions to facilitate teaching, communicating, and interacting with physicians. The two firms have developed value-added processes to help pharmaceutical companies build powerful collaborative relationships with physicians to re-establish their marketing and sales forces' role as trusted collaborative partners.

Among the offerings are branded CME programs for distribution to physicians; the materials can be segmented and serialized to allow sales reps to repetitively call on clinicians with an added value agenda; industry branded boards or exam preparation courses for physicians in areas where no such courses exist; and pharmaceutical client sponsorships of residency training programs that plant the seeds of long-term physician loyalty to a client and its products.

Observant LLC, a newly launched company, brings together marketing science and public-health perspectives to provide world-class strategic marketing solutions to global pharmaceutical business issues.

Observant leverages best-in-class methodologies to provide insight at all stages in the product life cycle.

Whether it be evaluating the marketing potential of prelaunch clinical-trial endpoints or understanding the implications of a patent extension on a manufacturer's portfolio of products, the company's goal is to improve sales performance.

"Ultimately, the focus has to be on behavior change, at the individual and organizational levels,"

Observant Offers

STRATEGIC MARKETING, CONSULTING, AND RESEARCH MANAGEMENT Solutions



Dr. Mike Feehan



Dr. Rich Durante

Dr. Mike Feehan and Dr. Rich Durante have launched Observant LLC, a specialized marketing consulting and research management company focused on the pharmaceutical and life-sciences industries.

says Mike Feehan, Ph.D., copresident of Observant. "Too often, market-research studies provide static descriptions of the status quo and lack insight into actionable levers for real change."

According to Rich Durante, Ph.D., copresident, the industry has yet to capitalize on the implications of building healthy populations rather than pro-

viding healthcare solutions.

"We recognize that a marketing strategy has to be informed by, and meet the needs of, a broadening constituency base," Dr. Durante says. "For example, the role of caregivers in the prescribing decision-making system currently is undervalued in many strategies."

Stinson Brand Innovation and ComBlu Offer PATIENT-ADVOCACY PROGRAM

Stinson Brand Innovation Inc. and ComBlu are offering life-sciences companies a new grassroots customer-advocacy program called The Evangelist Effect, a discipline developed by ComBlu to tap into social networks and build brand evangelists.

"We can now adapt the nine-step model of The Evangelist Effect to life-sciences companies," says Mark Stinson, president of Stinson Brand Innovation.

"That means we'll help define the preferred customer profile and then develop branded customer experiences that create external and internal evangelists. This is designed to increase the credibility of messages because they are delivered by experts, friends, or news media. It also provides connectivity because evangelists will share information using new tools and technology."

Representing ComBlu in the collaboration are its principals, Steve Hershberger and Kathy Baughman.

The Evangelist Effect has been successfully applied in consumer and business-to-business markets, including motorcycles, electronics superstores, airlines, personal computers, fast food, and automobiles.

Follow up

ACCELRY'S INC., San Diego, is a leading provider of software for computation, simulation, and the management and mining of scientific data used by biologists, chemists, and materials scientists, including nanotechnology researchers, for product design as well as drug discovery and development. For more information, visit accelrys.com.

AMGEN VENTURES, San Diego, is funded by Amgen, a global biotechnology company that discovers, develops, manufactures, and markets important human therapeutics based on advances in cellular and molecular biology. For more information, e-mail amgenventures@amgen.com.

BDSTRATEGICS INC., Buffalo, N.Y., is a pharmaceutical-focused salesforce effectiveness and collaborative relationship building organization that specializes in collaborative relationship development solutions for the pharmaceutical and healthcare industries. For more information, visit bdstrategics.com.

CENTER FOR ONCOLOGY RESEARCH MANAGEMENT, Bound Brook, N.J., a division of ClinPro Inc., provides clinical-trial services for the development, testing, and approval of anticancer drugs, oncology diagnostics, and cancer supportive care modalities. For more information, visit clinproinc.com/corm.html.

CME ENTERPRISE, Carmel, Ind., a subsidiary of Deborah Wood Associates, offers national and international medical marketing and communication services to

the healthcare industry. For more information, visit dwainc.com.

CHALLENGER CORP., Memphis, Tenn., is the creator of one of the the largest libraries of electronic physician education material in the world. For more information, visit chall.com.

COMBLU, Chicago, a joint venture of HLB Communications and The M Group, brings thought leadership and tools designed to reach, engage, and align both customers and employee populations using a tested, comprehensive process. For more information, visit comblu.com.

ENABLE HEALTHCARE, Herndon, Va., focuses on CME and professional education. For more information, visit enablehealthcare.com.

THE MANHATTAN INSTITUTE, New York, is a nonprofit think tank whose mission is to develop and disseminate new ideas that foster greater economic choice and individual responsibility. For more information, visit manhattan-institute.org.

THE NAVICOR GROUP, Columbus, Ohio, is specialty advertising agency focusing on oncology and immunology and is part of inChord Communications Inc., a global group of communications companies providing customized marketing solutions to healthcare clients. For more information, visit navicorgroup.com.

THE NEIGHBORHOOD, with offices in New York and Culver City, Calif., is a multicultural marketing and educational outreach agency focused on the healthcare and pharmaceutical industries. For more information, visit theneighborhoodhealth.com.

OBSERVANT LLC, Wellesley, Mass.,

manages complex and high-profile custom research engagements in the United States, Europe, and Asia. For more information, visit observant.biz.

OCTAGON RESEARCH SOLUTIONS INC., King of Prussia, Pa., is a process-centric solutions provider that offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry. For more information, visit octagonresearch.com.

PROCE INC., Bartlett, Ill., is an ACPE-approved provider of continuing pharmaceutical education and can arrange for ACCME credits for physicians. For more information, visit proce.com.

STINSON BRAND INNOVATION INC., Chicago, is a life-sciences brand consultancy that defines the core strengths of brands, then helps grow them through four service dynamics: strategic expression, idea facilitation, brand construction, and team motivation. For more information, visit stinsonbrandinnovation.com.

TORRE LAZUR MCCANN HEALTHCARE WORLDWIDE, Parsippany, N.J., is a healthcare company with 40 wholly owned offices worldwide that provides integrated healthcare solutions, translating global ideas into local markets. For more information, visit torrelazur.com.

THE ZIMENT GROUP, New York, is a full-service consultancy offering custom marketing research for the healthcare and pharmaceutical industries worldwide. For more information, visit ziment.com.