

Firecrest Establishes **U.S. OPERATIONS**



The use of our eclinical technology can enhance compliance. consistency, and the quality of execution for all study-related procedures and activities, savs Alan Horgan.

management systems to help U.S.-based companies solve the challenges faced during clinical trial management and site performance. Firecrest's products help investigators run complex tri-

Ireland-based Firecrest

has opened a facility in Prince-

ton, N.J., that implements the

company's site performance

als by specifically improving compliance, consistency, and quality of execution of all study-related procedures and activities conducted by investigator site staff and monitoring teams.

"We are thrilled to implement our capabilities into the U.S. market," says Firecrest CEO Alan Horgan. "We feel strongly about the guaranteed benefits and advancements our clients receive with the use of our e-clinical technology, which is proven to enhance compliance, consistency, and the quality of execution for all study-related procedures and activities."

MediciGlobal Center Focuses on TRIAL RECRUITMENT AND RETENTION

MediciGlobal is helping research sites succeed with patient recruitment, retention, and long-term patient follow up.

MediciGlobal's Study Resource Center is focused on streamlining the patient recruitment pull-through process and helping study sites and sponsors succeed with their patient recruitment and retention efforts. The Study Resource Center supports research sites with services that enhance recruitment efficiency, such as maximizing local media budgets, managing patient referrals, and sustaining the interest of patients.

The center integrates under one roof MediciGlobal's site support team with the services of the company's in-house patient contact center, ProtoCall. Centralizing these functions enhances the coordination of critical recruitment-retention support services to study sites. MediciGlobal also has named Pat Patterson, a registered nurse with almost 20 years of clinical research experience, as the center's director.

Services that can be accessed directly by sites include: education, including webinars to assist sites with patient recruitment using the Internet and social media; efficient pre-screening, including online/offline patient pre-screening questionnaires that track responses and data instantly; and logistical



The Study Resource Center helps study sites succeed with patient recruitment and retention well after the active treatment period has concluded, says Pat Patterson.

We are eager for sites to take advantage of our recruitment portal, our patient contact management systems. and our ability to enhance their overall recruitment/retention success, says Liz Moench.



support, including appointment scheduling and follow up with patient referrals.

"We at MediciGlobal are excited with the increased level of service and support to research sites," says Liz Moench, MediciGlobal's president and

Almac Solutions Help Companies Adopt **BIOMARKER STRATEGIES**

Almac has introduced Biomarkers for Biopharma, a range of solutions specifically designed to support biopharmaceutical companies in adopting biomarker strategies that enable them to maximize the potential of their drug candidates. The ability to identify those patients most likely to respond to a therapy greatly increases the chances of success and the licensing potential of

the drug. The Biomarkers for Biopharma portfolio includes pharmacodynamic solutions, patient selection markers, assay development, and bioinformatics/biostatistics consultancy.



It is of critical importance that companies maximize the potential success of the drugs in their pipeline, and the incorporation of a biomarker strategy enables them to do this, says Paul Harkin.

"We have combined a range of key solutions that are ideally suited to growing biopharma companies," says

Paul Harkin, president and managing director of Almac's diagnostics division.

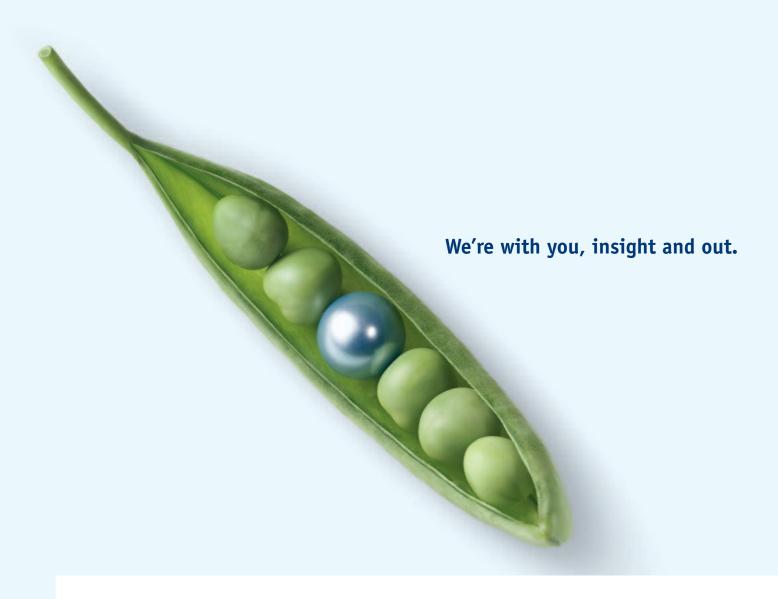
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Follow up

ALMAC GROUP comprises five integrated divisions offering a broad range of services to the life-sciences industry, including R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply and technology, and

commercial-scale manufacture. For more information, visit almacgroup.com. **FIRECREST CLINICAL** improves clinical site performance through e-technology solutions that provide investigator training and study management tools. For more information, visit firecrestclinical.com.

MEDICIGLOBAL is a specialty patient recruitment/retention company, developing programs for clinical trials around the world. For more information, visit mediciglobal.com.



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ON THE SHELVES

PHARMAPLASIA is a book written by PharmaReform.com blogger and former industry executive Michael Wokasch that offers an insider's perspective on how pharmaceutical companies grew too fast, creating organizations that were too large to manage effectively and efficiently given the complexities of the business in an increasingly challenging healthcare market. The book provides readers with an informative mix of history and case studies and recommends specific actions pharmaceutical companies must take if they intend to remain prosperous in an increasingly demanding and less tolerant healthcare market soon to be further complicated by healthcare reform.

For more information, visit pharmaplasia.com.

The U.S Department of Health and Human Services' Agency for

Healthcare Research and Quality (AHRQ) has published the second edition of **REGISTRIES FOR EVALU-ATING PATIENT OUTCOMES: A USER'S GUIDE**, providing information on designing, implementing, and evaluating patient registries. The second edition of the guide reflects the work of more than 80 contributors from government, academic, and private sectors and includes new methodological developments; emerging topics in registry science, including updates on safety; and technological

advances. The updated edition also includes four new sections: use of

registries in product safety assessment; planning for the end of a patient registry; interfacing registries and electronic health records;

For more information, visit effectivehealthcare.ahrq.gov.

and linking registry data.

AROUND THE GLOBE

▶ ABBOTT has acquired Piramal's Healthcare Solutions business, propelling Abbott to market leadership in the Indian pharmaceutical market and further accelerating the company's growth in emerging markets. The business has a comprehensive portfolio of branded generics, including market-leading brands in multiple therapeutic areas, including antibiotics, respiratory, cardiovascular, pain, and neuroscience.

For more information, visit abbott.com.

COLORCON has opened a new technical service laboratory in Turkey. Located in Atasehir, the southern area of Istanbul, the new laboratory contains fully equipped processing suites for laboratory-scale immediate and modified release film coating trials.

The facilities are operated under the highest standards of confidentiality and safety and provide a convenient resource for formulators to test aqueous or organic solvent coatings and to identify the most effective system and production process for their pharmaceutical or food supplement dosage formulations.

For more information, visit colorcon.com.

Independent institutional review board COPERNICUS **GROUP**IRB (CGIRB) has forged a strategic alliance with IRB Services of Canada. The partnership enables CGIRB to offer institutional review services to its clients whose clinical research protocols

review services to its clients whose clinical research protocols include Canadian sites, providing CGIRB clients a single solution for ethical review of clinical research protocols and sites in North

For more information, visit cgirb.com.

▶ INVENTIV HEALTH, a provider of end-to-end clinical development, launch, and commercialization services to the global healthcare industry, has acquired Substrat'Homme, commonly known as StarTerre Santé, a Paris-based group of healthcare marketing and communications agencies. As part of the inVentiv Communications Global Alliance, Star Terre Santé provides advertising and promotional services to inVentiv Communications' clients in France and the Benelux region.

For more information, visit inventivhealth.com.

▶ MEDIDATA SOLUTIONS, a global provider of SaaS-based clinical development solutions, has announced that South Korean contract research organization (CRO) MediCROstar has joined Medidata's channel partner program for CROs and other service providers. In addition to bringing the capabilities of the Medidata Rave electronic data capture and clinical data management solution, the partnership enables MediCROstar to further expand its presence in the Asia-Pacific region and to continue to build its stake in the global clinical trials marketplace.

For more information, visit mdsol.com.

▶ PROTEONOMIX, a biotechnology company focused on developing therapeutics based upon the use of human cells and their derivatives, has executed a joint venture agreement with a group of investors to create a new stem cell treatment and research facility in the United Arab Emirates. The joint venture company, XGen Medical, is 51%-owned by Proteonomix and 49% by the investor group.

 $For more information, visit\ proteonomix.com.$



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- Achieve transparency over your supply chain through understanding of AIDC and EU requirements in hospitals to maximise4 patient4safety4and4reduce4the4frequency4and4cost4of4adverse events with GS1 Germany and the Department of Health
- Advance your labelling systems through integration of e-lablleing at minimum economic impact with strategies from Medtronic, Radiometer and GE Healthcare

Expert Agenda Advisory Panel

Ms Janice Kite, Director Healthcare Traceability,

GS1 Global Office, Belgium

Mr Charles Sidebottom, Director of Corporate Standards **Medtronic**

Mr Jim Willmott, Global Labelling Manager, **Smith Medical**

18+ Renowned Industry Leaders Share Their Expertise

Mr Peter Schroeer, Director Europe, Quality Systems & Regulatory Affairs, Johnson & Johnson

Mr Joachim Wilke, Director Regulatory Affairs & Policy Europe, Medtronic GmbH

Mr Volker Zeinar, Global Coordination Auto-ID Affairs, B. Braun Melsungen AG

Dr Gert Bos, Head of Regulatory and Clinical Affairs, **BSI Group**

Mr Hiroshi Ishikawa, Assistant to President, Toshiba Medical Systems Corporation

Mr Martin Gabler, Regulatory Affairs Specialist, **Radiometer**

Mr Roland Back, Director of Regulatory Affairs & Quality Assurance, Bard Europe

Mr Charles Sidebottom, Director of Corporate Standards, Medtronic

Mr Philippe Lartigue, Regulatory Affairs Manager, **GE Healthcare**

Ms Janice Kite, Director Healthcare Traceability, GS1 Global Office, Belgium

Ms Bianca Gravenhorst Greve, Regulatory Affairs Manager, Coloplast

Mr Mika Reinikainen, Managing Director, **Abnovo**

Ms Bettina Bartz, Healthcare Sector Manager, GS1 Germany