

By Carolyn Gretton

PPD Expands Product Development

Consulting Services

TREND: Quick growth in sectors like biosimilars and adaptive trial design have life-sciences companies clamoring for consultants with specific knowledge of the challenges in these areas.

PD has established four new practice areas through its PPD CONSULTING arm that strengthen the global contract research organization's ability to help clients meet product development challenges across multiple disciplines: biosimilars, adaptive trial design, China regulatory strategy, and cardiovascular outcomes studies.

PPD Consulting's industry experts have first-hand knowledge in applying clinical, regulatory, and commercial program strategies to a range of development programs for small molecules, vaccines, biologics, biosimilars, diagnostics, and devices, and can help biopharma and medical device clients address gaps in their strategic resourcing. Clients can also take advantage of PPD's experience with regulatory agencies and seek strategic insight for long-term development and planning activities.

"PPD has a strong team of physicians, regulatory experts, scientists, and biostatisticians with extensive experience in creating and implementing product development plans from preclinical through postapproval on global and local levels," says PPD Chief Medical Officer Christine Dingivan, M.D. "We have aligned our consulting practice to the areas where we continue to see a strong need for our services to help our clients address significant regulatory market challenges."



Caliber Focuses on Quick **Delivery of Vaccines, Protein Therapeutics**

Caliber Biotherapeutics is a recently formed fully integrated biopharmaceutical company with a plant-based approach to vaccine and drug development. The company's pharmaceutical manufacturing facility in Bryan, Texas, is capable of producing 10 million to 100 million doses of infectious vaccines per month, as well as hundreds of thousands of doses of protein biotherapeutics such as monoclonal antibodies.

In addition to its plant-based facility, Caliber is developing a proprietary product pipeline for cancer and infectious diseases using cell- and microbial-based production systems.

Caliber is led by Chief Medical Officer Brett Giroir, M.D., and Chief Scientific Officer Barry Holtz, Ph.D.

Dr. Holtz explains that Caliber's plant-based system gives the company flexibility and scalability that "enables simultaneous production of multiple proteins and rapid changeovers from one product to another in order to meet patients' needs and respond to emerging infectious diseases and bioterror threats."

For more information, visit caliberbio.com.

In other news...

Promedica and Rosa & Co. have formed a strategic alliance to provide healthcare companies with a full suite of advanced market research and planning tools that combine Promedica's primary marketing research expertise in new



product planning for biotech, pharmaceutical, and diagnostic companies with Rosa's innovative, customized approach to conjoint analysis and market modeling.

Features of the new offering from Promedica and Rosa include project leadership by the companies' principals and senior-level consultants; close collaboration with client teams and internal stakeholders; and a flexible, userfriendly, Microsoft Excel-based market model that simulates a wide variety of product adoption scenarios in a dynamic, competitive context.

"We can now provide our clients with a premier conjoint research and market modeling offering, and the chance to work with leading experts in the that field," explains Promedica President Joan Day.

For more information, visit promedicainc.com or rosamarketmodeling.com.

Premier Research Group has rebranded its medical device business unit as D-TARGET, reinforcing the CRO's focus on and expertise in this sector through its team of medical device specialists with extensive experience in both the European Union and North America.

D-Target has locations in more than 30 countries with primary offices in Boston and Yverdon, Switzerland. Sponsors directly benefit from regional employees with their detailed knowledge of the local clinical research environment and ability to communicate with investigators and regulatory bodies in their own local language.

For more information, visit premier-research.com.

Icon has launched a new cytometry services offering from its Central Laboratories business unit, offering two types of services to better support the testing requirements and development phase of a client's compound.



Icon's cytometry services solution allows clients to collaborate with Icon at the early stages of development to create compound-specific assays that can be used throughout the compound's development life cycle.

"Flow cytometry has become a preferred testing method for many of our clients, particularly those with autoimmune, oncology, and immunodeficiency compounds that require more specialized testing," says Tom O'Leary, president, ICON Central Laboratories. "Our new cytometry services offering provides clients with a better range of options."

For more information, visit iconplc.com.

Wolters Kluwer Health & Pharma Solutions and Decision Resources have created an expedited third-party agreement (TPA) process for their mutual customers. This new arrangement streamlines the process for integrating critical managed markets data from the two companies, which includes Wolters Kluwer's Source Health Analytics Database and products from Fingertip Formulary and HealthLeaders-InterStudy, both Decision Resources companies.

"The between Decision Resources and Wolters Kluwer Health & Pharma Solutions signifies a crucial step forward and streamlines the process associated with serving our mutual customers," says Wolters Kluwer Executive VP Bob Jansen.

For more information, visit wolterskluwer.com or decisionresources.com.

The global regulatory advisory service recently launched by Decision Resources and InnerVation Health is the first advisory service to feature InnerVation Health's Regulatory Advisory Panel (IRAP), which includes former FDA and EMA di-



rectors, medical officers, and current consultants.

ON THE SHELVES

Barnett Educational Services has released

the PAREXEL BIOPHARMACEUTICAL R&D STATISTICAL SOURCEBOOK 2011/2012, a resource for statistics, trends, and proprietary market intelligence and analysis on the biopharmaceutical industry. Available in both hard copy and fully searchable e-stats versions, the latest version of the sourcebook includes new analyses and actual/projected metrics on the biosimilars market; a series of new dashboards on costs by phase of development, R&D attrition rates, product development times, and other areas; and new analyses on patient recruitment into clinical trials.

For more information, visit barnettinternational.com.

THE PARTNERING AND M&A DEALS IN **PHARMA AND BIOTECH YEARBOOK 2010**

provides comprehensive understanding and access to the partnering and M&A deals and agreements entered into by the world's

leading healthcare companies during 2010. Using this Cambridge Healthtech Institute report, dealmakers can gain insight into the partnering activities of the past year.

▼ For more information, visit healthtech.com.

Drug pricing has been at the forefront of political and public dissent for the past decade, and the pressure on pharmaceutical companies is only increasing. In THE PRICE OF GLOBAL **HEALTH: DRUG PRICING STRATEGIES TO BALANCE PATIENT ACCESS AND THE** FUNDING OF INNOVATION, global pharmaceutical pricing expert Ed Schoonveld, principal for the market access and pricing practice at ZS Associates, offers an in-depth analysis of how pharmaceutical companies determine global drug prices in an

increasingly complex global payer environment.

For more information, visit zsassociates.com.

AROUND THE GLOBE



Patient enrollment services provider **CLINICAL SITE SERVICES (CSS)** has expanded its portfolio to include global enrollment planning and implementation on a local, site-centric level. The CSS London office, headed up by industry executive Richard Anderson, is tapping professionals who have more than 20 years of experience in the lifesciences, healthcare, and patient recruitment industries to implement patient enrollment and retention campaigns that are solely based in global markets, or as an adjunct to North American endeavors.

▼ For more information, visit clinicalsiteservices.com.

C3 JIAN is creating a joint clinical research center (CRC) with the West China School of Stomatology at Sichuan University to test new oral healthcare products in human clinical trials. The C3 Jian/West China CRC, located in West China's facilities in Chengdu, China, is a strategically important site for C3 Jian as it moves its products from research to clinical development.

▼ For more information, visit c3-jian.com.

INFOMEDICS has expanded its global presence with the opening of a new office in Paris and an extension of its patient-physician communications programs in the Latin American and Asia Pacific regions. The company also announced the appointment of two regional directors to lead the company's strategy in these high-growth pharmaceutical markets. Mathieu Nabet leads European expansion efforts from within the Paris office, and Amy Weickert has assumed the account director position for Latin America and Asia Pacific.

For more information, visit infomedics.com.

IRD-CDS is a China-based clinical development services company created by GVI Clinical Development Solutions (CDS) of Winnipeg, Canada, and Guangzhou IRD Medicine Company of Guangzhou, China. The joint venture company is a full-service CRO supporting biotechnology, pharmaceutical, diagnostic, medical device, and nutraceutical companies looking to conduct Phase II and III clinical trials in China.

For more information, visit gvicds.com.

Japan-based OTSUKA PHARMACEUTICAL CO. LTD. has established OTSUKA SA, a Geneva-based subsidiary that serves as the company's central operations for developing and implementing public health policies and corporate social responsibility programs in connection with its global tuberculosis (TB) program. The company has appointed Patrizia Carlevaro, Ph.D., as managing director of Otsuka SA.

For more information, visit otsukaglobal.com.

PRA INTERNATIONAL has acquired KINSHIP TECHNOLOGIES, a Chennai, India-based software developer and services company. The addition of Kinship's flagship Exact data extraction system accelerates PRA's development of technology solutions that enhance service delivery and reshape how the industry manages trials and delivers trial data.

▼ For more information, visit prainternational.com or kinshiptech.com.

PUBLICIS GROUPE has acquired Beijingbased healthcare communications agency **DREAMS COMMUNICATION,** extending the Publicis Healthcare Communications Group (PHCG) footprint in China. The agency is now part of PHCG and has been renamed Publicis Life Brands Dreams. Bin (Simon) Sun remains at the helm of Publicis Life Brand Dreams as managing director, along with Kathy Zhao, who has been named general manager, Publicis Life Brands Dreams.

For more information, visit publicisgroupe.com.

Through the advisory service, the IRAP experts offer their immediate and long-term opinions and insights on events and critical shifts regarding regulatory issues impacting all stakeholders, including surveillance, insights and perspectives, and best practices. The service is being sold by disease category, with type 2 diabetes the first area to be offered.

"By leveraging InnerVation Health's relationships with experts in the regulatory industry and our deep therapeutic area expertise, Decision Resources can bring our quality research and analysis to the regulatory departments within the pharmaceutical industry, our key customer base," notes Jason LaBonte, Ph.D., chief operating officer of Decision Resources' portfolio planning, biopharma business unit.

For more information, visit decisionresources.com or innervationllc.com.

AccentHealth has added nine condition-specific networks that reach and educate more than 13 million patients in doctors' waiting rooms each month. In addition to its existing general health, silver, pe-

diatric, and ob/gyn networks, AccentHealth now offers networks focused on diabetes health, heart health, men's health, mental health, senior women's health, rheumatology, allergies, asthma, and GERD. The networks also include digitally delivered content that addresses the specific education needs of patients, designed to provide preventative health messages and to enhance the dialogue they are just about to have with their physicians.

"The digital age allows us to refine health messaging, directing specific information to only the most relevant patients, providing the information they want, when and where they are eager to learn and can discuss it with their physicians," explains AccentHealth CEO Daniel Stone.

"AccentHealth now fuses the micro-targeting that digital technology allows with the power of



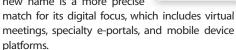


full sight, sound and motion programming at the point of care," says Edith Hodkinson, president, media division, AccentHealth.

▼ For more information, visit accenthealth.com.

MedPoint Communications has changed its name to MedPoint Digital to better reflect its evolution into a digital channel provider to the bio/pharma industry.

CEO Bill Cooney says the new name is a more precise



"We want our marketing clients to know that we complement, instead of compete with, the medical communications agencies that develop their creative and scientific content," Mr. Cooney explains.

For more information, visit medpt.com.



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