



BBK Expands

Ownership From Within

TRENDING NOW: Global patient recruitment company further defines how a small business can thrive.

BBBK Worldwide is bucking the trend by creating ownership opportunities from within. Celebrating 30 years, BBK remains one of the only independent and self-funded patient recruitment agencies, and is able to offer its global pharmaceutical and medical device clients levels of flexibility and creative innovation unmatched by its competitors. This history of vision and leadership has led BBK to name four additional principals who, together, will assume a minority ownership in the company. All long-serving employees, Matthew Kibby, Rob Laurens, Liz Ritchie, and Matthew Stumm have played key roles in shaping the company's success as a global leader in patient recruitment for the clinical R&D segment of the pharma, biotech, and medical device industries. As principals, they will partner with BBK's founding principals Joan F. Bachenheimer and Bonnie A. Brescia to maintain the company's core mission and values while driving growth in key market areas.

"These four individuals have made unyielding contributions to BBK over the years — contributions that have brought innovation and definition to the patient recruitment marketplace as a whole," Ms. Bachenheimer says. "Their new roles will allow for expanded growth in critical business areas, ensuring that current and future customers benefit from the most strategic and sophisticated thinking in the industry."

Each newly named principal will focus their efforts on expanding their current management areas. Mr. Stumm will draw upon his

creative vision to drive innovation for Agency320, BBK's partner company responsible for creative and media services. Mr. Laurens will apply his 19 years of industry knowledge to advance patient recruitment training and industry best practices. Ms. Ritchie, BBK's third longest-serving employee, will continue to manage corporate and legal services. Mr. Kibby will apply his innovative mindset to expanding and refining product offerings from BBK's technology partner TCN Technologies and its hallmark product TrialCentralNetSM.

"Our business model reflects our commitment to, and appreciation for, our employees and for their hard work and investment," Ms. Brescia says. "This dynamic model creates opportunities to expand ownership from within."



Matt Kibby



Rob Laurens



Liz Ritchie



Matt Stumm

MD Mindset's New Agency Services

MD Mindset LLC, a life-sciences marketing intelligence firm, has unveiled its new healthcare agency services, which includes novel, fast, and cost-efficient **HCP** project based market research and medical director on-call services.



Jessica Labita

The HCP project based market research offering provides customized and syndicated market

research to answer project specific questions. The research is turned around rapidly, so it fits within the pitch timeline and is available for reasonable costs. Critical qualitative and quantitative data are collected from HCPs on behalf of the agency with regard to creative testing of websites and materials, application testing, brand website reviews and testing, concept testing of advertisements and sales materials, and other related functions. Through this offering, MD Mindset is also able to gather physician data on products that fall outside of traditional market research, including over-the-counter products.

The research is specialty-specific and results are provided very quickly, thus eliminating the hours

burned on research during the pitch and launch process. The service itself includes the survey design and implementation, HCP recruitment and honoraria, data collection and analysis, and an executive report with recommendations, all from the HCPs' perspective.

In addition to the market research, MD Mindset offers medical directors on-call, providing physician consultation contracted at an hourly or project-based rate.

"We've found that many agencies do not have a medical director on staff," says Jessica Labita, VP, client services, MD Mindset. "This service offering allows us to provide agencies with a project-based, cost-efficient medical director only as needed."

AROUND THE GLOBE ►►

Catalent has announced two major expansions in **China**. The company is acquiring a majority share in Haining-based, privately held Zhejiang Jiang Yuan Tang Biotechnology Co. Ltd. The business produces nutritional softgel products for Chinese and Asia Pacific markets, and employs 120 staff. Catalent and Shang-Pharma Corp., a leading China-based pharmaceutical and biotechnology research and development outsourcing company, have formed a joint-venture called Catalent (Shanghai) Clinical Trial Supplies Co. Ltd. A new 31,000-square-foot facility in Shanghai (currently under construction) will be the first in China to provide end-to-end solutions for clinical trial supplies, including comparator sourcing, primary and

secondary packaging and labeling, and storage and distribution.

IMS Institute for Healthcare Informatics launches a branch in **India** to develop local partnerships with leading universities, research institutions, development agencies, and the government to reinforce the value of information and analytics in decision-making across a range of healthcare issues in India. The new branch, with the support of IMS Health India, will leverage relationships in the public and private sectors to deliver objective, relevant insights and research to advance the country's health agenda. In India, the IMS Institute's activities will focus on three areas: mobilizing and advancing health

services research; capacity-building and professional training; and analytics-based performance improvement.

PRA, a clinical research organization, has acquired privately held ClinStar LLC, a clinical research organization managing Phase I-IV clinical research trials in the **Russian Federation, Ukraine, Belarus**, and the **Baltic States**. Through its operations in the region, ClinStar provides clinical development services to a wide range of pharmaceutical and biotechnology companies. The ClinStar acquisition illustrates PRA's dedication to support its growth in Russia and Eastern Europe, a region that has proven to be very important to the biopharmaceutical industry.

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ON THE SHELVES ►

The American Association of Pharmaceutical Scientists (AAPS)

has released the 5th volume of the AAPS Advances in the Pharmaceutical Sciences Series of books. *Global Approach in Safety Testing: ICH Guidelines Explained* provides a general perspective as well as an overview of current scientific thinking and trends on preclinical issues such as toxicokinetics, duration of toxicity testing, carcinogenicity, reproduction and genotoxicity testing, safety pharmacology, and safety evaluation of biotech products. Edited by Jan Willem van der Laan and Joseph DeGeorge, it also covers the efforts made to reduce animal experiments without compromising the safe development of new treatments.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the

pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. This volume considers one of ICH's major categories, safety, covering topics relating to in vitro and in vivo preclinical studies (carcinogenicity testing, genotoxicity testing, etc.).

Theorem Clinical Research has released two site-level reference booklets for clinical research sites that explain and condense critical International Conference on Harmonisation guidelines related to Good Clinical Practice for the conduct of trials.

Authored by Judith Köhnen and Lee Spurgin, Ph.D., "Little Advisor ICH GCP for Investigational Product Trials" explains key concepts of the ICH GCP requirements. Their second book, "Little Advisor ICH GCP for In Vitro Diagnostic Trials," provides guidance on regulations specific to trials involving in vitro diagnostic devices. Both are available for purchase online.

Dr. Spurgin, senior VP for medical device and

diagnostic development, and Ms. Köhnen, senior project director for medical device and development, have years of experience with the conduct of clinical trials. Both manuals cover topics such as qualifications, regulatory authorities, ethics committees, the informed consent process, safety reporting, and more. The information, presented in an easy-to-read format, highlights and explains critical information and provides practical advice.

A third booklet, previously released by Theorem, has been popularly received by sites seeking to understand the International Organization for Standardization's requirements for medical device trials. "Little Advisor ISO 14155:2011 for Medical Device Trials" is also available online.

All three booklets provide full citations back to the original ISO or ICH GCP documents for those who need more detail. And, all the topics in the original document are included in the respective booklets.

Through this offering, MD Mindset resident physicians advise the pitch team from the doctor's perspective with support of KOLs from its Nationwide Network of Specialists.

All MD Mindset's agency services are contracted exclusive to the therapeutic area for a defined period before and after the pitch to eliminate any conflicts of interest.

Real-Time Alerts for Physicians

Everyday Health's website **MEDPAGE TODAY**, a medical news gathering operation for healthcare professionals, has launched mdAlerts, a multi-platform solution providing brands with a vehicle to reach physicians with news via mobile and desktop in real-time. Similar to MedPage Today's editorially driven Breaking News Alerts for physicians, mdAlerts allows marketers a dedicated opportunity to instantly alert physicians at the point of care to their safety data, imperative patient information, and manufacturing updates.

A recent Everyday Health study revealed that 98% of physicians cited clinical news as the No. 1 reason why they use their digital devices — computers, mobile phones, and tablets.

MedPage Today created mdAlerts to offer

physicians a streamlined, effective way to receive relevant and breaking industry news through the physician's desired channels.

"With the Affordable Care Act taking effect, an additional 30 million patients are entering the health care system and doctors will have less time to stay informed on pertinent drug information," says Jennifer Mormile, senior VP, strategic partnerships, Everyday Health. "mdAlerts offers pharmaceutical companies a new avenue to reach doctors directly."

mdAlerts represents a new direct-to-physician channel that can be tailored and distributed to target specialists on their mobile devices, as well as through an on-site message center, allowing companies to reach healthcare professionals across multiple platforms.



Jennifer Mormile

New Office of Computational Science

The Office of Computational Science (OCS) has been formed to lead and manage the transformation of **CDER'S** scientific computing abilities and operations. CDER's Computational Science Center (CSC) is one of the key initiatives that will be under the direction of OCS. The CSC provides services supporting the submission and use of high-quality data, and access to analytical tools, technology, and training thus supporting improved

efficiency and effectiveness of the overall regulatory review process.

Further, the CSC's goals are to help reviewers leverage technology at the intersection of analytical tools and science, and to propose appropriate analytical tools, processes, and approaches to enable consistency in the review process. The CSC will help empower reviewers to conduct their regulatory reviews with greater efficiency by providing targeted services supporting the evaluation and analysis of study data.

OCS will enhance the accessibility of data, strive to reduce data integrity issues, and support robust data governance. It will help to improve coordination and prioritization of CDER's scientific computing plans and activities. Through OCS, the agency is emphasizing the importance of coupling data, tools, and technology with reviewer-focused training. Further, it recognizes the significance of being at the forefront of innovation and the need to adapt to ever-evolving computational demands. Thus, OCS will facilitate the exploration of tools and technology to meet the demands of the modern review process.

Lilliam Rosario, Ph.D., has been named the director of OCS. Dr. Rosario is returning to CDER after serving in the Office of the Commissioner, Office of the Chief Scientist, as associate director in the Office of Science and Innovation. In this position, she provided strategic leadership and support for innovation in FDA scientific initiatives. **PV**

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