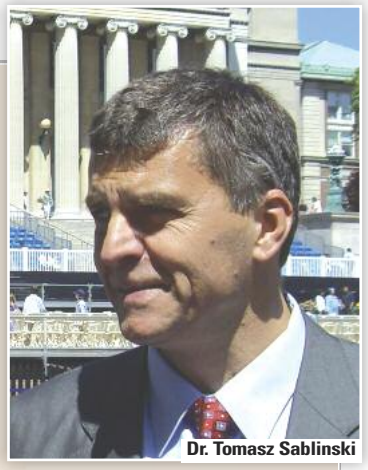
What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

By Carolyn Gretton

Transparency Life Sciences Launches with
Open Innovation-Based Model

TREND: This new breed of drug development company aims to achieve much greater efficiency in its patient-centric trials by harnessing the power of collaborative intelligence, advances in telemedicine, and full data transparency.


Dr. Tomasz Sablinski

Transparency Life Sciences (TLS) is a new drug development company launched in January. It is basing its drug development model on open innovation, with the goal of developing therapies for significant unmet medical needs by acquiring promising drug compounds and testing them in clinical trials that leverage 21st-century information technology to achieve greater productivity.

Tomasz Sablinski, M.D., Ph.D., founding CEO of TLS, notes that despite the continued evolution of communications and information technology, the design and execution of clinical trials have changed little in the past 40 years.

"Transparency Life Sciences intends to use its own pipeline of compounds to demonstrate that an open innovation approach to drug development can deliver high-quality results that facilitate regulatory review and are more patient-centric," Dr. Sablinski says. "And we believe that our approach can accomplish this faster and at a much lower cost than conventional clinical studies."

As part of its launch, TLS has made available a prototype of its crowd-sourced Web platform that allows patients, physicians, researchers, and other stakeholders to contribute to the design of clinical studies. The company also plans to leverage contemporary health information and communications technologies to implement patient-centric clinical trials that will reduce burdens on subjects and sponsors, and enhance data quality. TLS intends to be a leader in demonstrating how transparency throughout the clinical trial process can enhance drug development.

"Drug development has reached a crisis point, with clinical studies too often designed to meet commercial rather than patient needs, which we believe is one key factor underlying their unsustainable cost structure," Dr. Sablinski observes.

For more information, visit transparencyls.com.

PhRMA, CIRS Work Together on Benefit-Risk Assessment Framework


Lawrence Liberti

The Pharmaceutical Research and Manufacturers of America (PhRMA) has transferred its Benefit-Risk Action Team (BRAT) framework to the Centre for Innovation in Regulatory Science (CIRS) to further the program's technical development and broaden input from the scientific community.

CIRS is a neutral, independent, United Kingdom-based subsidiary company forming part of the Intellectual Property and Science business of Thomson Reuters, governed and operated for the sole support of its members' activities.

A voluntary pilot program conducted in 2011 among PhRMA member companies demonstrated that the principles and tools of the BRAT framework can be used effectively in a real-world setting.

But full implementation will require stakeholder input from beyond industry, improved incorporation of pilot program results, and further development of benefit-risk assessment principles.

CIRS is incorporating the BRAT framework into its Unified Methodologies for Benefit-Risk Assessment (UMBRA) Initiative. The goal of UMBRA is to improve benefit-risk assessments during the drug development and regulatory approval process and increase the transparency, predictability, and consistency with which benefit-risk assessments are conducted.

"Bringing together elements of two major initiatives will contribute to the shaping of novel approaches to benefit-risk assessment," notes Lawrence Liberti, executive director, CIRS. "The grant support provided by PhRMA complements funding from CIRS and will help maintain the momentum that CIRS has established from the relationships and support it has fostered across diverse stakeholders in mature and emerging pharmaceutical markets."

For more information, visit cirsci.org.

In other news…

CoreRx is adding the SuiteView video monitoring system to each of its GMP suites in its new facility in Tampa, Fla., giving clients an opportunity to securely log in with a unique user ID and password and monitor the manufacture of their products from anywhere in the world.

"Our business has continued to grow over the past several years, facilitating our need to expand


Dr. Todd Daviau

the analytical, formulation, and manufacturing services we provide to our wide range of international clients," explains CoreRx President and CEO Todd Daviau, Ph.D. "The SuiteView system will give our clients the ability to securely and cost-effectively monitor the production of their products from a remote location."

"SuiteView will give our clients an ability to not only have a bird's-eye view on their process; it will allow them to save on project costs by decreasing their travel budget," adds Mark Licarde, director of manufacturing at CoreRx.

For more information, visit corerxpharma.com.

D&R Lathian is the new multichannel marketing entity created by specialty direct marketing agency D&R Communications' acquisition of e-promotions provider Lathian Systems.


Reide Rosen

"With salesforce reductions and patent cliffs, pharmaceutical companies are facing marketing challenges at almost every stage of the product life cycle — from product launch, to midstage, to established brands working without reps," observes Reide Rosen, D&R Communications co-founder and D&R Lathian partner. "These companies need a partner that can provide customized, strategic campaigns across numerous promotional channels to effectively reach physicians and positively influence prescribing behavior."

D&R Lathian provides a full range of services that enable pharmaceutical clients to target and reach professional, consumer, and salesforce segments via a full range of printed and interactive digital tactics for Web and mobile, including custom strategic mail, e-detailing and interactive learning programs, and e-newsletters and dynamic email.

"In order to reach physicians and impact brand performance, pharmaceutical marketers are challenged to look across all tactics to develop an ongoing strategy that meets both their sales goals and budget," says Quang Pham, Lathian founder and D&R Lathian partner.

For more information, visit drcommunications.com. PV

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PharmaVOICE

Cold Chain

Management Company Launches

TREND: New company aims to enhance the reputation of clients by ensuring regulatory compliance, product quality, and patient safety during shipment of clinical trial materials.


Gary Hutchinson

Modality Solutions is a new company launched in January 2012. It is a privately held company delivering integrated cold-chain management solutions for highly regulated industries, including the biopharmaceutical, health, nutrition, and wellness sectors.

Modality Solutions provides engineering/logistics consulting, systems integration, and simulation laboratory services from discovery through distribution. The solutions are aimed at defining, minimizing, and potentially eliminating transportation environmental hazards in the supply chain.

"Until now, innovators needed to work with a variety of companies to deliver cold chain management solutions," says Gary Hutchinson, president of Modality Solutions and one of its five founders. "Our clients leverage years of biotech subject-matter experience in three critical areas: regulatory compliance guidance, package engineering, and controlled-environment logistics execution."

In addition to Mr. Hutchinson, Modality Solutions' founders include principals Paul Harber and Daniel Littlefield, and tech advisors Brian Wallin and Donald Wilson.

For more information, visit modality-solutions.com.

The **FDA** has issued three draft guidance documents on biosimilar product development to assist the life-sciences industry in developing such prod-

AROUND THE GLOBE

Catalent Pharma Solutions continues to expand its drug development and delivery capabilities in Europe. The company has expanded its facility in Schorndorf, Germany, to provide customers with solutions for their most difficult bioavailability, controlled release, or targeted delivery profile challenges. Catalent also has completed the expansion of its facility in Aprilia, Italy, to offer customers a complete turnkey service from product conceptualization to formulation, development, production, and packaging for prescription and over-the-counter products.

For more information, visit catalent.com.

Life-sciences companies can avoid costly delays in beginning clinical trials in China and Brazil by downloading local insurance certificates through **WORLDCERT**, an online system from the **Chubb Group** of Insurance Companies. WORLDcert can also be used to instantly obtain specimen policy language for trials in many countries where ethics committees require the review of insurance contract terms and conditions.

For more information, visit chubb.com.

IMS Health has acquired **PHARMARC**, an India-based company specializing in commercial analytics and services for the life-sciences industry. The acquisition adds significant scale to IMS's services delivery platform, strengthens IMS's business process outsourcing capabilities, and complements IMS's suite of proprietary technology and software applications.

For more information, visit imshealth.com.

INVENTIV HEALTH COMMUNICATIONS/EUROPE (IHCE), an **inVentiv Health** company, has opened its new headquarters in London to serve as a hub for all European offices and support the rapid growth of the company's consolidated communications business. iHCE's leadership team also announced the appointment of Nick Bartlett, Damon Caiazza, and Peter Comber to senior management roles. Mr. Bartlett leads iHCE's digital and social media business, Mr. Caiazza heads advertising, and Mr. Comber oversees the company's creative services.

For more information, visit inventivhealth.com.

As part of an expansion of its global clinical logistics services, **Parexel International** has significantly enlarged its depot in Santiago, Chile, to support the company's ability to assist clients in more effectively managing their global clinical trial material supply requirements. The Santiago expansion, as well as the addition of an ancillary warehouse in the greater Boston area, expand on Parexel's existing clinical logistics infrastructure throughout North America, Latin America, Europe, Africa, and the Asia Pacific region.

In other moves, Parexel has entered into an agreement with Seoul-based ASAN Medical Center (AMC). The alliance offers clinical trial sponsors based regionally and internationally with access to high-quality clinical trial services throughout Asia, with a focus on early-phase development.

For more information, visit parexel.com.

Pharmaceutical Product Development LLC (PPD) has forged an alliance with NHS Research Scotland (NRS) designed to increase the amount of clinical research conducted in Scotland, accelerate the development of new medical therapies, and enhance healthcare treatment options for the people of Scotland. PPD is working closely with the major health boards across Scotland to further reduce study start-up times, streamline regulatory approval processes, increase the number of patients recruited for clinical trials, and ensure the availability of resources and training to increase the number of physicians and support staff conducting research.

For more information, visit ppdi.com.

PROTRIALS GLOBAL is a wholly owned subsidiary created by **ProTrials Research** to help meet sponsors' increasing needs for multinational, multisite clinical trials. Based in the United Kingdom, ProTrials Global helps manage ongoing clinical trials in Italy, Spain, and the United Kingdom and is responsible for additional growth in the European arena. Gillian Reid is responsible for managing ProTrials Global as director of business operations.

For more information, visit protrials.com.

Quintiles has opened a business process outsourcing and project management center of excellence in Dalian, China, with a multilingual workforce and location ideally suited to serve the Japanese, Chinese, and South Korean biopharmaceutical markets. In addition to supporting clinical operations for study sites in northeast China, the Dalian office provides data management, biostatistics, medical writing, pharmacovigilance, postmarketing safety surveillance, and back-office support for administrative functions for global and local biopharma companies.

Quintiles also has expanded its strategic drug development and consulting services in Asia to bolster the probability of success in developing and commercializing new medications in the region.

For more information, visit quintiles.com.

ucts in the United States. Biological products include therapeutic agents such as vaccines, blood and blood components, gene therapies, tissues, and proteins. Unlike most prescription drugs made through chemical processes, biological products generally are made from human and/or animal materials. A biosimilar is a biological product that is highly similar to an already-approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency.

The Patient Protection and Affordable Care Act signed into law by President Obama in March 2010 amended the Public Health Service Act to create an abbreviated approval pathway for biological products that are demonstrated to be interchangeable with or highly similar (biosimilar) to an FDA-licensed biological product.

"When it comes to getting new biosimilar products on the market, FDA has taken an innovative approach to supporting their development at every step of the process," says Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "These draft documents are designed to help industry develop biosimilar versions of currently approved biological products, which can enhance competition and may lead to better patient access and lower cost to consumers."

For more information, visit fda.gov.

iMany has changed its name to Revitas and integrated its enterprise revenue dynamics (ERD) solutions for the automation and management of contracts, pricing, and compliance through its scalable and standards-based Flex software platform.

The company's rebranding is designed to reflect a changing global supply chain, where contracts are viewed as a source of strategic advantage in driving revenue and mitigating risk.

"Our new brand, evolving market position, and innovative platform provide an enterprise-scale solution for optimizing the opportunities that complex contracts with multifaceted pricing structures present to companies," says Paul Winn, chairman and CEO of Revitas. "ERD is quickly transforming the way companies view, manage, and measure the relationship between pricing, contracts, and compliance while improving profitability and minimizing risk."

For more information, visit revitasinc.com

In response to FDA guidance and growing requests from other regulatory agencies that place new emphasis on assessing and minimizing cardiovascular risk, **WorldCare Clinical (WCC)** has added a service offering that supports expert readers in completing cardiovascular endpoint committee reviews quickly and cost-effectively.

The recently launched WCC offering enables cost-effective, blinded independent central review (BICR) of adverse events using the Medical Dictionary for Regulatory Activities and other safety coding dictionaries.

Dr. Richard Walovitch

The service builds upon WCC's endpoint assessment committee services and employs the company's WorldPRO image management platform to capture, quantify, and consolidate virtually any type of clinical data for interpretation by subspecialty-trained experts.

WCC President Richard Walovitch, Ph.D., notes the cardiovascular endpoint offering is one of several services the imaging CRO will be offering to sponsors in the coming months.

"Through our longstanding strategic relationship with Massachusetts General Hospital, we're able to deliver the most accurate assessments by providing access to leading clinical experts to meet each trial's specific protocol requirements," Dr. Walovitch says.

He says this relationship combined with the company's proprietary digital portal, WorldPRO, provides the ability to streamline the BICR process and highlights the flexibility of our capabilities.

For more information, visit wcclinical.com. PV

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