Accenture Launches Accelerated
R&D Services

TRENDING NOW: New fully integrated, technology-enabled global business service are expected to drive more efficient and effective development of pharmaceutical products.


David Boath

Accenture has launched Accenture Accelerated R&D Services, a business service focused on delivering streamlined and integrated R&D functions that will help pharmaceutical companies bring new medications to patients using a more collaborative and efficient approach.

Accenture predicts that by the end of this decade, many pharmaceutical companies' R&D operations may no longer own or invest in their technology solutions. In fact, several trends substantiate the need for a fully-integrated, technology-enabled, global business service:

- Pharma companies are facing unprecedented business pressures, including increasingly stringent health authority requirements, unsustainable fixed-cost models, and the complexity of managing numerous vendor partners and technology systems.
- In the past three years, 18 R&D locations in the United States have closed, with an additional 14 in the EU over the past 15 years (1997-2012).

Accelerated R&D Services is leveraging capabilities of the cloud, mobility, and analytics to deliver integrated functions across clinical development, regulatory submissions, pharmacovigilance, and market launch predicated on delivering better patient outcomes. The new unit is expected to help life-sciences companies bring drugs to market faster, at less cost, and with reduced execution risks using a pay-for-performance business model for business process outsourcing. The business service encompasses:

- Clinical services that focus on the traditional pain points of effectively identifying the right patients, helping efficient capture of clinical trial data, and streamlining the process between data capture and reporting by leveraging the latest CDISC criteria.
- Pharmacovigilance services leveraging mobile and web-based data capture to drive compliance with new regulations to increase productivity and improve quality in the pharmacovigilance processes.
- Integrated cloud-based regulatory services leveraging CDISC standards and the industry's integrated cloud-based processing platform to improve regulatory quality, speed, and operational efficiency.

"An industry demand exists for new benchmarks that are driven by increasingly stringent health authority requirements, unsustainable fixed-cost models, and the complexity of managing numerous vendor partners and technology systems," says David Boath, senior managing director, life sciences Accelerated R&D Services, Accenture. "With R&D Accelerated Services, we offer an improved and advanced type of service focused on efficiency, effectiveness, and modern processes leveraging digital, the cloud and end-to-end solutions that draw on the management consulting, technology, and outsourcing skills of our people."

For more information, visit http://www.accenture.com/us-en/Pages/service-life-sciences-accelerated-research-development.aspx.

Parexel Launches New Functional Services Unit


Dr. Mark Goldberg

Parexel has launched a new **FUNCTIONAL SERVICES** unit within the company's clinical research services business segment.

The company created the unit to provide solutions for customers interested in outsourcing particular functions rather than full development programs in the clinical development process. The new operating unit provides clinical operations, data management, biostatistics, and medical writing, among other services.

"Clients increasingly need flexibility when choosing an outsourcing model that aligns with their path to drug development," says Mark Goldberg, M.D., president and chief operating officer. "By creating this operating unit, we are taking a more proactive and focused approach to compete in the growing global functional services market. Of particular importance, we'll be able to strengthen our relationships with clients of all sizes by providing a broader mix of full programmatic and functional outsourcing."

The new operating unit will be staffed by a dedicated leadership team and supporting resources, taking full advantage of global resources and expertise from across Parexel's existing operations.

For more information, visit parexel.com.


Richard Dudek

TGaS Advisors has launched a new **MARKETING ADVISORY PRACTICE** designed to provide decision support to pharmaceutical marketing leaders. This service offers customized insights in three critical areas: marketing leadership and brand management, marketing processes, and centers of excellence and functional support. The benchmarking and advisory services firm is a division of KnowledgePoint360.

Marketing Practice clients will have the ability to access customized peer set information from the proprietary TGaS database. This information includes aggregated data on more than 40 large, mid-tier, and specialty pharmaceutical and biotech

companies; data on team structures and headcount for more than 200 brands; and detailed tactical mix and marketing investments for more than 60 brands. All TGaS data are blinded and confidential.

"While marketing leaders typically rely on competitive intelligence, the TGaS Marketing Advisory Practice provides a novel approach by obtaining 'comparative intelligence,'" says Richard Dudek, who leads the new practice. "This critical information allows leaders to optimize strategy, investment and supportive processes."

As an example, clients can assess whether their marketing organization and key support teams are optimally resourced for an upcoming launch. At the executional level, they can gain insights about brand-level promotional mix and tactical investments and judge whether it makes sense to develop a Center of Excellence, such as digital relationship management, to support a launch or expanding product portfolio. From a leadership perspective, insights provided by TGaS will highlight marketing best practices, which can be used to establish above benchmark capabilities.

For more information, visit tgas.com.

Hudson and QuantiaMD Partner to Provide Personalized Service to Physicians


Eric Schultz

Hudson Global, a division of **DRAFTFCB HEALTHCARE, AND QUANTIAMD** have formed a partnership to deliver a full suite of personalized digital solutions that provide physicians education and service on their terms. This new partnership evolves beyond digital media to provide the first comprehensive personalized digital access solution. Hudson's compelling interactive digital content, live interactive broadcast events, and interactive Web sharing between physicians and experts are now integrated with QuantiaMD's ServiceLink products and with QuantiaMD's physician network online and on mobile. Clients such as payers, hospitals, and life-sciences companies can leverage these capabilities through a personalized digital channel to access and serve physicians effectively and transparently.

"Physicians are the core of healthcare," says Eric Schultz, executive chairman of QuantiaMD. "Their schedules are already overflowing, and the flood of new requirements on their time is rising fast. Physicians no longer have the time for traditional in-person meetings, learning or discussions with colleagues. By combining the strengths of our two companies, we are bringing a personalized approach to digital communication that provides physicians access and services on their terms, when and where they want it."

"Our partnership with QuantiaMD is a perfect synergy," says Robert Blink, president, Hudson Global. "By applying the latest social technologies to medicine, we are modernizing how physicians work together and interact with the major participants in healthcare, including hospitals, ACOs and life-sciences companies, to meet a variety of objectives that reduce costs and improve the quality of care."

For more information, visit quantiamd.com or draftfcbhealthcare.com.

TransCelerate BioPharma Unveils Collaborative Methodology for Risk-Based Monitoring of Clinical Trials


Dr. Dalvir Gill

TransCelerate BioPharma, an independent nonprofit organization focused on accelerating the development of new medicines, has released a position paper outlining a methodology for risk-based site monitoring that could significantly modernize and streamline the way studies are conducted and monitored. The RBM position paper reflects TransCelerate's collaborative approach to improve speed, efficiency, and capabilities in bringing new therapeutics to patients. With the release of the paper, the now 16-member organization delivers the first major milestone of its five clinical trials initiatives.

When it launched in September 2012 — founded by major healthcare, pharmaceutical, and biopharmaceutical companies — TransCelerate chose to focus on five initiatives related to clinical trial efficiency. Specific to the risk-based monitoring initiative, the organization's goal was to establish a common approach to high-quality, risk-based site monitoring to enhance patient safety, ensure the quality of clinical data, and create efficiencies.

"Biopharmaceutical companies often spend an extraordinary amount of effort monitoring clinical trials — data from each patient, for every study, at every global site, is reviewed — yet, there isn't much evidence to indicate that this level of review is effective at identifying systemic errors or substantially improving the quality of data gathered," says Dalvir Gill, Ph.D., CEO of TransCelerate. "Despite this, monitoring approaches have remained unchanged. In this position paper, we have outlined a methodology — procedures, algorithms, a toolkit — for risk-based monitoring that we believe will be effective and efficient for our member companies and others."

The RBM paper outlines a standard approach for risk-based monitoring that can be adopted for any type, phase, and stage of clinical trial, resulting in enhanced patient safety, quality clinical data and new efficiencies. The position paper was developed in response to draft guidance from the FDA and European Medicines Agency (EMA). Both agencies have reviewed the RBM methodology paper and TransCelerate looks forward to the agencies' final guidance documents.

For more information, visit transceleratebiopharmainc.org. PV

ON THE SHELVES

GLOBALHealthPR has published a new edition of the **THE GLOBAL GUIDE TO PHARMA MARKETING CODES.** Now in its third edition, the 169-page reference provides information on specific codes and regulations surrounding the promotion of medicines in 16 countries.

The publication provides an overview of basic healthcare promotional regulations and answers the most frequently asked questions about what is and isn't permitted with respect to the media and third-party involvement. The guide helps communicators maximize responsible healthcare public relations opportunities, nation-by-nation.

For more information, visit globalhealthpr.com.

CLINICAL TRIALS: WHAT PATIENTS AND VOLUNTEERS NEED TO KNOW helps demystify the clinical trial process, focusing on the process of drug development and the clinical trial itself. The author, Lorna Speid, Ph.D., provides important questions to ask those running a clinical trial, key definitions and terms for a participant to know and understand, as well as anecdotes illustrating the clinical trial process. Dr. Speid is president of Speid and Associates, a regulatory affairs and drug development consultancy.

The book is available through **Oxford University Press**. Use promo code 31820 for 20% discount.

For more information, visit oup.com/us.