



▶ Companion Diagnostics Key to Personalized Medicines

TRENDING NOW: Companion diagnostics have captured the interest of many drug companies, but face a number of development hurdles.

Companion diagnostics are central to the creation of personalized medicines, but face a number of hurdles that could impede development, according to a panel of leaders convened by the Tufts Center for the Study of Drug Development.

Still mostly in the early stages of development, companion diagnostics tests that link to a therapeutic medicine to help identify a population of patients who are likely to respond to the drug face a number of critical challenges, the panel said. They include reluctance on the part of investors to fund research, uncertainty regarding reimbursement from insurers, and questions about clinical and cost effectiveness due to insufficient data on the value that companion diagnostics deliver to patients.

"Despite these difficulties, interest in developing companion diagnostics remains strong," says Christopher-Paul Milne, director of research at Tufts CSDD. "That's because drug companies recognize that companion diagnostics co-developed with a therapeutic can increase the probability of winning regulatory approval for the drug."

Other key points made at the panel discussion, include:

- » Meeting high standards for U.S. regulatory approval of companion diagnostics will help position developers for regulatory success outside the country, but the diversity of diagnostics regulations, as well as lack of precedent for co-development elsewhere, remain challenging.
- » Drug developers that partner with a companion diagnostic company to co-develop and commercialize a diagnostic need to account for the fact that the two partners will have different business models based on different development platforms that employ different technologies.

▼ For more information, visit csdd.tufts.edu.



Christopher-Paul Milne

"With the countdown under way to the biggest overhaul of U.S. healthcare since the enactment of Medicare and Medicaid more than 50 years ago, it's do-or-die time for many institutions," says Steven Valentine, president of The Camden Group. "The changes are painful for all concerned. But they must adapt, while simultaneously operating under the current system, or become increasingly irrelevant."

▼ For more information, visit TheCamdenGroup.com.

Clinical Services Market TO EXPERIENCE GROWTH

The world market for pharma clinical trial services will be worth \$30.6 billion in 2015, according to visiongain. Between 2011 and 2017, the global market will grow with a high single-digit CAGR. Demand for late-phase trial services will drive growth to 2023.

Throughout the 10-year forecast period, late-stage trials will account for the greatest proportion of revenue for clinical research organizations. In the first half of the forecast period, lifecycle management strategies, demands from regulators for post-marketing safety studies and pharmacoeconomic data will drive growth in that industry.

Richard Lang, a pharmaceutical industry analyst for visiongain, say, "In the last decade, demand for outsourced clinical trial services grew rapidly as pharma pipelines grew and trials became increasingly large and complex."

▼ For more information, visit visiongain.com.

Pharma is Moving toward Dedicated

MANAGED MARKETS FUNDING

Two-thirds of top 20 and top 50 companies allocate a dedicated budget to their managed markets teams, while at least half of small pharma and device companies do the same, according to a study by Cutting Edge Information.

2013 Healthcare OUTLOOK

With the Affordable Care Act set to go into effect on January 1, 2014, the U.S. healthcare industry is in a full-out sprint to transform. Hospitals, physicians,

and insurers will continue putting in place the building blocks for handling new payment and care models and the expected influx of newly insured patients, according to The Camden Group's 2013 annual Top 10 Trends in Healthcare. (Editors' Note: see chart on next page.)

The study, U.S. Managed Markets: Driving Commercial Success through Outcomes-Based Reimbursement, found that brand teams and therapeutic areas contribute to a high percentage of managed markets teams' activities, reflecting managed markets teams' commonly decentralized structure, as well as the shift toward unifying marketing and managed markets messages.

▼ For more information, visit cuttingedgeinfo.com.

More RX to OTC SWITCHES EXPECTED

Rx to OTC switches continue to be a popular tactic with pharmaceutical marketers and new OTC drugs could be classified in coming years, according to Kalorama Information. In fact, there is a \$7.6 billion U.S. market for products with switched ingredients. The market for products with switched ingredients has increased by 3.5% from \$6.4 billion in 2007. The allergy segment contributed the most to growth due to the switch of Zyrtec in 2007 and Allegra in 2011. Additionally, sales for Claritin remained strong. The gastrointestinal and other product categories also saw fast revenue growth.

▼ For more information, visit KaloramaInformation.com.

HEALTHCARE PREDICTIONS FOR 2013

- » Progress is a double-edged sword. Efforts to reduce readmission rates and length-of-stay are positioning providers for new payment models but the resulting declines in volume leave them with big gaps to fill.
- » Mergers and acquisitions accelerate. Hospitals and physician groups will rush to capture scale, lower costs, and gain a greater portion of the healthcare continuum. Health plans will continue consolidating while also diversifying into related businesses, from buying medical groups to adding support services for population health management.
- » Physicians (and primary care in particular) remain the dance partner of choice. As the linchpin to treating across the continuum of care, physicians will be wooed by hospitals and medical groups through new arrangements including patient-centered medical homes, bundled payments, joint ventures, and accountable care organizations.
- » Government is a wild card. States and federal government are searching for solutions to cope with Medicaid and Medicare expansion, insurance exchanges, government employee costs, and infrastructure costs to manage the changes.
- » Investments rise despite poor financial outlook. Healthcare operating expenses will continue to outpace payment increases.
- » IT will consume a greater portion of providers' budgets. The right technology is essential for operating in the new era of health reform, from electronic medical records and computerized physician order entry to data warehouses and health information exchanges that will enable population analytics and Web portals for patients and physicians.
- » Employers keep up the pressure on providers, health plans, and employees. With continuing double-digit premium increases over recent years, employers will continue to pass along costs to employees, with high-deductible and narrow network health benefit plans here to stay.

Source: The Camden Group

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