

### Drug Company Success Depends ON NEW DEVELOPMENT PARADIGMS

While many drug developers continue to improve clinical trial operational efficiency to increase the pace of new product introductions, their medium-

and long-term success increasingly will depend on their ability to embrace more efficient R&D models, according to the Tufts Center for the Study of Drug Development.

“Pharmaceutical and biotech companies — large and small, established and early-stage — are forging strategic alliances,

collaborative partnerships, and multi-company consortia,” says Tufts CSDD Director Kenneth Kaitin. “Early results indicate that sharing knowledge and leveraging resources is helping sponsors find new drugs to treat many of today’s most challenging and complex indications.”

#### Other findings from Tufts:

- » Growing concern over expensive, late-stage clinical failures will lead firms to reassess their use of meta-analyses and subgroup analysis and make more realistic assessments about the likelihood of candidate success.
- » The FDA will foster greater use of patient-reported outcomes to support labeling claims in drug applications and make greater use of social media and the Internet to communicate with patients, caregivers, and patient advocates.
- » Sustaining the recent pace of investments in new biotech companies will be a major challenge in 2014, spurring further development of alternative financing approaches, e.g., industry based venture capital groups and patient support foundations.
- » More approvals of co-developed companion diagnostics and therapeutics are likely, but diagnostics without evidence of positive impact on health outcomes will continue to face reimbursement challenges.



Kenneth Kaitin



Laura Schumacher, AbbVie Executive VP, External Affairs and General Counsel, and Joel Pollack, Deputy Superintendent, North Chicago Public Schools, with the company’s recent award for math education.

### AbbVie Provides Grant for MATH EDUCATION

AbbVie has provided a a **\$350,000** grant for math education to the North Chicago public schools. The grant will enable educators to strengthen and reinforce the math curriculum for students (K-8) in the district and assist in the implementation of an engaging, common core aligned curriculum designed to increase both the educator and

student understanding of and proficiency in mathematics.

The district will use the donation to invest in curriculum materials, obtain coaching support for instructors, and initiate a math curriculum that is in line with state standards. The grant will also provide related technology upgrades, digital and hardcopy access to textbooks, including teacher editions, and assessment kits for all grade levels.

### What Keeps Executives Up AT NIGHT

The changing commercial business model is a major pain point for life-sciences executives, according to a new survey by CegeDIM Relationship Management. In fact, **61%** of respondents indicated the changing commercial business model was a concern, followed closely by regulatory reform (**57%**).

In terms of current operational changes, participants resoundingly identified an increased focus on market access strategies (**54%**) and primary salesforce realignment (**46%**) as top priorities. Further, **34%** report that their companies have a head of

innovation and dedicated innovation budgets, positioning themselves for sustained growth.

“Life-sciences companies are now functioning within a new reality, and are leveraging technology to reach their multi-stakeholders via multichannels,” says Laurent Labrune, CEO of CegeDIM Relationship Management. “Innovation in all of its forms is the key to success in today’s market.”



Laurent Labrune

### Top Health Industry ISSUES FOR 2014

Implementation of the Affordable Care Act (ACA) is only one of the factors forcing a rapid reshaping of the \$2.8 trillion U.S. healthcare industry in 2014, according to PwC’s Health Research Institute (HRI).

According to HRI, 10 issues stand out as the top focus for the health industry in the year ahead:

**1.** Price transparency is growing as purchasers — consumers and employers — are demanding and

- receiving more information on cost and quality.
- 2.** Employers are exploring new health insurance options through private exchanges.
- 3.** New regulation aims to eliminate counterfeit medications in the drug supply chain.
- 4.** States are turning to managed care to help contain Medicaid long-term care costs.
- 5.** All healthcare companies need to rethink their roles and business models in the new health economy.

- 6.** Healthcare companies will need to change their rules on innovation — embrace fail fast approaches.
- 7.** Social, mobile, analytics, and cloud technologies are driving new health industry business models.
- 8.** Corporate venture capital is picking up the slack as traditional venture funding slows for pharmaceutical start-ups.
- 9.** Technology is redefining the healthcare job market.
- 10.** Drugmakers must rethink their clinical trial research methods, embracing alternative approaches.

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**Healthcare Cost Growth Slowed; COST CONTROLS MUST BE IMPLEMENTED**

According to a recent study "Health Care Spending: A Giant Slain or Sleeping?" published in the New England Journal of Medicine, health spending rose just **0.8%** per person in **2012**, slightly less than the rate of growth of the GDP per capita. This trend marks a departure from the previous five decades, and may be fueled in part by payment reforms contained within the Affordable Care Act (ACA).

While analysts are divided on whether the trend is a result of the recession or recent efforts to control spending, the authors say either way the U.S. needs to reengineer health services to make them more efficient to go after the one-third of health spending that is estimated to be wasteful.

Health policy experts agree the following actions are needed to achieve this goal:

- » **Provider payment reform:** Discarding current fee-for-service payment models in favor of arrangements such as capitation or partial capitation, global budgeting, or risk-sharing arrangements such as those supported by the ACA's accountable care organization program.
- » **Reforming the delivery system:** Strengthening three areas: the usability of health information technology, care coordination for the sickest and most expensive patients, and primary-care services.
- » **Engaging consumers in making better healthcare choices:** With better information and incentives, patients should be rewarded for choosing providers that have better outcomes and lower costs of care.
- » **Making healthcare data more available:** Patients should have better information about the prices providers charge as well as the quality and safety of their care.
- » **Reducing administrative expenses:** While standardization of billing and claims forms and processes has begun under the ACA, much more needs to be done.

**Innovation Corner...****GSK Offers Prize for BIOELECTRONICS RESEARCH**

GlaxoSmithKline is offering a \$1 million prize for innovation in the emerging area of bioelectronics research. The prize will be awarded to the scientists who are first able to solve the challenge of creating a miniaturized, fully implantable device that can read, write, and block the body's electrical signals to treat disease.

GSK's Bioelectronics R&D unit is pursuing a relatively new scientific field with the hope that a new class of medicines can be developed. GSK researchers believe that these devices could be programmed to read and correct the electrical signals that pass along the nerves of the body, including irregular or altered impulses that can occur in association with a broad range of diseases.

▼ For more information, visit [gsk.com/media/press-releases/2013/gsk-announces-1-million-innovation-prize-for-bioelectronics-res.html](http://gsk.com/media/press-releases/2013/gsk-announces-1-million-innovation-prize-for-bioelectronics-res.html)

**Sanofi's Second PiPH INNOVATION CHALLENGE**

Sanofi US has launched its second Partners in Patient Health (PiPH) Innovation Challenge: Collaborate | Innovate, which will award \$100,000 to the winning team. This year's theme is Co-Creating for Breakthroughs: Moving toward a collaborative research and development ecosystem. The challenge calls on nonprofit patient, provider, and

professional associations to partner with other associations and/or academic institutions to propose new approaches that translate patient insights into improvements in the drug development process.

▼ For more information, visit [sanofi.mediaroom.com/2013-12-09-Sanofi-US-Launches-Second-Innovation-Challenge-Collaborate-Innovate](http://sanofi.mediaroom.com/2013-12-09-Sanofi-US-Launches-Second-Innovation-Challenge-Collaborate-Innovate).

**Industry Partners Launch INNOVATION APP CHALLENGE**

Partnerships in Clinical Trials, in conjunction with Lilly, UBC, and Enlight Bio, is launching the 1st Annual Innovation challenge to promote patient-centered clinical research through the Patient Engagement App Challenge.

This competition challenges developers across the globe to submit apps that educate, engage, and empower participants enrolled in clinical studies. Using the Health IT movement as a launching pad, developers can help transform the clinical trial experience for patients by using software to improve patient education, communication, scheduling, medication adherence, and more.

Winners will receive cash prizes and invitations to unveil their application onsite at the 2014 Partnerships in Clinical Trials conference in Las Vegas.

▼ For more information, contact Marina Adamsky at [madamsky@iirusa.com](mailto:madamsky@iirusa.com).

**Top 10 Supply Chain Initiatives FOR 2014**

Elemica identifies **10** top initiatives to help increase business performance.

- 1. Have a come-as-you-are approach to business.** Be flexible to work with and meet your trading partners on their terms.
- 2. Build more effective collaborations.** Speak the language of your trading partners to create clear communications.
- 3. Capture more keen insights.** Operate your business with a supply chain that properly responds to market demand or supply disruption.
- 4. Foster an easy-of-doing business with mindset.** Find common ground with your customers.
- 5. Create clear differentiation.** Deliver an experience with outside-in capabilities.

- 6. Find greater cost advantages.** Automating key business processes ensures better and faster responses, optimized inventory levels, better materials, and more.
- 7. Respond smartly and rapidly.** Knowing with certainty the right response, and acting faster to opportunities, is dependent on insight derived from a critical mass of connected trading partners on a powerful network.
- 8. Mitigate risk.** Knowing sooner what challenges or disruptions you may be facing and how to best respond, is dependent on clear visibility.
- 9. Exceed sustainability goals.** Automating processes lowers energy usage, saves trees and water, and lessens greenhouse gas emissions.
- 10. Become a lifelong learner.** Inform your decisions and share relevant information from collected data, evolving practices, research, etc. to stay competitive and become a true supply chain innovator.