

PHARMA TRAX

SALES, MARKETING,
AND R&D TRENDS AFFECTING
THE HEALTHCARE INDUSTRY

Service Consolidation Recommended for **CLINICAL TRIAL OFFICES**



Dr. Elaine Rubin

Academic health center leaders should examine the organization and structure for clinical trials administration within their respective institutions, says Dr. Elaine Rubin.

Emerging centralized clinical trial offices (CTOs) are among the newest developments within the research administration infrastructure of academic health centers. Little uniformity exists in the structure or functions of existing CTOs, however, and a recent report says that models are needed for the future.

According to the Association of Academic Health Centers (AAHC) report — Clinical Trials Offices: What's New in Research Administration? — while a trend toward consolidation or centralization in the administration of clinical trial functions has been ongoing for several years, it is far from accomplished. A review of CTOs at eight academic health centers shows little uniformity in the structure or functions designated to the CTOs. While they were hubs for clinical trial operations, some were control points and gatekeepers on all budgeting and billing, while others provided educational or liaison services.

"Academic health center leaders should examine the organization and structure for clinical trials administration within their respective institutions and determine what, if any, changes are needed to consolidate and optimize the research infrastructure," observes Elaine Rubin, Ph.D., AAHC VP for policy and program and one of the authors of the report.

The current economic crisis provides a new win-

dow of opportunity to address some of these challenges as institutions look to create increased efficiencies and effectiveness while conserving resources. To identify a select number of appropriate CTO models that can be easily adopted by academic health center leaders, stronger collective action may be needed through groups such as The Forum on Regulation of the Association of Academic Health Centers.

For more information, visit aahcdc.org.

WHAT CTOs SHOULD PROVIDE

Academic health center leaders should make sure their clinical trials administration infrastructure is consolidated and revamped so that it provides the following:

- A focal point for all billing and compliance activities
- Increased communication and coordination of activities and policies
- Consolidated education and training function
- Decreased redundancy and costs for staffing and infrastructure
- Increased access to information for university and academic health center leadership

Source: Association of Academic Health Centers, Clinical Trials Offices: What's New in Research Administration? For more information, visit aahcdc.org.

AMERICANS WARY OF HEALTHCARE REFORM, Confident in Ability to Pay for Services

According to research from Thomson Reuters, while Americans lack confidence that healthcare reform will deliver more affordable or better quality medical care, they have grown increasingly confident about their ability to pay for healthcare services.

Based on one segment of the PULSE Healthcare Survey, which tracks consumer attitudes toward healthcare reform, only 37.9% of respondents surveyed in July and August 2009 believe healthcare reform will improve the cost of care, and just 30.3% believe it will improve quality of care.

The survey found that 71% agree that Americans are entitled to the best available healthcare, but fewer than half (46.3%) consider the United States healthcare system to be the best. Still, a majority of respondents appear satisfied with the status quo. When asked to rate their satisfaction with their healthcare providers, costs, and insurance coverage, about 80% said they were satisfied with

their doctor, nearly 70% were satisfied with their health insurance coverage, and about 53% were satisfied with the amount they pay out-of-pocket for healthcare.

"It's easy to see why there is considerable disagreement about healthcare reform; people are generally satisfied with what they have, skeptical that change will improve the system, and divided on the role the government should play," observes Gary Pickens, chief research officer for the Healthcare & Science business of Thomson Reuters and lead author of the study.

Another report based on PULSE Healthcare Survey data, Thomson Reuters Healthcare Indexes: Consumer Confidence, found that consumer confidence related to healthcare expenditures increased 12% between March and July 2009. A sub-index reflecting respondents' belief that they will be able to pay for their healthcare expenses in the next three months rose 18% during the study period, while sub-indexes that reflect respondents' anticipated ability to access routine care, urgent care, medical testing, elective surgery, and therapies all increased between 8% and 15%. But these numbers change dramatically when looking at those without insurance coverage; their overall confidence levels were 80% lower than average in July.

"There is growing optimism among many healthcare consumers, but also there is a clear disparity in outlook between those with higher income levels who have insurance coverage and those who are uninsured," Mr. Pickens says.

For more information, visit thomsonreuters.com.

Firms Seek Maximum Outreach Through **ONLINE MARKETING PROGRAMS**

With almost universal access of broadband technologies in the lab and the growing sophistication of multimedia advertising formats on the Web, life-sciences suppliers have become increasingly interested in online video opportunities to promote their products and companies. Life-sciences companies are investing large dollar amounts in creating videos that entertain, inform, and call



Gary Pickens

We're seeing wide variance of opinion across demographic profiles, suggesting it will continue to be challenging for legislators to find the middle ground, says Gary Pickens.

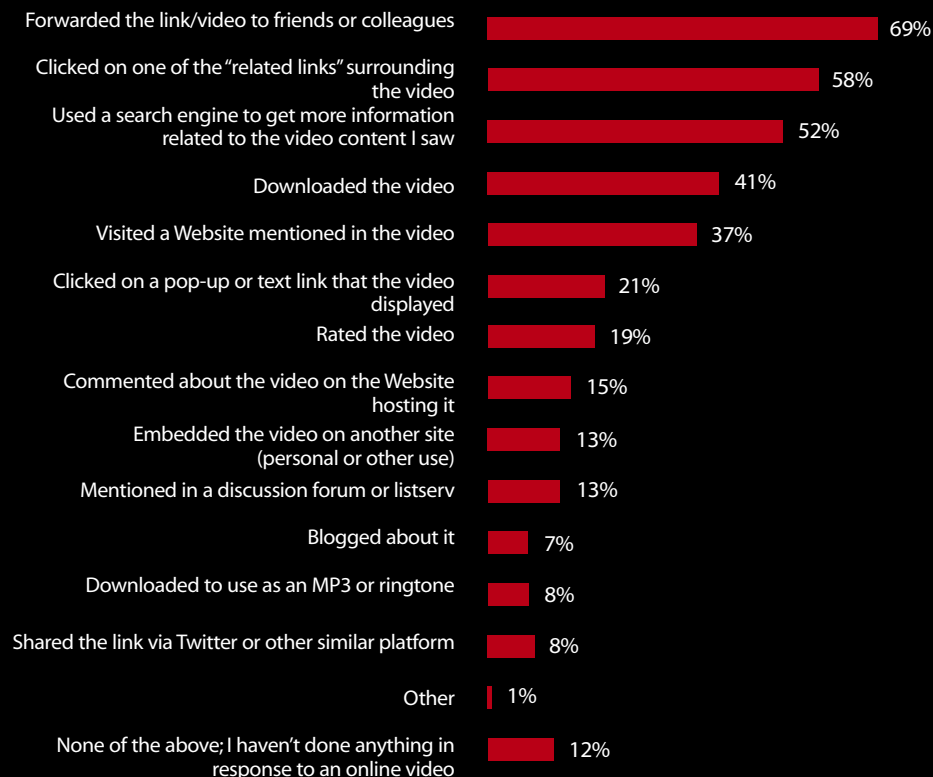


Dr. Tamara Zemlo

This report explores researchers' receptivity and responsiveness to online video advertising, says Dr. Tamara Zemlo.

CALL TO ACTION

QUESTION: Which of the following have you ever done as a result of watching an online video? (check all that apply)



Source: BioInformatics, New Media Marketing Channels: Creating Effective Online Life Science Promotional Videos. For more information, visit gene2drug.com.

the scientific consumer to action. According to BioInformatics, 65% of scientists believe that life-sciences suppliers should circulate videos to promote a brand or a product; however, suppliers need to understand what components of a marketing video will inspire a scientist to do more than watch.

The BioInformatics report, *New Media Marketing Channels: Creating Effective Online Life Science Promotional Videos*, surveyed nearly 1,300 scientists for their opinions on marketing videos produced by life-sciences suppliers to find out how videos are discovered, used, and shared, and to understand impact on brand awareness and purchasing behavior.

"Our goal is to help life-sciences suppliers leverage online video for Internet advertising campaigns," explains Tamara Zemlo, Ph.D., MPH, VP of advisory services.

About three-quarters of the scientists surveyed for the BioInformatics report said they have accessed short videos online in the past 12 months — just about equal to the use of news portals such as CNN and information-related Websites (i.e., weather, stock data). Of the nearly 1,000 respondents who viewed short online videos in the past 12 months, 88% took some kind of action as a result of viewing an online video; more than two-thirds forwarded the video to a friend or colleague, and more

than half clicked on a related link or used a search engine for more information related to the video.

For more information, visit gene2drug.com.

Federal Incentives Could Boost **HEALTHCARE IT SALES**

The Obama administration is providing incentives to push doctors and hospitals to upgrade their healthcare IT solutions, spurring providers to replace antiquated computer hardware with newer, more powerful systems that can support the vast amounts of information created by electronic medical record (EMR), electronic physician order entry (CPOE), and other advanced software.

According to the Kalorama Information report, *Healthcare Computer System Markets and Trends in HIT Buying*, approximately 56% of healthcare organizations in the United States have increased their IT department budget for 2009 despite the recession.

While discussions have mainly focused on HIT software applications, Kalorama also anticipates an opportunity in healthcare for hardware providers. According to the report, hardware sales represent

about 23% of healthcare computer system sales, or \$1.11 billion. With increased investment in healthcare IT, Kalorama expects spending on this sector to grow at a faster pace than IT spending as a whole in the near term, or about 10.7% annually through 2013.

"The EMR incentives in ARRA (the American Recovery and Reinvestment Act of 2009) are aimed at software, but they will open up conversations between customers and vendors for new IT spending, and hardware will be part of that," says Melissa Elder, a Kalorama analyst and author of the report.

For more information, visit kaloramainformation.com.



Melissa Elder

The top IT-related technologies and applications that physicians and facilities are focusing on include identity management, bar coding technology, speech recognition, and hand-held PDAs, says Melissa Elder.

ONCOLOGISTS VISIT PHARMA SITES More Frequently Than Physicians Overall

Oncologists are more likely than the overall population of U.S. physicians to visit pharmaceutical, biotech, and device corporate and product Websites on a regular basis. In fact, according to a recent Manhattan Research study, almost 70% of oncologists visit product Websites monthly or more often. Additionally, oncologists are three times more likely than physicians overall to be high-frequency contributors of online health-related content.

According to findings from Manhattan Research's study of physician adoption and use of the Internet and other technologies, the field of oncology is rapidly changing, and physicians in this specialty rely on digital resources to receive the most up-to-date clinical and product news at the moment they need the information.

Manufacturers are now realizing the importance of supplementing in-person details with relevant online brand content that these specialists can access on demand. For example, the Pfizer site pfizeroncology.com offers useful videos, extensive product information, and patient education materials via an easy-to-navigate portal.

"The insight that oncologists are 'above average' in the digital realm is no surprise to the enlightened brand manager with an eye towards the future — a future in which reps are simply part of the promotional mix and not the center of it," notes Mark Bard, president of Manhattan Research. "The findings also highlight the need to further refine a professional strategy based on the needs of individual physician specialist segments. Clearly, companies can't use a one-size-fits-all approach when addressing a physician audience online."

For more information, visit manhattanresearch.com.

QUICK FACTS

- The global market for products used in the fight against influenza is projected to hit an estimated \$5.5 billion in 2009, and is expected to increase to \$6.3 billion in 2014, for a compound annual growth rate (CAGR) of 2.7%. The vaccines segment has the largest share of the influenza market and is anticipated to grow at a CAGR of 5.6% to reach nearly \$4.2 billion in 2014, from \$3.2 billion in 2009. By contrast, the therapeutics segment is expected to decline from \$2.1 billion in 2009 to \$1.9 billion in 2014, for a negative CAGR of 2.4%.

Source: BCC Research, The Global Influenza Market. For more information, visit bccresearch.com.

- Despite generic erosion of many branded agents, most notably Novartis' Diovan, the hypertension drug market is expected to experience only modest decline over the next decade. The market will decrease by an estimated 1.4% annually through 2013, and the annual decline will thereafter slow to 1% through 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor report on Hypertension. For more information, visit decisionresources.com.

- Sales of therapies for major depression in France, Germany, Italy, Spain, the United Kingdom, and Japan are expected to increase by \$500 million from 2008 to 2018. This is due to increasing diagnosis and drug treatment rates in these countries and the patent protection of key agents. By contrast, the U.S. market will decrease by \$1.4 billion from 2008 to 2018, owing primarily to widespread generic erosion of major therapies such as Lexapro and Effexor XR.

Source: Decision Resources, Pharmacor report on Major Depressive Disorder. For more information, visit decisionresources.com.

- The uptake of novel therapies is expected to drive a more-than-sixfold increase in the obesity drug market, from \$512 million in 2008 to more than \$3.2 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The most notable novel therapies expected to launch by 2018 include Arena Pharmaceuticals' lor-

caserin and Amylin Pharmaceuticals' pramlintide/leptin combination; combined sales of these two compounds is projected to capture 87% of the total obesity market in 2018.

Source: Decision Resources, Pharmacor report on Obesity. For more information, visit decisionresources.com.

- Following its launch and uptake, GlaxoSmithKline's angiogenesis inhibitor Votrient for the treatment of renal cell carcinoma is expected to garner sales of \$640 million by 2018 and steal significant market share away from Pfizer's Sutent in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. In 2008, Sutent accounted for 61% of sales in the angiogenesis inhibitor drug class.

Source: Decision Resources, Pharmacor report on Renal Cell Carcinoma. For more information, visit decisionresources.com.

- The market for diabetes therapies generated global revenue of \$27 billion in 2008 and is projected to reach \$44.7 billion in 2015 as increasing knowledge related to the pathology of diabetes results in the introduction of improved drugs to treat the disease.

Source: Frost & Sullivan, Global Diabetes Market. For more information, visit pharma.frost.com.

- The overall healthcare IT market for the Asia Pacific region in 2008 was around \$4.7 billion, and is expected to rise by around 3% to 4% in 2009. While countries such as Australia and Singapore, where healthcare is primarily publicly funded, will be considerably sheltered from the worst of the current global economic turmoil, overall healthcare providers' spending may face internal pressures to divert funds away from IT departments and toward care delivery.

Source: Frost & Sullivan, Revising Sales Strategy the Best Strategy — Likely Effects of Changing Global Economy on Healthcare IT Spending in APAC. For more information, visit frost.com.

- Ion channels represent a significant opportunity to address an underexploited class of therapeutic targets, but major pharmaceutical companies presently account for just over one-third of the nearly 150 ion channel modulators reported to be in clinical development. The estimated 100 ion channel modulators that have been approved for clinical

use have generated considerable revenue, with sales of the branded versions at about \$20 billion in 2007.

Source: Insight Pharma Reports, Ion Channel Modulator Pipelines: Targets and Agents in Development. For more information, visit insightpharmareports.com.

- Rapid increase in output from second-generation DNA sequencers has enabled new levels of productivity and new experiments. This, along with funding from the stimulus bill, has caused rapid adoption of these machines, helping to fuel sales of DNA sequencers to \$480 million in 2008 and is expected to drive sales growth of 19% annually through 2013.

Source: Kalorama Information, DNA Sequencing Equipment and Services Markets, 2nd Edition. For more information, visit kaloramainformation.com.

- The trend toward more patient-friendly drug-delivery options has helped fuel a \$2.7 billion market for pharmaceutical products combined with needle-free technology. A recent convergence of synthetic materials and computerized design software is expected to propel the market for such product delivery systems to 9.7% annual growth over the next five years.

Source: Kalorama Information, Drug Delivery Markets: Implantable/Injectable and Needle-Free Systems. For more information, visit kaloramainformation.com.

- The most substantial growth in the \$8.4 billion market for infectious disease diagnostics is in molecular testing, which includes diagnostics like nucleic acid-based tests (NATs). An expanding population of drug-resistant bacterial strains, including methicillin-resistant *Staphylococcus aureus* (MRSA), is the most important justification for NATs.

Source: Kalorama Information, Infectious Disease Diagnostic Markets. For more information, visit kaloramainformation.com.

- The global autoimmune treatment market is expected to surge from an estimated \$37.84 billion in 2009 to \$68.81 billion by 2014, an estimated CAGR of 12.7%. The North American market is expected to account for nearly 42% of the category's total revenue.

Source: MarketsandMarkets, Global Autoimmune Treatment Market (2009-2014). For more information, visit marketsandmarkets.com.

U.S. Slow to Regulate DTC GENETIC TESTING

The United States has become an attractive market for direct-to-consumer genetic testing companies because the regulatory barriers for DTC marketing and sales of genetic tests are extremely low. There are no overall federal requirements for a physician to serve as a gatekeeper for consumer access to genetic tests, or for premarket approval for analytical or clinical validity of these tests by any government agency.

In addition, there are no federal laws or regulations prohibiting a company from marketing or selling a genetic test directly to the public in addition to

a healthcare facility or physician's office. The lack of federal oversight has, however, led to wildly varying state regulations, creating confusion for DTC genetic testing companies, according to Insight Pharma Reports' Direct-to-Consumer Genetic Testing: Business Prospects in the United States.

Many doctors and researchers have vigorously criticized the consumer genomics field, saying the nascent industry is trying to ramp up faster than the science can interpret what genomic scans really mean.

Some critics have even called for a ban on DTC marketing of such services and for greater oversight from the U.S. Food and Drug Administration (FDA), the report notes.

These concerns, the wave of new gene-chip

technologies, and the ease of starting a consumer business offering genetic information have captured the attention of the Department of Health and Human Services (DHHS), which oversees the FDA, and a number of other regulatory oversight and trade commissions.

The federal dialogue has started over the medical legitimacy of the genetic tests offered to consumers; their sometimes uncertain clinical validity and utility; how the information is being used; privacy issues; and the appropriate way to make sure that good scientific, medical, and ethical standards are set and not compromised and consumers are protected from fraud, all at a time when current regulatory oversight is shared between several agencies.

For more information, visit insightpharmareports.com.

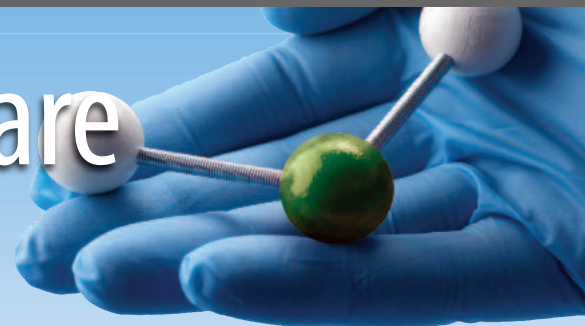
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