Carolyn Gretton

A Bridge to BETTER OUTCOMES

The medical affairs organization within pharmaceutical, biotech, and device companies has moved beyond its traditional support role, evolving into a global group that provides a critical conduit between a wide range of internal stakeholders and the external clients they serve.

"Medical affairs is uniquely positioned to be able to help physicians translate results from clinical trials into actionable information for their patients."

According to Best Practices, today's medical affairs group enhances a company's scientific reputation and complements the work of research and development to communicate the value and proper use of a company's products, therapies, devices, technologies, and diagnostics. In addition to its more traditional clinical data, medical education, and publication planning functions, medical affairs has expanded to include critical responsibilities such as comparative effectiveness and health outcomes research, biostatistics, and reimbursement.

"As our healthcare system focuses on increasing value by improving outcomes while managing costs, the medical affairs function is evolving from an essential support function to a key strategic function," says John Yee, M.D., VP, U.S. head medical officer at AstraZeneca Pharmaceuticals. "Internally, medical affairs is the essential bridge between R&D and commercial organizations; externally, the medical affairs team is a key interface with providers, payers, and policymakers."

Catherine Blackwell, director of medical affairs, North America, for Nucletron, notes that medical affairs has traditionally been a company's most credible liaison with thought leaders and external stakeholders.

"Traditionally, there has been a strong internal collaboration between marketing and medical affairs," Ms. Blackwell says. "To really become an effective partner, I truly believe that medical affairs should sustain a balance by maintaining an understanding of commercial and customer needs and challenges while staying in compliance with all the regulations we have to adhere to."

Paul Chew, M.D., U.S. chief science officer and U.S. chief medical officer, Sanofi US, also uses the word "bridge" in describing the medical affairs function.

"Medical affairs has always been a bridge; it's what goes across that bridge that has changed," Dr. Chew explains, adding that basing approval and physician uptake solely on the clinical-trial data included in the traditional FDA dossier is no longer sufficient.

"What go across the bridge now are data from comparative trials, which may not have been done as frequently in the past, as well as health outcomes data," he says. "These types of data now have to surround the registration dossier to the FDA, and if this information isn't available, it's hard to get patients access to medications, which makes it hard to affect outcomes. We all want to reduce negative outcomes, such as premature death from cardiovascular disease, cancer, and diabetes."

A Plan for Publishing

"Medical affairs is uniquely positioned to be able to help physicians translate results from clinical trials into actionable information for their patients," says Faith DiBiasi, associate director, knowledge management, medical affairs, for Human Genome Sciences. "Evidence-based scientific communication provides the opportunity for physicians to get the data they need to make decisions, and medical affairs provides this communication in the form of publications, medical information letters, medical science liaison resources, and so forth."

Calvin Roberts, M.D., executive VP and chief medical officer, Bausch + Lomb, stresses that a detailed publication plan continues to be an essential element of the medical affairs function's core capability when bringing a product to market or upgrading an existing portfolio.

"A carefully executed publication plan that includes peer-reviewed literature plays a major role in ensuring additional critical product data reaches our customer base," Dr. Roberts says. "Making this information available through additional channels also increases medical education in general, helping to maximize the benefit the healthcare community receives from a company's investment in new technology."

FAITH DIBIASI *Human Genome Sciences*

Medical publications groups' strategic importance within medical affairs is growing, but maintaining adequate resource levels and gaining upper management buy-in remain significant challenges, according to Cutting Edge Information.

"Whether we're talking about an article, a

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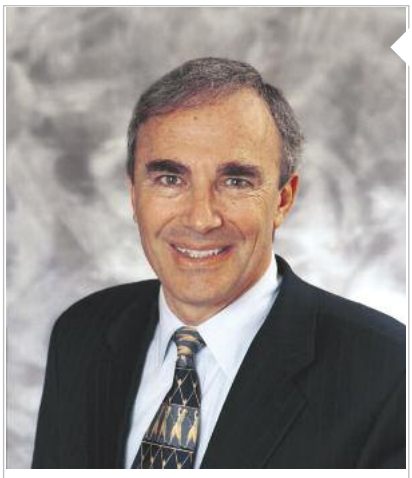

DR. CALVIN ROBERTS *Bausch + Lomb*

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presentation, a poster, or support for wider commercial activities, medical publications are crucial to advancing brand education and awareness," says Ryan McGuire, senior research analyst and lead author of the recent Cutting Edge study, Strategic Medical Publications Management: Plan Development and Resource Benchmarks.

"If the data aren't published, the other functions can't use the information, and relationship-building opportunities with thought leaders are lost," Mr. McGuire adds.

The study notes that communicating clinical trial findings to meet regulatory requirements remains a top objective of medical publication teams, followed closely by educating physicians about a drug, differentiating the product from its competition, and increasing brand awareness. The biggest challenge facing publications teams is winning sufficient resources to meet the requirements of external stakeholders as well as internal clients across clinical development, medical affairs, marketing, sales, market access, and other functions.

Other top challenges cited in the report include demonstrating return on investment, communicating the corporate value of publications groups' work, and winning senior management buy-in, all of which tie in to managing limited resources. Showing a quantitative ROI is an inherent challenge because of the firewall between the marketing and medical affairs functions, according to benchmarking partners participating in the Cutting Edge study.

"Companies must demonstrate active support through sufficient resources and a commitment to long-term planning," says Jason Richardson, president of Cutting Edge Information. "Adjusting performance measurement for publications to include softer metrics such as message uptake and physician reach will go a long way toward a comprehensive understanding of the medical publications team's impact."

Dr. Chew says while he believes publications are still the backbone of science, they need to be targeted not only to physicians, such as with the major medical journals, but also to payer-physicians and the payers themselves.

"We need to focus not just on the efficacy of a drug, but what analyses we can show to increase utilization of resources and improve quality of life and even patient-reported outcomes," he says. "So the publications have to be strategic and focused on the audience you want to reach."

Regarding Reimbursement Issues

According to Dr. Roberts, medical affairs serves as the voice of the customer among internal stakeholders; thus, medical affairs participation is expected at every stage of product development.

"As a liaison between its company and its customer base, the medical affairs function is a critical communications channel that can help drive product improvements and new product developments," he says.

Ms. Blackwell says because of its understanding of basic research and clinical-trial data and the needs of patients, healthcare providers, and payers, she believes the medical affairs function is in a unique position to leverage this insight to engage health economics outcomes research leaders, managed care organizations, reimbursement leaders, and policymakers.

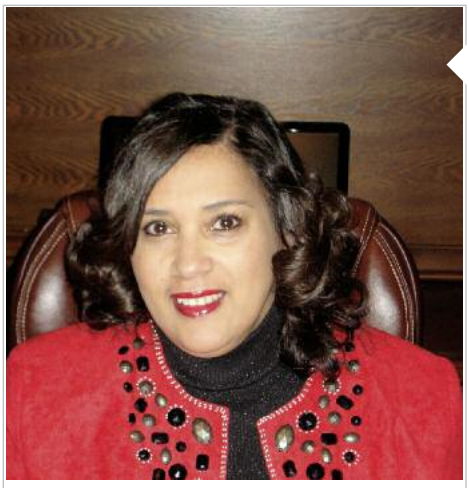
"We need to engage these stakeholders early on in the development process, because ideally the burden of disease epidemiology and cost of disease studies should be done a year before the launch of any drug or technology," she explains. "As an industry, we need to come away from the whole rock-star, blockbuster-drug mentality and focus on dealing with real-world outcomes and testing the drug or device in real-world situations, so that in the end, when we go to get reimbursed for the product, there are no surprises."

DR. JOHN YEE *AstraZeneca Pharmaceuticals*

"Payers are expecting customized solutions for their populations so they can understand the value proposition, so we have to work very closely to make sure we provide those sorts of analyses," Dr. Chew says. "I don't think independent medical education traditionally based on knowledge transfer is good enough. We need to see if we can translate that education into patient outcomes, so that patients have better control of their diabetes, or blood pressure, or cholesterol."

Dr. Yee says AstraZeneca has established a partnership with HealthCore to conduct real-world evidence studies as a first step toward discovering whether health outcomes can be improved while lowering the total cost of care, especially in chronic diseases.

"By combining claims, pharmacy, laboratory, and other clinical data, it is possible to assess the impact of various treatment options on health outcomes and the total cost of care," he says. "As a next step, we are expanding our collaboration to include a broad consortium



CATHERINE BLACKWELL *Nucletron*

"To become an effective partner, medical affairs should sustain a balance by understanding commercial and customer needs and challenges while staying in compliance with regulations."

of private and public healthcare organizations and enlightened communities that are already using integrated data to improve health.

"By including a variety of key stakeholders committed to making meaningful changes in the delivery and quality of healthcare, we hope to accelerate national and regional investment in evidence-based strategies for improving health outcomes and managing total cost of care," Dr. Yee concludes.

"It's really now medical value that drives the access, and it's the access to medication and solutions that drive the outcomes," Dr. Chew says. "It's also important not to just look at the question of efficacy — whether a product works — but whether it is effective in the real world of patients with multiple diseases and multiple medications. We have to design our whole clinical program with that end in mind, that we have to have effectiveness rather than just efficacy."

One of the most important responsibilities of medical affairs, according to Dr. Roberts, is to field detailed questions from clinicians that often deal with key nuances of products such as formulations, physical properties, and mechanisms of action.

"These questions give us a unique opportunity in medical affairs to increase our innovation platform because they are often rooted in hypotheses about potential limitations and/or alternate applications of our products," he says. "By investigating the best answers for our clinicians, we often find ourselves developing product improvements and/or new product ideas in the process."

Another area in which medical affairs has become more involved in recent years is safety, an area that Dr. Chew describes as evolving.

"Instead of reporting what's happened, it's taken on more of a surveillance and risk-management approach, for example, looking for early signals in real-world usage compared with comparable products." he says. "I think safety is becoming a more active partner in managing risks and continuing surveillance of products, which is in line with the main mission of medical affairs in ensuring that the right patient gets the right product at the right time."

Making More Meaningful Connections

Ms. Blackwell strongly believes in the value of medical affairs as providing a central connection for coordinated stakeholder management across the organization.

"I think that providing a centralized function with clearly identified roles and responsibilities for coordination of internal stakeholder communications with external customers is a critical success factor for achieving a more client-centric business model," she says.

"Medical affairs professionals need to keep their scientific focus and avoid promotional activities to maintain their credibility as a source of evidence-based scientific informa-

VIEWPOINTS

RAMANA YALAMANCHILI, PH.D.
Senior VP, Chief Clinical Strategist, SCI Scientific Communications & Information, part of *Ogilvy CommonHealth Worldwide*

Evidence-Based Coordination

As a central point of coordination within the organization and a primary point of contact with therapeutic area experts, medical affairs has an opportunity to foresee the evidence needs of each product and proactively recommend appropriate studies early in the development process. This will allow a cost-effective clinical development program of appropriate scale, which in turn may accelerate product approval, offer greater patient access, and optimize returns on investment.

MARTIN SKELTON, PH.D.
President, Ogilvy Healthworld Medical Education (NY), part of *Ogilvy CommonHealth Worldwide*

Scientifically Rooted

Medical affairs is firmly rooted in scientific evidence and uniquely able to drive R&D efforts toward innovative solutions and help early-stage molecules evolve as more effective, clinically meaningful assets through thoughtful clinical trial design; label optimization; strategic, complete, and timely dissemination of data; and early communication of essential supportive educational concepts for HCPs. Such activities also inform the economic and health outcomes rationales critical to the compound's value story at time of commercialization.

JIM MERCANTE
Senior VP, Innovation, TGaS Advisors, a division of *KnowledgePoint360*

Dialing In for Success

Medical affairs, including those serving global functions and local or regional markets, must be intimately dialed into overarching corporate, area, and regional goals. To do this effectively, medical affairs leaders are advised to develop a business planning road map that focuses scarce medical affairs resources on areas holding the greatest promise for improved healthcare and corporate success.

Defining a Road Map

Critical to success of any innovation initiative is a clearly defined road map for implementation, monitoring, scenario planning, metrics of success, and metrics/governance for either mainstreaming or shutting down. The most dynamic medical affairs organizations design innovation initiatives and pilot programs to leverage the wealth of new information at their disposal, including pooled research data, claims databases, electronic medical records, and even social media content.

EXPERTS

CATHERINE BLACKWELL. Director of Medical Affairs, North America, Nucletron, an Elekta company specializing in radiation oncology products and services and committed to developing solutions focused on improving patient care. For more information, visit nucletron.com.

PAUL CHEW, M.D. U.S. Chief Science Officer and U.S. Chief Medical Officer, Sanofi US, a company committed to developing safe and effective medicines, vaccines, and consumer health products to help improve the lives of patients and their families. For more information, visit sanofi.us.

FAITH DIBIASI. Associate Director, Knowledge Management, Medical Affairs,

Human Genome Sciences, a biopharmaceutical company with the goal of placing new therapies into the hands of those battling serious disease. For more information, visit hgsi.com.

RYAN MCGUIRE. Senior Research Analyst, Cutting Edge Information, a research, consulting, and publishing firm focused on best-practice benchmarking for the pharmaceutical, biotech, medical device, and healthcare industries. For more information, visit cuttingedgeinfo.com.

JASON RICHARDSON. President, Cutting Edge Information, a research, consulting, and publishing firm focused on best-practice benchmarking for the pharmaceutical, biotech, medical device, and healthcare industries. For more information, visit cuttingedgeinfo.com.

CALVIN ROBERTS, M.D. Executive VP and Chief Medical Officer, Bausch + Lomb, a company specializing in products and services for eye health. For more information, visit bausch.com.

JOHN YEE, M.D. VP, U.S. Head Medical Officer, AstraZeneca Pharmaceuticals, a global, innovation-driven biopharmaceutical business focused on the discovery, development, and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology, and infectious disease. For more information, visit astrazeneca-us.com.

tion," Ms. DiBiasi says. "In the case of publications, this means following best practices at all times to ensure that data are reported in an accurate and transparent manner."

Dr. Roberts observes that medical affairs teams are ideally positioned to receive the positive and negative experiences, perceptions, and opinions of physicians who prescribe the company's products.

"By being responsive to our customer base and providing the feedback in a timely, transparent manner to key internal stakeholders, medical affairs becomes central to the coordination of product development activities," he says.

Dr. Yee agrees that the broad perspective and experience of medical affairs team members creates important opportunities for interaction across a range of internal and external stakeholders, many of whom often appear to be at odds with one another, with differing goals and priorities.

"The medical affairs team has the unique opportunity to gain alignment and lead win-win initiatives toward the fundamental mission shared by all parties: the desire to make a meaningful difference in improving patient health," he says. "In our medical affairs team at AstraZeneca, we hold the strong belief that as we work together to improve the health of patients, we also increase the strength of our business." PV