EXECUTIVE SUMMARY

ASS
MEDICAL AFFAIRS STRATEGIC SUMMIT

Manage Medical Affairs, Communication, Information and Research Collaborations to Increase Strategic Positioning in the Marketplace

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If you were not able to join us, here is what you missed at ExL Pharma’s Medical Affairs Strategic Summit East.

A can’t-miss event for medical communications professionals, the Medical Affairs Strategic Summit (MASS) East, held April 13-15 in Morristown, NJ, brought together three conferences and five plenary sessions in one location. MASS East was designed to convey strategies and techniques to medical communications leaders in the ever-evolving healthcare market, recognizing that efficient medical communications are essential to an organization’s product development life cycle and overall success.

MASS East began with three master class workshops focused on facing the next wave of process improvement from leaders in the field, and the main event featured three educational tracks:

1. **The 10th Medical Affairs Executive Forum**, which addressed the expanding role of medical affairs teams as they become more involved in the research and prelaunch phases of product development

2. **The 18th Medical Science Liaison Best Practices Congress**, which featured techniques for managing relationships with key opinion leaders (KOLs) and analyzing the latest trends in off-label communications

3. **The 23rd Research Collaborations and Investigator-Initiated Studies Symposium**, which highlighted case studies on developing an IST program in a startup business and exploring innovative techniques for tracking research teams.

The following section includes session summaries and highlights to give you an idea of what you may have missed at MASS East 2016.
Sheila Komara of Mallinckrodt Pharmaceuticals delivered information on how to “Overcome Communication Challenges Due to a Lack of Data,” focusing on both internal and external stakeholders. The MSL’s role is to coordinate the flow of clinical information and manage KOL relationships, which can be critical to a product’s success at any stage during its life cycle. In addition, MSLs must possess and display expert neutrality and demonstrate balance. Compelling data is that which has a powerful effect or helps to push toward a certain course of action. MSLs need to focus more on pulling information in and integrating it into business decisions. Together, outcome data and quality of life data can demonstrate value. Beyond good communication skills and abilities, other mandatory skills for MSLs are presentation prowess, relationships with KOLs and scientific merit. Technology does not run an enterprise — relationships do.

Peter Lee of Heron Therapeutics discussed strategies for “Navigating Medical Affairs in a Commercial World” and learning how to keep commercial and medical initiatives separate through careful planning. Medical affairs teams and actions are afforded certain protections under the concept of scientific exchange, and the FDA has stated that though off-label and preapproval promotion are inappropriate, it does not intend to “restrict the full exchange of scientific information.” What does this mean? Sales representatives cannot act like MSLs, and medical affairs activities are not and must not be viewed as promotional. To that end, Lee recommended the following actions: engage with a compliance officer early on; build relationships with commercial colleagues, but be smart; be collaborative, but not overly flexible; set annual medical/scientific objectives early on; and clearly define roles and responsibilities.
Shannon Brow of Medtronic Diabetes presented “Techniques to Foster and Expand MSL Team Talent,” explaining how to integrate clinical experts into respective therapeutic areas and optimize the skills of team members from within. When assessing the business team need for diversity, first assess your customer base. If you have a narrow audience, an MSL team comprised of similar technical/scientific experts would meet the need. When targeting varied specialists, then it makes business sense to build an MSL team with therapeutic expert members representing the breadth of your customer base — and that makes even more sense when working with varied healthcare practitioners. Communication skills are paramount for MSLs. Training techniques for medical affairs managers and directors vary, with independent reading, face-to-face lectures and mentoring leading the way. Mentoring programs benefit both the employee and the company and should be a part of every onboarding process.

“The Establishment and Growth of a Medical Science Department in a Device Organization” from Colleen Baird of Abbott Vascular discussed management techniques and evaluation metrics for leadership throughout the department. Six team members, at a minimum, add up to success: the connector, the dreamer, the visionary, the doer, the innovator and the taskmaster. Rules of engagement include establishing independence from commercial departments; reporting up to C-suite; and ensuring that funding isn’t reliant on sales, is on a separate budget and is adequate for appropriate staffing levels. Start out on the right foot: establishing clear guidance for MSLs can help to ensure that they don’t become an extension of the sales department. Establish practices and policies. Use metrics that are both quantitative and qualitative. View challenges as opportunities, bridging the gap between what you want to do and what you can do within a highly regulated environment. And, of course, always remember that the patient remains the most important customer.
Mary Voehl Hirsch of Sanofi offered a session on “Multi-Site Investigator-Initiated Trials,” noting that challenges with such IITs occur regardless of size or complexity. Moreover, increased risks include IP/ownership of data, recruitment of patients and preapproval. Multi-site investigator-initiated trials may require multiple contracts as well as external vendors and statisticians, milestone payments, drug shipments, multiple sources of funding, and other complicating factors. Regulatory requirements include registration and product approvals per country, as well as compliance with CTA/IND requirements. Data management and safety reporting are other key considerations companies must tackle. However, benefits include global effort, reduced duplication, speed of enrollment/study completion, increased efficiency, cost reduction, data integrity and easy-to-communicate outcomes. All of this can benefit clinical research and patients.

Darshan Kulkarni of the Kulkarni Law Firm shared “Macro Trends Affecting Medical Affairs,” including expanded roles for medical affairs, MSLs and medical writers. Hot topics for off-label promotions include PRC review, social media guidance, and CME and pharma payments. Off-label promotions are off limits because they could potentially be untrue or misleading, while also promoting unsafe usage and circumventing more than 50 years of drug approval history. On the other hand, label approval takes a long time and off-label uses can be the standard of care. Current CER funding priorities are priority populations, health disparities, people with disabilities, under-represented populations, and personalized medicine and patient subgroups. Finally, patient opinion leaders — those who are well-versed in a disease who readily share their knowledge with others — should be a priority for companies. This group has good communication skills and good basic knowledge of treatment options/research, and can guide others to clinical trials, specialist doctors and medical centers while sharing information about treatment options.

Joan Cannon of Lundbeck US presented “MSL Warm Transfer Pilot,” which covered the process enabling medical affairs to instantaneously answer unsolicited questions around the safety of a neurology product. The warm transfer product involves several steps: sales rep meets with HCP + unsolicited off-label question + signed MIRF + warm transfer to medical affairs = question answered. Via a universal number, calls are routed to an on-call MSL. The pilot program took place in a region with historically high levels of questions; success was measured by resolution, call duration and satisfaction. HCPs were enthusiastic about the new option. Next steps included supported rollout of product safety data via the on-demand MSL and a review of technology options and investments.
“Optimizing Field Medical Teams Through Home Office Integration” from Vanessa Johnson of Bayer Healthcare focused on optimization for all stakeholders. Integration allows companies to create and adapt teams to meet the most important field medical needs, creating maximum value for every stakeholder. This begins with a strategic plan where objectives align to needs and opportunities. MSL teams are not created equal — ideally, they should reflect the needs of the organization in terms of size, experience, location and so on. Since there is no single solution, companies must anticipate and adapt. Integration helps build the skills for tomorrow’s MSLs, including technical and analytical skills, understanding of the industry, adaptability, commercial awareness, scientific credibility, interpersonal skills, and more. Metrics should reflect progress toward objectives. Communication is absolutely essential.

Rachel Couchenour of OxiGene illuminated the process of “Establishing a Medical Affairs Department in a Startup,” including lessons learned from experience, challenges along the way, and the outsourcing and use of virtual teams. In this case, the company had to prioritize department needs and find the right balance between infrastructure and launch preparedness. Startup challenges can include financial resources; human resources; rapidly shifting priorities; and the need for partners, not vendors. Medical affairs operational accountabilities include medical communications, pharmacovigilance, grants, NDA support and more. Organizations need to choose between a contract team or direct hire. Regardless, initial one-on-one interviews are critical, as is thought leader definition alignment. Communicate and communicate again. Finally, offer flexibility, including NDA support.
Jason Bradt of Lundbeck discussed “Medical Affairs’ Responsibility in Regulating an Organization’s Social Media Presence.” Together, the industry and the world are transforming — growth and innovation are key imperatives in the industry while changing consumer dynamics and evolving industry regulations point to the need for an agile business environment. With the increased use of health sites and social channels to understand symptoms and treatments, the voice of the patient is more important than ever. To create new opportunities and maintain competitiveness, leaders must embrace the emerging digital technologies that connect data, patients and collaborators. Traditional healthcare decision-makers are now moving to social media. Presently, medical affairs is in a unique position since many standard activities are directly translatable to social media platforms and can touch all stakeholders. Medical affairs can contribute to both branded and unbranded activities. Marketing and medical affairs alignment in brand strategies is critical; brand messaging should be driven by scientific data, and the functions should work together to develop messaging strategies. In addition, greater social listening leads to better measurement, capturing of real-time healthcare information, better insights into treatment perception and efficacy, enhanced engagement at conferences, and more. The company’s case study revealed that medical affairs can be positioned to lead digital strategy while patients, caregivers and community advocates need to be engaged on social media — they are a valuable and often untapped resource.

Kathleen Guindon of Puma Biotechnology shared “An Assessment of MSL Roles When Transitioning Between Biotechnology Companies,” providing a primer on how to fit into a new organization. The first 90 days are always a transition period; in that time, it is important to showcase enthusiasm, find your routine, take notes, establish goals and increase your participation. Ask yourself: What am I being asked/paid to do? Then evaluate resources, size of pipeline, level of risk and overall company structure. To show that you are a good fit, affirm acknowledgement, dress the part, do not disturb, take notes, make friends with the IT team, understand the business case for your hiring and show your work.
Lisa Roessel of Actelion Pharmaceuticals discussed “Medical Affairs Leadership Roles with MSL Functionality,” explaining how experienced MSLs can use their communication skills and subject matter expertise to enter a rewarding medical affairs leadership role. Advantages of the new role can include increased salary and benefits, 401k plan and stocks, travel benefits, gym membership, and more. On the other hand, challenges can include a poor work/life balance, increased travel, loneliness, most work done via phone/computer and MSL crossover. To maximize your talents, ask what your true passions are and then look for your niche.

“RIPPLE: Member Registration and Credentialing System Trial Delegation Log,” presented by Lam Pho and Corey Willman of the Canadian Cancer Trials Group (CCTG), was a case study on the web-based RIPPLE system, which delegates IIT duties for sponsors and monitors requirements to GCP guidelines. As a sponsor, CCTG must ensure trials are conducted by qualified personnel; investigators must meet the applicable credentialing requirements. The trial delegation log indicates the trial’s principal investigator for the cancer sites, as per regulations, and is used by the PI to provide documentation of trial delegation to qualified clinical trial personnel. It is required prior to a site joining a trial and for all additions and removals of CTP. RIPPLE includes member account registration and administration, submission of credentialing documents, submission of other training/required documents, trial delegation log administration, and trial PI review. The goals for RIPPLE are to streamline mechanism for account registration and management, integrate electronic registration/credentialing/trial delegation log systems to ensure participation of qualified personnel, centralize trial delegation log and essential documents, and increase efficiency and compliance. The electronic system also helped gauge prior inefficiencies cited in paper implementations that sparked this innovation.
Lindsay Jubelt of Mount Sinai Health System presented “KOL Engagement and Management Strategies for Population Health Projects.” Financial risk is shifting to providers and assuming risk requires changes in health systems. Health system leaders and staff have little exposure to innovation occurring in other health systems and most KOLs have spent years at their institution to gain that status and may have limited awareness of change occurring outside their environment. By contrast, MSLs can provide information about what is happening in other systems, marketplace trends and benchmarking. MSLs need to explain their role to KOL partners — many physicians don’t understand what a MSL does — and be up front about goals. Bundled payments and shared savings can be complementary; standardized care reduces variation in costs. In terms of monitoring systems, a balanced scorecard can track strategy and vision goals. Ultimately, solving population health problems means partnering across specialties and working with external groups. MSLs should support connections within the institution and externally by creating venues.

Surabhi Sharma of Novartis tackled “IIT Management from Concept to Contract Negotiation,” including the process and metrics used to evaluate an IIT proposal and its journey to contract negotiations. Issues in the IIT contract process can include principles that aren’t understood clearly by all parties, lack of standardized contract negotiation and poor resource allocation, among others. Actions for process improvement include predetermining signatories and the approval and escalation path, creating a draft contract, ensuring strict document control, including fallback language, having a trained IIT contract negotiator and backup, and setting up process and timelines in the beginning. Key points in the negotiation of an IIT contract are intellectual property, indemnification, adverse event reporting, amendments, data access and usage, confidential information, governing law, termination, financial terms, and signatures. Execute contracts before beginning work and be flexible. Find win-win situations for all. Keep contract language easy and seek clarity; be transparent.