

ASSISTANCE AND ASSESSMENT: HELPING PHARMA MEASURE AND MAXIMIZE MEDICAL AFFAIRS PERFORMANCE

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Effective Medical Affairs
More Critical Than Ever

“The days of knocking on the doctor’s door with a box of doughnuts are fading fast — if they’re not over completely. Our research indicates that more than 60 percent of physician practices are limiting visits by traditional pharmaceutical sales reps and replacing them with medical science liaisons. That makes an effective Medical Affairs more critical than ever.”

THE STATE OF MEDICAL AFFAIRS

Over the last several decades, a number of regulations have forced pharmaceutical companies to separate their traditional commercial activities from those that address medical science. Medical Affairs groups are a response to these changes, and they will play a bigger role going forward. In its report, “Pharma Medical Affairs 2020 and Beyond,” McKinsey & Company note that the move toward patient-centricity and the need to address extended stakeholder value will drive an expansion of the Medical Affairs role. However, in an environment of increasingly tight budgets, Medical Affairs groups are under increasing performance pressure.

HOW CLINICALSCORE CAN HELP

ClinicalSCORE has developed a four-pronged research approach to assist Medical Affairs groups in successfully navigating these expected changes and assess how their MSLs are currently performing. ClinicalSCORE can:

- » Assist Medical Affairs teams by identifying need segments within the population of their key opinion leaders
- » Assist Medical Affairs teams by quantifying the views of key opinion leaders regarding the science behind disease states at various times during the lifecycle of the sponsor’s products and competitors’
- » Assist Medical Affairs teams by providing them with a deep understanding of actual patient experiences based on interviews with patients actively enrolled in clinical trials
- » Assess the value that Medical Science Liaisons (MSLs) bring to key opinion leaders within therapeutic area and identify where MSL teams excel and where their performance is below that of a company’s primary competitors.

LET'S LOOK AT EACH OF THESE POINTS IN DETAIL:

ASSIST MA TEAMS BY IDENTIFYING NEED SEGMENTS WITHIN THE

THEIR KOL POPULATION: Internal and external consultants identify KOLs, and most Medical Affairs teams perceive that these thought leaders all have similar needs. This is not the case. Research has shown that KOLs in virtually every therapeutic area have varying expectations from their MSLs. In fact, identifying need segments within the population of KOLs can help Medical Affairs teams better service their thought leaders. I outlined this in detail in a presentation at MASS West 2016 and in a previous whitepaper, “Is Using Survey Research Valuable in Assessing Science Liaisons? A Strategic Assessment.” Both are available at <https://clinicalscore.com/knowledgebase/>.

ASSIST MA TEAMS BY QUANTIFYING THE VIEWS OF KOLS RE-

GARDING THE SCIENCE BEHIND DISEASE STATES: Medical Science Liaisons are responsible for providing health care professionals and identified key opinion leaders with unbiased medical information and serve as scientific experts to the medical community. MSLs are consultants and not sales representatives, so traditional approaches aimed at measuring the successes and/or failures of their ability to “sell” a KOL on accepting a specific scientific approach to a disease state will not pass muster with Compliance groups.

Clinical SCORE's approach to assessing KOLs' views of scientific approaches to disease states is independent of the MSL and, therefore, more compliance compatible. The technique uses neither the company's name nor the name of any specific drug, but requires respondents to identify their treatment preferences. It provides pharmaceutical companies with a dashboard to better understand how company-identified KOLs would approach a series of medical problems.

Each respondent receives up to 16 cards created specifically for a disease/ailment in the KOL's or HCP's therapeutic area. Each card displays patient demographics, the severity of the disease or ailment, and specific aspects of either lab results or the patient's current medical history. On each successive card, the patient demographics, the severity of the disease and the lab results are altered. The content will require a fair amount of up-front work to craft, but once the series of scenarios are created, operationalizing the research and creating the dashboard is very straightforward.

A 52 YO WM PRESENTS WITH ASTHMA

Poor symptom control: ACQ consistently GT 1.5

Frequent severe exacerbations: 4 bursts of systemic CSs

Airflow limitation: after appropriate bronchodilator withhold
FEV1 = 65%

From the following list of possible treatment options, which would you select as your initial treatment choice?

1. Corticosteroid
2. Inhaled Corticosteroids
3. Slow and longterm beta-adrenoceptor agonist
4. Leukotriene modifiers
5. Long acting Muscarinic antagonist

Figure 1: A series of cards like the one shown here solicits feedback on each respondent's treatment preferences in the specific therapeutic area.

The questionnaire includes an additional research exercise, a MaxDiff, which identifies the sources of information that most influence and educate the KOL. This approach gives Medical Affairs teams two important pieces of information that they can use to assess their own MSL teams:

- An understanding of how the KOL views the science of their company's products relative to competitive products
- Insight into how the KOL ranks MSLs, regardless of company, among key information sources

ASSIST MA TEAMS BY PROVIDING THEM WITH A DEEP UNDERSTANDING OF ACTUAL PATIENT EXPERIENCES: ClinicalSCORE has developed a product that delivers the inside story from patients actively enrolled in clinical trials and provides real-time actionable information. The Clinical SCORE approach publishes hands-on patient experiences as they occur, providing unique and substantial value to clinical development, patient advocacy, commercial launch preparation and Medical Affairs teams. Information is often obtained at more than one time during a trial; this approach increases the associated benefit by assessing patient progression during the trial and identifying patient support materials required at key points in the patient journey. The data collected is sufficiently robust for to medical and scientific journals, thereby enabling its use by Medical Science Liaisons.

Prior to operationalizing the research, all documents utilized for a research program — including protocol goals, research methodology, survey instrument, all informed consent forms, all patient-facing materials and regulatory documents — are submitted to an IRB for approval. Some of our programs

include patients who are enrolled in long-term extension trials, resulting in a broader range of patient data.

Clinical SCORE never conducts patient recruitment. Patients are guaranteed privacy. To assure this privacy, Clinical SCORE reaches out to the CRO, and the client reaches out to the site. Once both the CRO and the site have granted approval, Clinical SCORE contacts the site. Then, the study coordinators at sites that have agreed to take part in the program reach out to study subjects and provide them with a link to the survey. Clinical SCORE has no contact with the study subject until the patient has contacted us through the survey link.

The results of the research provide input not previously available for scientific articles, which Medical Affairs personnel use extensively.

ASSESS THE VALUE THAT MSLS BRING TO KOLS WITHIN THERAPEUTIC AREA: Clinical SCORE routinely conducts research programs with Key Opinion Leaders in 13 different therapeutic areas to assess the relative strengths and weaknesses of client MSL teams as well as their key competitors. Overall, we have found that KOLs can clearly differentiate between MSLs. They also can address benefits as well as very specific concerns they have with each of the MSLs they have seen in the past year. In addition, they can fully articulate the value they are looking for from an MSL and how each MSL either achieves or fails to accomplish that goal.

We ask respondents to indicate which companies' MSLs they see regularly. We select two company's MSL's at random and ask respondents to rate each of the two MSLs on 11 categories or attributes. Our research has identified these attributes as encompassing MSL responsibilities in their interaction with KOLs. The results enable Medical Affairs teams to see how their MSLs rate in comparison to their primary competitors and monitor often substantial differences by:

- Managerial region
- Type of KOL (i.e., Extremely important, Very important, Important)
- KOL need segments (Determined by grouping KOLs based on their identified relevance of MSL offerings — i.e., scientific consultation, information on clinical trials, presentation materials, etc.)

Similarly, we can assess the value that each company's MSL brings to the KOL. The KOL can fully identify where some companies' MSLs add value and are critically important, where other companies' MSLs waste the thought leader's time. It is not uncommon for the KOL to offer a very specific explanation as to why a given MSL provides value (or not) — for example, “[Company A]’s MSL has great knowledge in the [therapeutic area] and provides excellent support for our patients” or “When I spoke to [Company B]’s MSL regarding getting their medication into the hands of the indigent, what I got was the same old speech and three more representatives coming to my office telling me what a good job [Company B] does.”

Objective third-party research can and should be used within Medical Affairs to assist Medical Affairs teams in strategic decision-making as well as to assess the MSL and the Medical Affairs approach that has been developed and to identify where MSL teams excel and where their performance can be improved. To learn more, visit <https://clinicalscore.com/medical-affairs/>.

REFERENCES:

“Pharma Medical Affairs 2020 and Beyond,” McKinsey & Company — http://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/pharma_medical_affairs_2020.ashx.



Gary Kaplan is director of research and analysis for Clinical SCORE. His main areas of expertise are sample design, study design and data analysis. He has extensive experience, having spearheaded and directed survey research in more than 15 industry sectors, including commercial pharmaceuticals, operational pharmaceuticals, converged technology (IT and telecommunications), expedited shipping and political polling. He has served as director of analysis at Consumer/Industrial Research Services, chief statistician at Chilton Research Services, director of the Advanced Methods Group at TNS US and the US director of Leger Marketing. Mr. Kaplan has presented design approaches and survey results worldwide to audiences in 20 countries and at academic institutions including McGill University, Montreal, Canada; Emory University, Atlanta, Georgia; and the University of Washington in Seattle. His articles have appeared in Advertising Age, the Journal of Marketing Research and Quirks Marketing Research Review, and he has authored white papers for the Advertising Research Foundation. He holds a Bachelor of Science degree in psychology and a Master of Science degree in urban studies, both from Tulane University in New Orleans, Louisiana, and a Master of Science in applied statistics from Temple University, Philadelphia, Pennsylvania.