ICPM 2018 (International Conference in Pharmaceutical Medicine)

Panel Discussion: Medical Affairs and MSLs*

Chaired and written by Honorio Silva[1], Pol Vandenbroucke[2]

Topics: The growing role of medical affairs in the medicines development process
Medical Affairs (MA) and leadership in biopharma organizations
Medical Affairs in Contract Research Organizations
Medical Science Liaisons (MSLs) as field professionals: The Japanese perspective
The future

Presenters: Domenico Criscuolo[3]
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Learning objectives

The medicines development process is undergoing a seismic shift. Vast volumes of real world data and clinical research are being used to communicate evidence and create value. The Medical Affairs (MA) related functions are emerging as a suitable interface with key stakeholders to link the scientific and clinical results to patient outcomes, adding value during the entire product lifecycle. This session will focus on the helping and hindering factors to establish MA as a key business unit in biopharmaceuticals.

Learning outcomes

(1) Contrast the current and projected business circumstances impacting the various medical affairs function in pharmaceutical companies and contract research organizations
(2) Summarize the contributions of the various MA functions to the business success
(3) Consider the need for the MA professional to assume a leadership role within the organization

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Color version: http://cont.o.oo7.jp/47_2/47_2contents_e.html

(4) Discuss the complex role and stakeholder's expectations for the field medical function

(5) Conclude on the need for competency-based education and training to leverage performance

Outcomes

According to learning outcomes set in advance, achievements of this workshop can be described as follows:

The Panel discussion on Medical Affairs and Medical Science Liaison (MSL) was chaired by Drs. Honorio Silva (IFAPP Academy, US) and Pol Vandenbroucke (Pfizer, US). The objective of the session was to focus on the helping and hindering factors to establish Medical Affairs (MA) as a key business unit in biopharmaceuticals as the medicines development process is undergoing a seismic shift and vast volumes of real world data and clinical research are being generated and used to communicate evidence and create value.

Learning outcomes included to contrast the current and projected business circumstances impacting the various medical affairs function in pharmaceutical companies and contract research organizations; summarize the contributions of the various MA functions to the business success; consider the need for the MA professional to assume a leadership role within the organization; discuss the complex role and stakeholder's expectations for the field medical function; and conclude on the need for competency-based education and training to leverage performance.

Pol Vandenbroucke discussed the growing role of MA in the medicines development process, explaining the fundamental changes in the environment for pharma over the last decade and their impact on the MA function. Changes include the shift from acute to chronic disease burden, the emergence of patients and payers as key stakeholders, the technological revolution, the open-innovation pharma R&D model and globalization. This has led to a growing role for MA in the Medicines Development Process which requires a strategic approach that is Patient-centric and Value-oriented, utilizes Technology to reach and understand stakeholders, is involved in the complete life cycle from idea generation on, forms Strategic Alliances and Collaboration in a holistic eco-system and plans in a global context.

Domenico Criscuolo (Italy) emphasized in his presentation on Medical Affairs and Leadership in biopharma organizations that Medical Affairs will be a key strategic function of future biopharma, and will be based on a close interaction with commercial, for business success; a clear vision of the products portfolio, to identify opportunities; a strong personality in the interactions with KOLs; a prompt reaction to implement FV programs; an open mind approach, for the support of patient needs; and a collaborative attitude in interactions with Regulators.

Marco Romano (Chiltern, Italy) in his review of Medical Affairs in the context of Contract Research Organizations offered a glance of the future of CRO Medical Affairs. As technologies advance and data collection continues to grow, the role of the CRO medical team will continue to evolve. With the downsizing of biopharma over the past years, the CRO medical team have recruited ex-industry people, benefitting from their skills and experience. The growing complexity of clinical trials and the huge amount of data to be analyzed is likely to favor the involvement of CRO Medical Teams.

Finally, Hideyuki Shiba (AZ, Japan) presented the Japanese perspective on MSLs as Field Professionals. The MSL function has been growing and rapidly recognized in Japan. MSLs in Japan have diverse backgrounds, and a certification program definitely helps to establish the role both internally and externally. The

next challenge however is to show the tangible impact made by MSLs on patients, medical practice and the business.

Conclusion

The session concluded with participants agreeing that competency-based education and training are needed to ensure MA performance in a rapidly changing environment, including for MSLs and CRO Medical Teams.

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