The Evolving Role of Medical Affairs: Opportunities for Discovery, Preclinical and Clinical Research

Historically, many, if not all, of the medical affairs functions were the responsibility of other teams, groups and departments.

Historically, the emphasis of medical affairs with regard to data generation was simply to support the acquisition of the additional local datasets required for regulatory approval per country and region throughout the world. Though medical affairs would support additional trials, the key role at this time was the efficient communication of data from the initial regulatory approval. Throughout the evolution of medical affairs, the original intended function was supposed only to support marketing and sales activities from a medical perspective, for instance, development of observational studies as a marketing tool.

Within this context, medical affairs and marketing worked hand in hand but at the same time this relationship was sometimes also conflictual. Indeed, it was common for the marketing department to see medical affairs as the "sales prevention department". This vision is changing now towards a solutions-focused partnership with marketing. Importantly, the function of medical affairs in many companies is under ongoing change. This change, however, is not harmonised yet, and there is still space for improvement in the partnership between medical affairs, marketing, market access, and other departments.

Based on the experiences of the past, the current ongoing changes within medical affairs have given impetus to a function seen as being completely independent from commercial activities. These changes offer the opportunity for a new type of partnership between medical affairs and commercial activities. This collaboration can create scientifically-minded and medically-driven marketing.

How Different Terminology can Foster Relationships Between Medical Affairs and External Experts

The terminology used in the past in medical affairs has been heavily influenced by expressions that underline the marketing perspective. The use of expressions like "key opinion leaders" (KOLs) or "key decision-makers and influencers", emphasises the economic value for the company of medical experts within the medical field (or indication) of interest for the company. This use is based on the idea that external medical experts are organised according to a hierarchical structure, and that the opinion of a medical expert working within a higher international context might be perceived as being of higher value than the opinion of a local colleague.

This perception of different values for different functions and levels at global, regional or local levels, is however often an assumption which does not reflect the reality. It is therefore recommended to replace marketing terminology with other titles which are unlinked to commercial interests. For example, replacing "KOL" with the title of "external medical expert" is preferable because it facilitates the establishment of partnerships between internal and external medical experts. This is particularly pertinent in the development of relationships with healthcare professionals, because those relationships are primarily based on trust and common understanding. In the context of medical collaboration, the exchange of information cannot be biased by commercial considerations.

Indeed, medical affairs has primarily a data-driven scientific nature based on the interpretation of facts, instead of the communication of opinions.

Reshaping the Key Functions of Medical Affairs

There is an increasing number of tasks and complexity of interactions foreseen for medical affairs.

The changes within medical affairs develop at different paces within big pharma compared to a biotech environment. Biotech companies have often a more flexible structure, not only due to the inherent size, but culturally they are generally quicker to adapt to a changing environment than big pharma.

A medical affairs department typically has diverse functions, encompassing the provision of information and education, management of publications, clinical trials input, developing field-based relationships, and providing both clinical and commercial support.

However, while it is generally understood that medical affairs departments deal in facts and provide information on medicines, the key functions of medical affairs vary according to the size and location of the company. The spectrum of activity across the industry differs significantly between companies. All these activities rotate around the key function of the physician assigned to a therapeutic area, a specific indication or to a brand. Most companies include within medical affairs functions like publications, medical communication/medical information, health economics & outcomes research (HEOR). In some companies, these groups are then functionally led by the physician of the medical affairs department.

Medical affairs is increasingly seen to be playing a central role in coordinating internal company stakeholders (including commercial, market access, regulatory, clinical development and drug safety teams) with the needs of external stakeholders. Medical teams need to communicate data in a clear and consistent way, and educate internal and external key stakeholders on the value of those data.

Four components characterise medical affairs and are equally important:

- Data generation and research
- Communication
- Intelligence
- Medical governance

The following section will describe how these four classical functions can further evolve to meet the new requirements medical affairs has to satisfy.

Data Generation and Research:
Feeding the Pipeline through Post-marketing Studies

In comparison to past practice, regulatory approval is only the first hurdle to reach the market and maintain market share over time.

Nowadays, society has to consider the situation of spiraling healthcare costs. There is, therefore, the need for strong, value-based decisions. Consequently, the need for data to clearly demonstrate the value of the drug has been extended from a situation in which only safety and efficacy were shown through pivotal trials to data sets, which includes also data from health economics analysis, comparative efficacy trials and real-world settings. This latter conglomerate of data sets is intended to show that those randomised clinical trials actually reflect efficiency of treatment and safety in the patients who are receiving – in a post-marketing situation – the prescribed drug, once approved.

Thus, the medical affairs role has evolved to become an integral part of the drug development process. On one hand, medical affairs now ensures that the drugs are being developed to address access and reimbursement challenges, and on the other hand, medical affairs pursues opportunities to feed the companies' discovery, pre-clinical and clinical research. Indeed, within an ideal context, medical affairs can be integrated into the entire drug development and commercialisation process from at least proof of concept up to the end of the life-cycle.

Within this concept, a hypothesis developed during preclinical research about the potential mechanism of action of a drug will be developed further and tested also in medical affairs. Indeed, in early clinical development, through the use of proof-of-mechanism and proof-of-concept studies, this preclinical hypothesis will be confirmed in humans only partially. Clinical development is needed to reach the market, but frequently its mechanism of action and clinical value can be fully investigated only once the drug is prescribed when the use of the drug is available to the scientific community.

Indeed, the full development and education process begins only once the drug is on the market. The full understanding of opportunities related to a drug, at present and in the future, can be developed best through a joint effort between pharmaceutical companies and academia together. In this way, there might be opportunities to identify biomarkers of prognostic value for the disease course or predictive in terms of treatment response. In addition, there might be opportunities to identify new treatment targets, new indications or any other benefits. Medical affairs drive the collection of these data, disseminate internally the findings from these post-marketing studies, even to the earliest stage of drug discovery. It is in this way that a life-cycle of a drug can be extended and used for the development of new life-cycles.

If a pharmaceutical company conducts continuous research about the commercialised drug, this research, conducted within medical affairs, will nourish an actively developed pipeline of new drugs. The scientific value of the commercialised drug is then enhanced by other formulations or with the development of new drugs within the same indication.

Though research may occur at various stages of drug development, pre- and post-marketing authorisation, the number of post-marketing clinical trials sponsored by the company is relatively limited. It is more common to financially support investigator initiated trials (IITs).

Pharmaceutical companies have the ethical responsibility to allow scientists to study the commercialised drugs. They might in this way find answers to questions which were not part of the company's original clinical development plan. This type of interaction represents an opportunity for the pharmaceutical companies to enrich their strategic planning by selecting studies which might help to identify new targets, indications, subpopulations and other advances.

It should be, therefore, part of the company's strategy to identify new opportunities through post-marketing research programmes or IITs. The decision to fund these projects requires deep medical insight and knowledge combined with the ability to think out-of-the box: a role which for consistency can be covered only under the guidance of medical affairs.

Though it is not possible to solicit the investigator in doing a study that the company might wish to be done and the company is not allowed to influence the nature of the IIT, it is possible for the company to assume sponsorship of a trial, if the investigator agrees. It might be therefore possible to transform the original idea of an IIT into a larger trial sponsored by the pharmaceutical company.

The medical affairs group will then help design this study, which the company will support and take responsibility to develop and deliver. This type of significant medical affairs activity should be done, ideally, in alignment with the R&D organisation.

These Phase IV medical affairs studies can be designed and sponsored at the global, regional or country level; mixed sponsorship models are possible as well.

They raise new questions which have not been investigated in the global R&D trials, such as aspects of the drug in specific populations, or to consider other scientific issues which might be of interest to a limited part of the scientific community.

Despite the wide-ranging opportunities within Phase IV clinical trials and IITs, the decision for investment in any of these trials should be based on a structured strategic plan, such as an extension of the clinical development plan of the drug. This choice would allow companies to better streamline research and to invest in further development of the drug in an efficient way.

Another area in which medical affairs is increasingly involved is real-world evidence. Within this context, the medical affairs team is aligning with the market access group in trying to generate data that will demonstrate to payers the value of their products. While this type of study is cheaper to perform than the randomised controlled trial, it is still not without costs or complexity. To achieve value from investment in these studies, it is important that they are properly planned from a methodological view and that they are conducted with the same quality expectation as a randomised controlled trial. Otherwise, there is a risk of collecting a huge amount of flawed and useless data (the big data phenomenon).

Communication: Become the Voice and Face of the Company to the Outside World

From a communication standpoint, many of the medical affairs activities, including independent medical education, speaker training, activities at medical congresses and publication planning, were historically managed by the marketing department. In some companies, these activities were first made part of R&D's responsibility. Quite recently, however, these activities have become part of the tasks assigned to medical affairs. The same strategy should be applied to many other functions as well. A key example is health economics and outcomes research.

Nowadays, medical affairs plays a key role in communication, assuring that there is transparency to all of the data that are generated and that the data are disseminated in an ethical fashion to ensure questions from patients, payers and providers are answered in an accurate, fair and balanced way.

For this reason, medical affairs should become the voice and the face of a company to the outside world, including payers, patients, physicians, regulators and government agencies. At the same time, medical affairs is, in essence, the voice of the payer, the patient and the provider within the company because it is involved in all aspects of a drug's life-cycle.

Internally, the medical affairs department plays an important bridging role between R&D and commercial with respect to education and communication within the company.

Among the key aspirations for medical affairs departments is to clearly demonstrate value to practitioners and payers throughout the life-cycle of each product. For this purpose, medical affairs should engage with a wide range of healthcare stakeholders in order to fully understand the different needs of patients and to be able to provide tangible value to patients.

While the interaction depends on which stakeholders you are dealing with, this type of exchange has to be on a meaningful scientific basis that incorporates the medical affairs understanding of what the need is to treat patients better and the facts surrounding the drugs being developed.

Intelligence: Enhance Value by Medical Understanding

Intelligence was historically assigned to the sales representatives who were considered the eyes and ears on the ground, and who brought in "the voice of the customer", i.e. the prescriber of the drug. Nowadays, what is considered the voice of the customer has become much more complex and does not refer to healthcare providers exclusively. For this reason, it is now required that medical affairs steps into this role, too. The medical affairs function in this vision is, however, not in competition with the sales organisation. Indeed, in most pharmaceutical companies, medical affairs has become the voice of the customer: i.e., the patient, the payer and the provider. Medical affairs has to play a crucial role in listening to the outside world, bringing that intelligence into the company and making sure that this information is incorporated into all aspects of the company's activities and strategies.

Only with these insights from medical affairs, can a company address important questions which are relevant for future research and clinical development about the commercialised drug or for the development of new drug entities.

The medical affairs role is, therefore, pivotal – not only in gathering intelligence, but in preparing a structured communication package and communicating it to the various stakeholders within the company and outside.

Medical Governance: Deliver Training that Supports Objective Decision-making

Among the key functions of medical affairs, the only one that has not significantly changed is medical governance.

Medical governance is, indeed, the foundation of what medical affairs does. From a commercial standpoint, medical affairs ensures that promotional materials are accurate; they are fair, balanced and they are not overstating the facts, but are merely communicating what is in the label and what the data support. Medical governance, therefore, underlies how companies participate in ethical dissemination of data, and how they conduct their research. At the same time, the constantly changing regulatory framework makes this aspect of the role the most challenging to keep current.

Part of medical governance are also the tasks related to "training and education", which is a relevant activity due to time investment and strategic relevance. It allows both individuals and the company to develop their expertise within the therapeutic areas of interest. This type of training might also enable sales representatives to be perceived by healthcare providers as knowledgeable partners who understand strengths and weaknesses of a product and the data and scientific support required for an objective decision-making process.

In the past, there was a widespread use of external experts for this purpose. However this should be replaced by high-quality educational training from the internal experts of the company.

Similarly, external experts are asked to talk on the company's behalf about its products or disease areas. They might also be asked to present the results of the data collected and analysed by the company to audiences who can prescribe or influence prescribing. Instead, pharmaceutical companies should increase their awareness of internal resources and the value they can provide. In this way, the internal medical and scientific capabilities can be strengthen to appropriately engage with healthcare providers. Through this engagement, they will be recognised outside of the company as experts in their field and gain the same degree of respect as external experts.

This paradigm change of internal medical experts speaking as in-house representatives of the company also would provide more transparency to the scientific community and might abolish, over time, the view that science and business interests might be incompatible.

The Relationship Between Medical Affairs, Market Access and Commercial

While medical affairs operates in a strictly non-promotional environment, there has to be co-operation between market access, commercial and medical affairs, even though each department has its own defined tasks.

Indeed, while there is a clear distinction between medical affairs and commercial operations, there is a need for the two to work together, particularly at a strategic level. Medical affairs within this context can support marketing messages by identifying and eventually collecting the data to prove commercial statements, such as having the best-in-class drug for a particular disease. Medical affairs can further promote the commercial need by using the facts and science. It is worth remembering that the marketing of drugs has to be guided medically and can only be driven by scientific data.

Within the context of distribution of marketing material, medical affairs acts also as a control mechanism, avoiding both the external spreading of incorrect statements, and the use of publications of disputable quality for commercial claims.

This kind of internal firewall helps to ensure that there will not be any legal complications by stating concepts which are not proven or not true.

Similar changes are observed in the collaborative relationship between medical affairs and market access. In the past, medical affairs and market access were two clearly distinguished groups. Market access today cannot be seen alone without medical affairs' support.

Market access people are specialised in analysing the market, particularly providing meta-analysis and cost models; they are very much health economics-focused. On the other hand, there are medical directors in medical affairs who understand the clinical nature of a problem, and the clinical benefit that a drug may provide. Thus, if it is about dealing with a stakeholder, a third payer or a health authority, it is important to defend the true clinical benefits, as well as justifying the economic model.

The Partnership Between Medical Affairs and CROs

CROs are classically involved in the operational conduct of clinical trials from Phase I to Phase III.

There is also an increasing use of CROs for the conduct of Phase IV trials when they are sponsored by a pharmaceutical or biotech company. The conduct of a clinical trial at academic level such as in the cases of IITs, is a context in which CROs more rarely act, though their presence would increase the confidence about the quality and consistency of the data collected.

The medical & scientific affairs department of a CRO is represented by medical directors and physicians with broad expertise in their field. These additional resources should be more intensively used to support the activities of a medical affairs department in a pharmaceutical or biotech company, because their experience is not limited to the clinical development of one or a few drugs within the same indication. Due to the nature of their business, they see many trials, and are able to understand the reasons for success and failure of a trial. They also frequently have an understanding about when a study design is methodologically flawed and how to put corrective measures in place. Considering the extended life-cycle of clinical development forecasted here in this article, there is an increased need to use this knowledge when clinical trials are planned to rejuvenate the life-cycle of a commercialised drug.

Looking forward, further change can be expected in medical affairs, the concept of clinical development and the life-cycle of a drug, as well as parallel changes in the relationship between medical affairs working with internal departments and external partners, like CROs. Ongoing development and deployment of data integration/visualisation, personalised medicine and mobile technology will continue to change the science and practice of clinical research, as well. Despite all the changes we might be able to anticipate, the value of medical knowledge and expertise will continue to be a fixed reference point for all of them. In the future, there might be an opportunity for a real partnership between pharmaceutical/biotech companies and academia, for the purpose of joint ventures in the clinical development of new drugs. The CROs within this context might take over a bridging function among all of these parties, and ensure the quality of the data collected and the exchange of their extensive experience.

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