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Célia Picard. Medical affairs: its role and added value within pharmaceutical industry. Pharmaceutical sciences. 2021. dumas-03172099

HAL Id: dumas-03172099

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Année : 2021

**LES AFFAIRES MEDICALES : LEUR RÔLE ET LEUR VALEUR AJOUTÉE
AU SEIN DE L'INDUSTRIE PHARMACEUTIQUE**

THÈSE

PRÉSENTÉE POUR L'OBTENTION DU TITRE DE DOCTEUR EN
PHARMACIE

DIPLÔME D'ÉTAT

Célia PICARD

[Données à caractère personnel]

THÈSE SOUTENUE PUBLIQUEMENT À LA FACULTÉ DE PHARMACIE DE
GRENOBLE

Le : 11/03/2021

DEVANT LE JURY COMPOSÉ DE

Président du jury :

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AHU : Assistant Hospitalo-Universitaire

ATER : Attachés Temporaires d'Enseignement et de Recherches

BCI : Biologie du Cancer et de l'Infection

CHU : Centre Hospitalier Universitaire

CIB : Centre d'Innovation en Biologie

CRI : Centre de Recherche INSERM

CNRS : Centre National de Recherche Scientifique

DCE : Doctorants Contractuels Enseignement

DPM : Département de Pharmacochimie Moléculaire

HP2 : Hypoxie Physiopathologie Respiratoire et Cardiovasculaire

IAB : Institute for Advanced Biosciences

IBS : Institut de Biologie Structurale

LAPM : Laboratoire Adaptation et Pathogenèse des Microorganismes

LBFA : Laboratoire Bioénergétique Fondamentale et Appliquée

LCBM : Laboratoire Chimie et Biologie des Métaux

LCIB : Laboratoire de Chimie Inorganique et Biologie

LECA : Laboratoire d'Ecologie Alpine

LPSS : Laboratoire Parcours Santé Systémique

LR : Laboratoire des Radio pharmaceutiques

MAST : Maître de Conférences Associé à Temps Partiel

MCF : Maître de Conférences des Universités

MCU-PH : Maître de Conférences des Universités et Praticiens Hospitaliers

PAST : Professeur Associé à Temps Partiel

PRAG : Professeur Agrégé

PRCE : Professeur certifié affecté dans l'enseignement

PU : Professeur des Universités

PU-PH : Professeur des Universités et Praticiens Hospitaliers

SyMMES : Systèmes Moléculaires et nanoMatériaux pour l'Energie et la Santé

TIMC-IMAG : Laboratoire Technique de l'Imagerie, de la Modélisation

UMR : Unité Mixte de Recherche

UVHCI : Unit of Virus Host Cell Interactions

DÉDICACES

À Matthieu,

De Kuopio à Paris en passant par Lyon et bien sûr Grenoble, tu as toujours été d'un soutien sans faille. Je ne pouvais tout simplement pas rêver mieux. Je te remercie d'être tout simplement toi. Je t'aime.

À mes parents,

A vous qui m'avez toujours soutenue, conseillée et encouragée dans mes choix. Votre écoute, votre bienveillance et votre amour sont inestimables. Sans vous rien de tout cela n'aurait été possible. Merci pour tout, je vous aime.

À mes frères,

Discrets mais présents, je sais que vous êtes fiers. Merci d'avoir toujours été là.

À mes grands-parents,

Vous avoir comme exemples a été le meilleur des cadeaux et des enseignements. Je ne vous remercierais jamais assez de m'avoir montré le chemin.

À Marion,

Malgré la distance, je sais que tu es et que tu seras toujours là et pour cela, merci ! À tous nos voyages, à toutes ces années passées à tes côtés et aux prochaines.

À ma Pharmille : Julie, Salomé et Léa,

À vos côtés, j'ai passé les plus belles années de ma vie. Citer nos bons moments serait en omettre d'autres tellement ils sont nombreux. Merci d'avoir toujours été là.

À Camille,

Le binôme infernal. Un regard aura suffi pour que l'on ne se quitte plus, probablement le destin. Tout nous oppose et tout nous rapproche. Merci pour ton soutien inconditionnel !

À tous mes amis,

Séverin, Victor, Alexandre, Maud, Mathilde, Anissa, Marie et tous les autres, merci pour tous nos moments d'amitié. J'ai beaucoup de chance de vous avoir comme amis !

REMERCIEMENTS

Aux membres du jury,

À la Présidente du Jury,

Mme Anabelle Gèze,

Je vous remercie de me faire l'honneur de présider mon jury de thèse.

Soyez assurée de ma sincère reconnaissance et de mon grand respect.

À mon Directeur de thèse,

M. Redha Bourouina,

Je tiens à te remercier pour ton encadrement tout au long de cette thèse. Je suis ravie d'avoir travaillé à tes côtés. Merci pour ta gentillesse, ta disponibilité et surtout pour tes précieux conseils d'une pertinence sans faille.

À mon Tuteur universitaire,

M. Denis Wouessidjewe,

Je vous adresse tous mes remerciements pour m'avoir accompagnée tout au long de mon cursus universitaire jusqu'à la rédaction de cette thèse. Merci pour vos conseils, votre soutien et votre bienveillance.

Au membre du jury,

M. Maxime Detavernier,

Je te remercie sincèrement d'avoir accepté de faire partie de ce jury de thèse. Travailler avec toi lors de mon externat a été très enrichissant. Je suis heureuse que tu sois présent pour ce dernier travail universitaire.

**Aux Chefs de Produit, Médecins Produit et Référents Médicaux Régionaux
ayant pris de leur temps pour participer aux entretiens,**

Un grand merci pour la richesse de nos échanges et pour toute cette matière
partagée qui m'a permis de rédiger cette thèse.

Aux professionnels de santé ayant répondu à l'enquête en ligne,

Je vous remercie pour l'intérêt que vous avez porté à ce travail.

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LISTE DES ABRÉVIATIONS

AI : Artificial Intelligence

CSP : Code de la Santé Publique (Public Health Code)

DMOS : Diverses Mesures d'Ordre Social (Various Social Measures)

EMA : European Medicines Agency

FDA : Food and Drug Administration

HCP : HealthCare Providers or HealthCare Professional

KOL : Key Opinion Leader

KPI : Key Performance Indicator

MA : Medical Affairs

MKT : Marketing

MSL : Medical Science Liaison

QoL : Quality of Life

RWD : Real-World-Data

RWE : Real-World Evidence

R&D : Research & Development

SmPC : Summary of Product Characteristics

TUA : Temporary Use Authorization

US : United States

INTRODUCTION

Le rôle des Affaires Médicales dans les entreprises pharmaceutiques ne cesse de croître depuis ces dernières décennies. L'environnement en constante évolution est l'un des éléments clés expliquant la nécessité d'une telle fonction. Tout d'abord, l'apparition de produits innovants complexes et de médicaments orphelins ainsi que l'augmentation des coûts de santé conduisent les professionnels de santé à demander des messages scientifiques précis et de qualité avec des résultats cliniques avérés. Ajouté à cela, le besoin de transparence des sociétés pharmaceutiques envers toutes les parties prenantes impliquées dans le circuit du médicament (professionnel de santé, patients et autorités) augmente et participe au développement des Affaires Médicales. Pour finir, l'évolution de la définition de la valeur qui se fonde toujours davantage sur des preuves et demande donc des données de vraie vie qui sont collectées et analysées par les Affaires Médicales explique également l'essor de ce département.

Ce projet vise à décrire le rôle actuel du département des Affaires Médicales ainsi que ses différents liens avec les acteurs externes et internes afin de mettre en évidence sa place au sein de l'industrie pharmaceutique. L'objectif est également de qualifier et de quantifier la valeur des apports du département des Affaires Médicales.

Pour cela, une revue détaillée de la littérature expliquera le rôle de ce département puis décrira son évolution de l'année 2001 à nos jours.

La valeur qualitative des Affaires Médicales sera ensuite analysée au travers d'entretiens avec les départements des Affaires Médicales et du Marketing pour qualifier leur rôle en interne puis grâce à une enquête en ligne réalisée auprès de médecins afin de caractériser leur implication externe.

Un cas pratique sur le cancer de la prostate tentera d'expliquer comment ce département apporte de la valeur quantitativement pour le laboratoire pharmaceutique.

1. Développement en français

Les Affaires Médicales (AM) ont su s'adapter et répondre à un besoin résultant des divers changements environnementaux dans lesquels évolue l'industrie pharmaceutique. Cependant, leur évolution rapide et continue fait que ce département demeure méconnu et sa valeur reste complexe à estimer. Ce projet a donc pour objectifs de décrire précisément l'implication et les différentes fonctions des Affaires Médicales puis d'évaluer sa valeur ajoutée au sein de l'industrie pharmaceutique. Pour cela, une revue de la littérature, des entretiens, une enquête en ligne ainsi qu'un cas pratique viseront à répondre aux questions suivantes :

- Quels sont les rôles des Affaires Médicales pour les laboratoires pharmaceutiques ?
- Comment estimer la valeur des Affaires Médicales au sein de l'industrie pharmaceutique ?

La revue de la littérature a montré que les Affaires Médicales ont pris un rôle central au sein des entreprises pharmaceutiques avec de nombreux interlocuteurs internes et externes. Ce département doit continuer de s'adapter aux nouveaux changements environnementaux et doit notamment évoluer avec la digitalisation, l'adoption de l'orientation patient, le besoin de génération de données de vie réelle tout en démultipliant le nombre d'interlocuteurs. Bien qu'elles aient désormais un rôle stratégique clair, l'évaluation de leur valeur ajoutée reste un défi. Une partie de ce problème pourrait être résolue par

l'intelligence artificielle (IA), la technologie devenant un moyen de quantifier la valeur de données qualitatives.

La méthodologie de recherche de cette étude est séparée en deux parties distinctes correspondant aux deux différentes mesures permettant d'évaluer la valeur des Affaires Médicales : les paramètres qualitatifs et les paramètres quantitatifs.

Tout d'abord, la valeur qualitative des AM sera explorée à la fois en interne et en externe. La collecte de mesures qualitatives est essentielle pour rendre compte des relations que les AM entretiennent avec leurs différents interlocuteurs :

- Dans une première partie, la réalisation d'entretiens semi-structurés avec des collaborateurs des départements des Affaires Médicales et du Marketing de différents laboratoires pharmaceutiques permettront de confirmer le rôle pivot des Affaires Médicales en interne. L'objectif sera de recueillir la perception des deux départements (AM et Marketing) sur le rôle des Affaires Médicales et de repérer d'éventuelles incohérences par rapport à ce qui a été décrit dans la littérature et/ou de décrire la compréhension que ces départements se font l'un de l'autre. Le guide pour l'entretien semi-structuré se décompose en quatre parties principales décrites dans la Figure n°9.
- La deuxième partie de l'analyse qualitative portera sur la caractérisation des liens entre les Affaires Médicales et les professionnels de santé et plus particulièrement avec des leaders d'opinion via le recueil de leur perception de ce département grâce à

une enquête en ligne. Les leaders d'opinion sont identifiés selon leur fréquence d'apparition en tant qu'auteurs de publications scientifiques ou en tant qu'intervenants lors de congrès. Cette étude s'oriente spécifiquement vers des leaders d'opinion dans le domaine de l'oncologie. L'enquête porte sur les interactions qu'entretiennent les médecins avec les Affaires Médicales, leur perception de cette relation mais aussi leur compréhension du rôle de ce département par rapport aux autres départements de l'industrie pharmaceutique qui interagissent avec les professionnels de santé.

Pour compléter cette étude, la valeur quantitative des Affaires Médicales sera abordée par l'évaluation numérique des actions de ce département dans le cadre d'un cas pratique de la prise en charge du cancer de la prostate dans une entreprise pharmaceutique. L'extraction de ces mesures quantitatives concernent à la fois les activités de l'équipe siège et de l'équipe de terrain.

Cette analyse comporte néanmoins quelques limites : la valeur qualitative externe n'a été étudiée qu'auprès des professionnels de santé leaders d'opinion en omettant les autres interlocuteurs externes des Affaires Médicales (professionnels de santé non-leaders d'opinion, associations de patients, autorités sanitaires...). Seul le domaine thérapeutique de l'oncologie a été ciblé. La valeur des sous-départements de l'Information Médicale, des Opération Cliniques ou de la Formation Médicale n'a pas été analysée. Enfin, cette étude se focalise sur la pratique des Affaires Médicales telle qu'elle est exercée en France.

Les principaux résultats des différentes parties décrites dans la méthodologie sont résumés ci-après.

Les entretiens réalisés en interne auprès des départements des Affaires Médicales et Marketing montrent un alignement global entre ces deux entités avec, néanmoins, quelques incohérences majeures. Si l'on considère la perception du département Marketing, les points de vue des personnes interrogées (départements Marketing et Affaires Médicales) sont globalement alignés. Les différences constatées lors de ces entretiens concernent principalement le rôle stratégique du département Marketing où les réponses montrent un manque d'information sur certaines de ses activités (prévisions de ventes ou gestion du KOL) et à l'opposé une surestimation de son activité de communication qui ne semble pas correspondre à son rôle. En ce qui concerne la perception du département médical, les résultats révèlent une réelle incompréhension des caractéristiques fondamentales de ce département et de ses rôles en interne. En effet, le département Marketing semble ne pas citer le rôle de garant scientifique qui est le fondement même de leur fonction, et sous-estime le nombre d'acteurs internes avec lesquels les Affaires Médicales interagissent. Les résultats montrent un bon alignement concernant les opportunités de collaborations entre ces deux départements, comme la co-construction de plans stratégiques de marque ou la collaboration sur des symposiums / opérations marketing. Les personnes interrogées des Affaires Médicales et du Marketing s'accordent à dire que les Affaires Médicales sont un département ayant à la fois des fonctions de soutien et des fonctions stratégiques.

Les principaux résultats de l'enquête en ligne auprès des professionnels de santé leaders d'opinion montrent qu'une majorité des personnes interrogées ont déjà été en contact avec les AM. Cependant, ces collaborations profiteraient en premier lieu aux entreprises pharmaceutiques (cas où le leader d'opinion apporte son expertise lors de conseils consultatifs ou en tant qu'intervenant lors de réunions scientifiques) et bénéficieraient ensuite aux professionnels de santé par le biais de soutien aux programmes de recherche (collaboration sur des études cliniques). Toutefois, le panel interrogé estime que cette collaboration est équilibrée. Le panel différencie bien l'activité des MSL (*Medical Science Liaison*) de celle des délégués hospitaliers ainsi que de l'activité des équipes des AM du siège. Dans l'ensemble, les médecins interrogés estiment le service, l'utilité et le soutien des AM à 3,65 sur 5. L'analyse en sous-groupes selon le degré d'influence des leaders d'opinion montre des résultats généralement semblables entre les sous-groupes. Néanmoins, ces résultats soulignent que les sous-groupes ont des besoins différents de la part des AM en fonction de leur degré d'influence : les leaders d'opinion majeurs demandent de l'information sur les données récentes tandis que les leaders d'opinion mineurs expriment davantage un besoin de soutien.

Les résultats quantitatifs portant sur l'étude du cas pratique de l'implication des Affaires Médicales dans une entreprise pharmaceutique dans l'aire thérapeutique du cancer de la prostate confirment que la quantification de la valeur des Affaires Médicales est complexe. Ces résultats ayant été obtenus au sein d'une seule et même entreprise pharmaceutique, d'autres analyses portant sur davantage d'entreprises et sur d'autres aires thérapeutiques

devraient être réalisées pour conclure définitivement sur la valeur quantitative des AM.

Cette étude a confirmé le rôle pivot des Affaires Médicales en mettant en avant les avantages que ce département apporte au sein de l'industrie pharmaceutique. Les différentes analyses ont en effet montré que la place centrale des AM est tout d'abord liée à la caractéristique même de ce département : son expertise scientifique. Ce haut niveau de connaissances médicales permet à la fois de devenir l'interlocuteur privilégié auprès des professionnels de santé leaders d'opinion qui ont montré une opinion positive envers les Affaires Médicales au travers de l'enquête en ligne, mais aussi de devenir un acteur non substituable en interne auprès des autres départements et notamment du département Marketing. Au sein des entreprises pharmaceutiques, les Affaires Médicales semblent néanmoins manquer d'une définition claire auprès des autres départements qui permettrait à la fois une meilleure délimitation des activités mais aussi une meilleure performance par amélioration de la synergie. Les leaders d'opinion semblent conscients de leur relation interdépendante avec les AM mais ils ont davantage mis en avant la dépendance de l'industrie pharmaceutique à leur égard que le contraire. Les Affaires Médicales doivent veiller à ce que cette relation reste équilibrée. Les entreprises pharmaceutiques doivent trouver la bonne place pour les Affaires Médicales tout en intégrant les changements environnementaux afin d'optimiser leur efficacité et de développer leur rôle stratégique.

Cette analyse a également mis en avant la difficulté à évaluer la valeur quantitative de ce département puisque la plupart de ses activités concerne des

données qualitatives et que le peu de données quantitatives disponibles ne reflètent pas correctement l'activité des Affaires Médicales. La constante amélioration technologique contribuera sans doute à pallier, dans les prochaines années, à cette difficulté grâce, notamment, à l'utilisation de l'Intelligence Artificielle comme outil de quantification d'activités qualitatives.

2. Literature Review

As a background, the following literature brings the key concepts describing the role of Medical Affairs department with a description of its organization and the talent management of people working into this area. This literature review also focuses on a state of the art of the evolution of the Medical Affairs role from the past twenty years until today while sensitizing on the main concerns through the years that Medical Affairs department have been facing.

2.1. Medical Affairs: structure and roles

Medical Affairs' activity differs a lot depending on the life cycle of the product (pre-launch, launch or mature product), on the product itself (therapeutic area involved, innovative product, diagnostic associated product) but also on the pharmaceutical company. Nevertheless, more generally, "Medical Affairs" is described as the department within pharma companies dedicated to interact with healthcare practitioners, included physicians, who are implicated into clinical studies on the companies' products or care providers who just use it (1). Therefore, Medical Affairs department is dedicated to be the guarantor of the scientific and clinical information diffused for both internal collaborators and external stakeholders. Consequently, Medical Affairs interact with several departments internally (Clinical Operations, Commercial, Market Access, Pharmaceutical Affairs...) not forgetting the strong external relationships they built with healthcare professionals and patient organizations. Two main activities drive the Medical Affairs department: collection and management of data, and knowledge diffusion (2).

MA play a pivot role into pharmaceutical companies from integrate, generate, and disseminate data coming from Global Research & Development teams or local clinical operational team to support Health Care Professionals (HCP) needs through the product life cycle. Medical Affairs department create a real link between Global R&D and commercial departments that were completely separated before. The main core functions of Medical Affairs are the following (3) (Figure n°1):

- Medical Advisor
- Medical Science Liaisons (MSLs)
- Medical information
- Clinical operation
- Medical Education

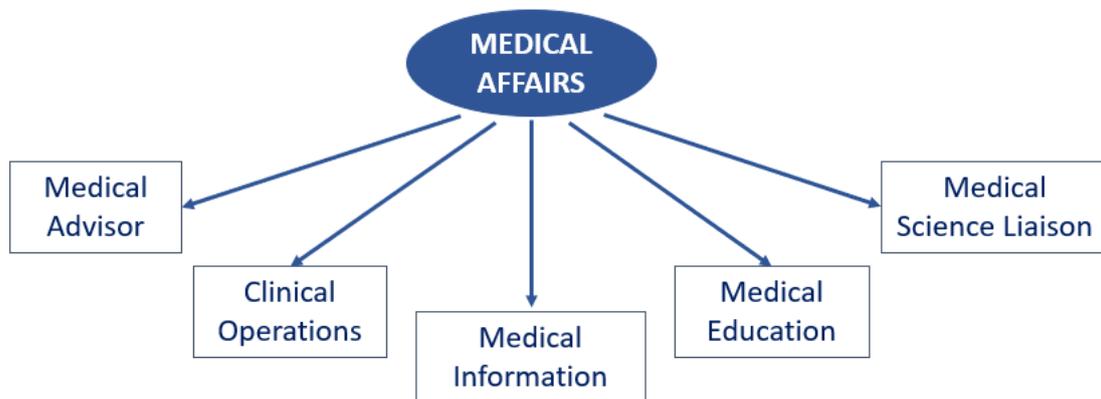


Figure n°1 : Medical Affairs main functions

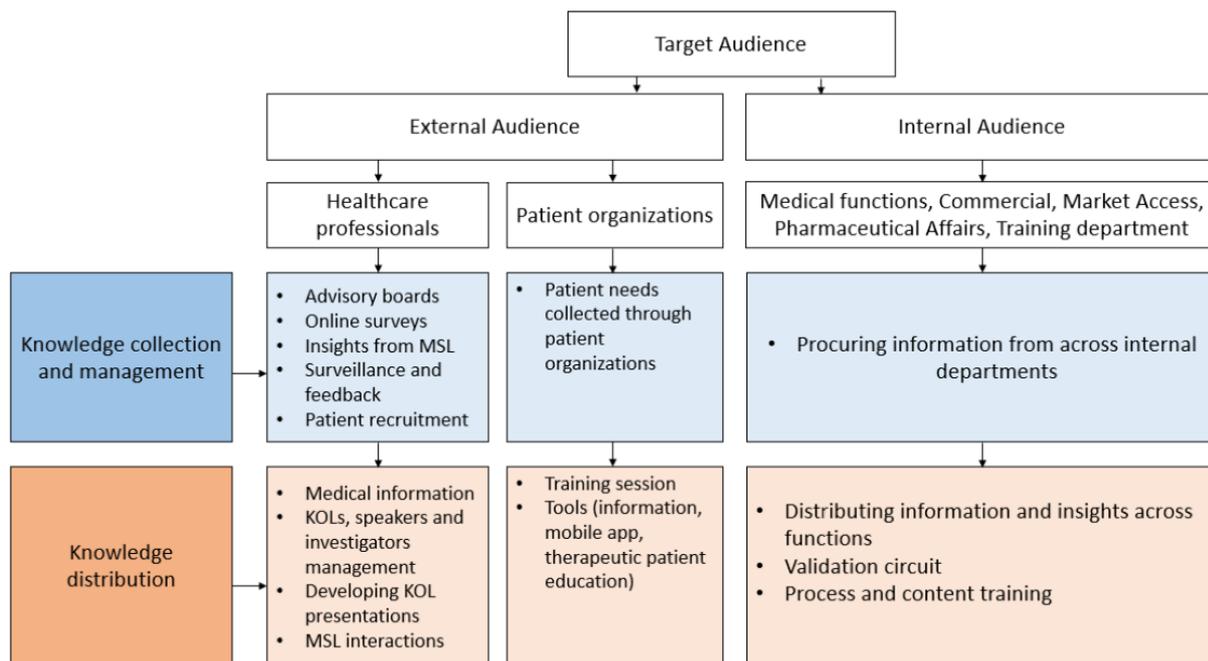


Figure n° 2 : Medical Affairs' activities for both external and internal audiences adapted from Jain, S. (2017) (4)

As shown in Figure n°2, activities depend on the target that could be external or internal. For both audiences, Medical Affairs' activities are driven by two main objectives: collect and manage data followed by the diffusion of these data. This is the key infinite process leading this department.

2.1.1. Medical Advisor

The Medical Advisor of a therapeutic unit has a key role into the pharmaceutical industry and occupies a central place at the heart of the Medical Affairs department. Indeed, by definition, the Medical Advisor is the expert of a pathology, its environment and products related to this disease. By being the scientific expert of the disease inside a pharmaceutical company, he is, hence, the guarantor of the quality and the accuracy of the scientific message. He shall

ensure that every data used is correct and well interpreted. To do so, the cross-functionality is inevitable (Figure n°4):

- With other internal functions:
 - **Marketing/commercial department:** the Medical Advisor is responsible for the validation of every promotional document concerning the scientific content. More generally, every document diffused externally and internally is validated by the Medical Advisor including market research study. For instance, promotional documents provided to sales rep and made by the marketing department or any internal education document need a Medical Advisor scientific validation.
 - **Market Access department:** since the market authorization of new drugs or label extension is highly regulated, the need of clinical data is essential. The Medical Advisor has a role to identify and highlight data that could be useful for market access team into every of their application dossiers. Newly, a new trend of Real-World Data (5) (RWD) appear and again, Medical Advisor plays a critical role for the generation of this kind of data upstream of the register application. RWD are complementary data in addition to classical randomized clinical studies that confirm in a real-world setting what was found in clinical settings. The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) even described the increasing role of this data on their regulatory decision making (6,7). Therefore, the collaboration between

Market Access and the medical department lasts during all the medication life cycle management.

- **Clinical operation:** the Medical Advisor is locally the source of creation of new non interventional studies. By identifying a need with healthcare professional or for the company, he establishes the study concept. Once the concept is defined and endorsed internally, clinical study department will ensure the realization of this study after confirmation of the feasibility and the relevance of this study.
- **Pharmacovigilance department:** for the resolution of pharmacovigilance cases, often, it requires the expertise of Medical Advisors either for pathology or product questions but also for bibliography references. On the opposite, if the Medical Advisor hears about a pharmacovigilance case, for instance during their discussions with healthcare professionals, he must declare it.
- **Medical Information:** sometimes, when the question is too specific, Medical Information does not have the answer and asks for the Medical Advisor expertise. Medical Advisor's service could also be necessary for bibliography demands from HCPs.
- **Education department:** the Medical Advisor is the source of every training documents for the attention of every collaborators concerning the pathology, its environment and treatments associated. Medical Advisors are also in charge of training each new collaborator and of the continuing education.

- **Regulatory Affairs:** validation the update of Summary of Product Characteristics (SmPC) made by the Regulatory Affairs department.
- With other internal MA subdepartments:
 - **Global Medical Affairs** team with bilateral interactions (Figure n°3): downward adaptation of the global strategy at a national scale but also Medical Advisors bringing local insights to the global team. Global and local medical teams collaborate on the follow-up of clinical studies and the dissemination of publications.
 - **MSL team:** Medical Advisor has a supportive role for the MSL team including training, presentations content creation (slide decks for HCP presentations) or national strategy sharing for the regional declination.

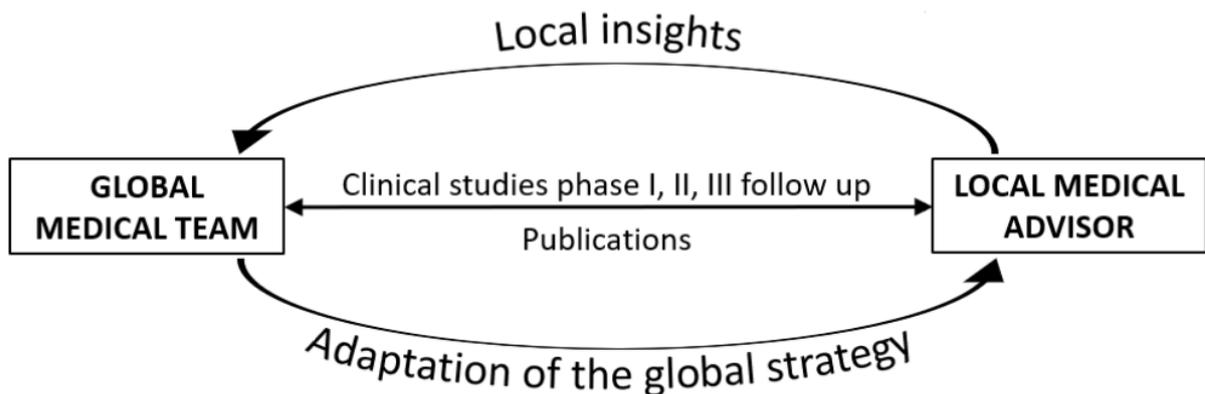


Figure n° 3 : Interactions between Global and Local Medical Teams

- With external stakeholders:
 - **Healthcare professionals:** Medical Advisors have several occasions to interact with HCPs. Firstly, and mainly, Medical

Advisors have a role of service towards HCPs. They collaborate for support research projects through donations, Investigator Sponsored Research (ISR) or collaborative study depending on the type of research the physician is planning to do. Those research projects can then lead to publications for which Medical Advisors is in close link with HCP implicated. HCPs and Medical Advisors also interact for company's symposia in a congress or for events on behalf of the company where the HCPs is chosen as an orator. On the other hand, interactions with HCPs also allow the collection of insights, needs and potential opportunities.

- **Health authorities:** in the context of the market authorization of a new product: scientific positioning with selection of data to demonstrate the place of the product in the therapeutic strategy given the efficacy and tolerance compared to other products.
- **Patient organizations:** those organizations interact increasingly with HCPs, health authorities and patients and hence, have an important place. Medical Advisors have a pivotal role in gathering the patient organization needs to set up projects responding those needs. As pharmaceutical industry, there is no direct interaction with patients. Medical Affairs are often the only department interacting with patient organization.
- **Learned societies**



Figure n° 4 : Medical Advisor role: internal and external interactions

In addition to these external and internal collaborations, the Medical Advisor is also in charge of its own medical lead tactics. It could be a medical symposium, medical events on behalf of the company or advisory board that consists to understand better the environment of the disease management and answering questions by asking them to pundits in this domain.

To ensure his expertise, the Medical Advisor is constantly updating his knowledge by reading literature or going to congress.

2.1.2. Medical Science Liaison (MSL)

As the regulatory framework and compliance requirement are more and more restrictive for the commercial sales force, the MSL function emerged to respond to new requirements, collect local insights and satisfy the growing demand of HCPs asking for complex scientific data. To do so, pharmaceutical companies created a new role allowed to talk of off-label information (clinical data without marketing authorization indication) but with the constraint to respond mostly reactively to demands (Table I summarizing MSL versus Sales rep characteristics). That is how MSL became the first non-promotional field function. Hence, MSLs are scientific experts trained to communicate complex scientific and medical information to HCPs. In addition of this scientific communication role, MSLs main activities are:

- Meetings with healthcare professionals and Key Opinion Leader (KOL) Management: in a reactively and non-promotional way, MSLs can be asked by HCPs to communicate about new clinical results (could be off label information), management of a disease or to talk about support for research projects. MSLs also ensure study follow-up with local investigators.
- KOL Mapping: the first identification and the update of main KOL are essentials during the pre-marketing authorization but also during the entire product lifecycle. KOL mapping will be used by medical colleagues but also by sales department.
- Sales rep education: MSLs oversee the training continuity by communicating most important information coming from the latest

congresses or publications and that could be useful for the sales rep activity.

- Regional medical strategy: MSL oversees the declination of the global medical strategy on a regional scale. Guided by their knowledge of the specific environment and actors of a region, MSLs build their strategic plan summarizing the main medical activities responding the needs of local external stakeholders.
- Regional medical project management: often, headquarters events on behalf of the company can be disseminated regionally. It also concerns events directly on the initiative of the MSL and specifically adapted to a region.
- Scientific literature monitoring: MSLs must be always aware of the evolution of the disease management, disease environment and all the treatments associated so that they stay scientific experts and they can anticipate their positioning concerning competitors.
- Support on headquarters operations (symposia, events on behalf of the company)
- Insight collection and reporting: since MSLs are the link between HCPs and headquarter's teams, the insights reporting is an important activity. It allows the company to adapt its medical strategy regarding information they got.

Table I : MSL versus Sales rep

	MSL	Sales rep
Reporting department	Medical Affairs	Commercial
Category	Non promotional	Promotional & environmental
Knowledge	Scientific expertise	Commercial expertise with scientific basis
Communication	Off label information authorized	On label only
Type of response	Reactive essentially	Reactive and proactive

Rutherford and Smith (2016) described MSL major functions depending on the product lifecycle phases (8):

- During early stages of development, the role of MSL is to develop the interest of external HCPs for the molecule and make the molecule widely known. He also has a major role of follow-up with clinical trial center (recruitment, study progress...)
- On pre-launch phase, the role is the same as it is in early stage but added to this, MSLs will help to build the market access plan and if needed begin to fill the data gaps by initiating new studies through HCPs.

- When the medication is available on the market, MSLs keep the previous roles but now have the responsibility to educate HCPs for its use.
- On the post launch, at this stage, MSLs start their role of responding to KOLs requests on the clinical development or more generally on prescription questions. It also states the emerging need of Real-World Data and therefore the beginning of establishment of observational studies.

Finally, MSLs main functions are to allow the optimal disease management for patient and to optimize the medication use by ensuring the medication to be taken at right stage of the disease by the right patient profile (9).

2.1.3. Medical information

Medical Information was heavily involved into the creation of Medical Affairs department. Indeed, Medical Information was the foundation of this department when at that time a real need of medical expertise about pharmaceutical company's product portfolio emerged. This need was for both internal collaborators but also for external stakeholders asking for greater transparency associated with an increasing need for more detailed knowledge about treatments prescribed, received (patients/patient's organizations) and authorized on the market and reimbursed (for health authorities). Added to this, the increased number and complexity of new drugs, Medical Information has grown out.

According to Tiwari (2006), Medical Information could be defined as *"the provision of unbiased, evidence-based and critically evaluated information*

about medicines". Main Medical Information activities are answering medical queries, providing information proactively, reporting adverse drug reaction they become aware, providing an online medicine information service for public, training and education, keeping databases of published and unpublished information updated (10). In France, Medical Information to HCPs is a regulatory obligation for pharmaceutical industry. It is optional for patients.

2.1.4. Medical Education

The medical education are project managers setting up medical education projects for HCPs and working in close collaboration with the Medical Advisor (who makes the content). It bridges the gap between Medical Advisors, service providers and support functions such as legal (for the contractual part) and purchasing departments. It is a growing department: since marketed products are more innovative and complex, it is a priority to improve HCPs knowledge and skill in order to disseminate the good practices in the use of this new products (11).

2.2. Managing talents

Historically, Medical Affairs department was considering as a support function and it is now clearly moving from this previous support role to a complete strategic role. This fact that Medical Affairs became a real advantage is a real challenge for pharmaceutical industry and more specifically to find the right talent facing these new requirements (12). Indeed, even if ten years ago, the classical Medical Affairs profile was physician with clinical background, it is now insufficient to have only a scientific knowledge. Medical Affairs department

now needs real leaders able to interact with several stakeholders internally and externally. Consequently, business acumen is now inevitable for Medical Affairs profiles.

Requirements for Medical Affairs described by Bedenkov et al. (2020) are particularly high (13):

- Science knowledge and understanding associated with a R&D collaboration
- High understanding in regulations surrounding pharmaceutical activities and compliance/legal departments requirements
- Strategic capabilities of their Marketing colleagues associated with customer interaction skills

To meet all these expectations, Bedenkov et al. (2020) established the six core competencies needed for Medical Affairs talents (Figure n°5)



Figure n° 5 : Core Medical Affairs competencies (extracted from Bedenkov et al. 2020) (13)

This evolution of Medical Affairs position explains the shift of profiles that were entirely physicians ten years ago and that are now opened to other scientific profiles such as PhD or pharmacists always with the aim to find people with both scientific expertise and business acumen. Nevertheless, there is almost no educational program in France allowing working in the Medical Affairs department. Main MA profiles are mostly coming from other departments such as pharmacovigilance or marketing. The reason is probably the too rapid evolution of Medical Affairs and, hence, the implementation of a new training that could not follow.

2.3. Evolution of Medical Affairs since 1999

In 1999, the MA department was at its beginning and numerous big pharma companies didn't have yet a real department as known today. One core task that MA was already doing is the drug information through medical queries. At that time, the MA department was then almost entirely dedicated to this task and the department was besides called "Medical Affairs/drug information department" (14). A benchmarking survey on this department was carried out on twenty-four major pharma and biotech companies at that moment in order to provide information on how measure their performance and it showed that MA at that time employed 7 to 53 people to respond to 27 to 196 queries per healthcare professional per week on average (14). It should be noted that in the 90s pharma companies had not the current technology allowing the staff to be more efficient and all queries were answered without the help of internet but most of the time it was already written responses. In this paper, Hopkins et al. also described the transformation that MA department will soon go through

even if it was not official tasks, responders of the survey affirm that apart from the medical queries activity they also have early stages activities of the current MA department such as: training sales force, adverse event reporting, supporting internal teams on Food and Drug Administration (FDA) submission and FDA approval.

In 2001, the importance of the MA department started to be a fact and Wolin et al. wrote an entire paper on how MA is becoming to be a real need for the future of pharma companies (15). It is one of the first time that a real description of this department was made. Two functions where MA has a role to play are described. First, MA has a role to fill the gap of post approval clinical studies conduct and follow-up. Secondly, the arrival of new indications with small markets require a specific expertise that only MA can satisfy. Those two tasks are primordial and explain how MA place falls between the clinical development team and the Marketing/sales department. The balance between collaborating Marketing and participate to clinical trial completion at the same time is a key success factor of MA department success. Again, activities such as training, adverse event reporting are described as full part MA' task.

Later, in the 2010s, papers concerning MA had multiplied with a broader view that allowed a more accurate description and a view of the possible evolutions MA could encounter. Indeed, in 2012 came the first papers that suggest what MA will become in the next years. One paper first described the main changes that pharmaceutical industry is facing that will cause in the

meantime a radical change into MA department. At that time, three main forces that MA needs to take into consideration for its transformation emerged (2):

- **Value definition** - The need of a broader definition of value due to healthcare costs which constantly increase will deeply transform the healthcare landscape. Since costs are rising, authorities and more globally healthcare systems from all around the world are trying to adapt by increasing control. To do so, to make decisions, payers are more and more asking for Real-World Data with the aim to clearly define the effectiveness of a product and be able to compare it to alternative solution.
- **Cost pressures causing the emergence of new decision-maker stakeholders and need of transparency** - This paper anticipated the future increase consumerism of patients and hence of healthcare expenditures that will cause a rise in costs pressure obligating firstly, physicians to shift their decisions making power to other stakeholders that are closer to control costs and secondly, pharmaceutical companies for transparency towards public for financial disclosures.
- **Data proliferation** - In this era of data production, MA cannot escape from seeing the number and the types of data increasing with notably the apparition of Real-World Data and patient-generated data used not only separately but also in an integrated manner in the whole data sets. With the need of transparency which leads to data over-diffusion, MA will have then a crucial role to control the use of data by avoiding misuse of the data and will have to handle the rising compliance pressure regarding this issue.

Those forces need to be considered and Evers et al., 2012, propose solutions for MA to both deal with these changes while creating value. Firstly, MA should demonstrate value while improving patient access and maintaining the best use of medications. The key point of value demonstration is to understand what value definition is done according to the different stakeholders: “while patients focus on out-of-pocket costs, physicians focus on reimbursement, and payors/governments focus on cost to the health system”. The second point is to expand their relationships with broader stakeholders to follow the patient-centric trend. The third lever is to diffuse from complex and numerous data, a clear, transparent, and unbiased message that allows MA to gain credibility and recognition from the external stakeholders. Finally, MA will need, to face this evolving healthcare landscape, a strong organization with broader personnel profiles allowing to get a multidisciplinary team to respond to the wider role of MA.

In 2017, it was already a fact that MA, that was once defined with a narrow activity with only support responsibilities, is now a department with strategic decisions to take (16). It is recalled that drug development pipeline is shifting from chronic diseases to orphan diseases (Figure n°6) which needs high scientific expertise that MA can bring. Again, technology improvement is described as a key challenge. MA department needs to follow this trend not to lose their customers since both physician and consumers are using new technologies to find information.

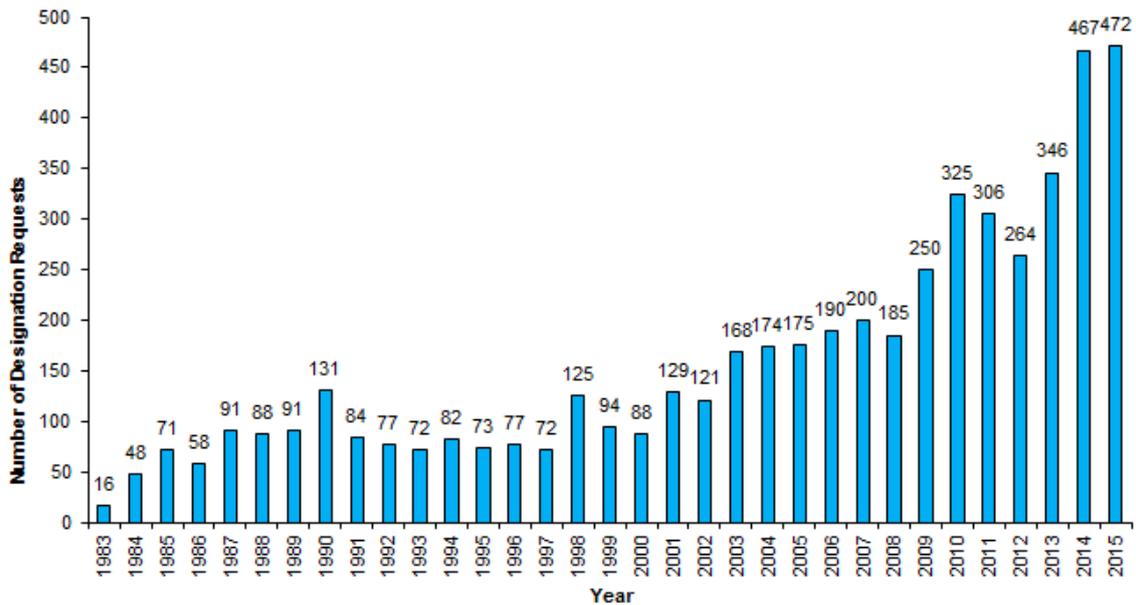


Figure n°6 : Number of Orphan Drug Designation Requests by Year (extracted from Geete and al. 2017) (16)

More recently, in 2020, technology challenge is not anymore a challenge but a reality. MA is now facing a new shift following technologic advances and digitalization catalyzed by the recent COVID-19 pandemic (13). Healthcare systems are currently adapting to new technology and MA is no exception in that regard. Even if pharmaceutical industry was already trying to adapt to digital evolutions, it was lagging behind compared to other industry. COVID-19 crisis urges pharmaceutical companies to digitize quickly and MA was one of the most concerned department regarding this accelerated shift. Indeed, MA that has a lot of external links has a decreased access to HCPs and also institutions but in the same time, HCPs rise their virtual engagements (17). Those two trends lead to a deep change in the way of interacting on a digital way (email, videoconference or phone exchange). In addition to diversify communication channels, the COVID-19 crisis also reinforces the need of RWE

data generation. It will be their responsibilities to fill the gap between data found on Randomized Clinical Trial (RCT) and data fall within real-world settings.

To resume, since 1999, MA went from a department almost entirely dedicated to medical information to one of the most complex department pharmaceutical industry ever knew dealing with R&D and science, regulations and compliance, strategy through interactions with both Marketing and sales and all of that keeping in mind that the heart of this department is the patient care. Medical Affairs should therefore find the right balance between supporting commercial interests while keeping the right external link to gain public trust with the help of new innovative ways of communication (2). The first involvement of Medical Affairs that was at the beginning the Medical Information is besides more and more outsourced, which clearly indicates the deep evolution of this department which was created for a basic supporting activity and became a critical transversal group. MA evolved from a support role to strategic collaborator at several degrees. It is constantly reinventing itself and the recent worldwide COVID-19 pandemic has already accelerated the new shift of digitalization.

2.4. Focus on compliance

In 2011, Werling, Carnell and McCormick, laid foundation of a real description of how Medical Affairs departments should focus on compliance and described the best practices linked with this notion. At that time, MA was not led by clear regulatory requirements. Hence, issues that MA could face about compliance are listed and best practices to confront those challenges have been searched. First of all, the increase of MSLs activity lead to a growth of

compliance issues linked with this practice and pharma companies have to remember the separation between sales rep who not insure an off-label promotion and MSLS function which is devoted to do this off-label information. Moreover, grant funding must be independent and not initiated by the commercial department so that results will not become suspicious. Another important point concerns the diffusion of off-label literature which means the diffusion of scientific papers about unapproved uses of a medication. It must be rigorously managed, and in the US, the FDA proposes a guidance to handle this type of publication that could be diffused and how. Lastly, the globalization of Medical Affairs should not be an impediment to standardized procedures between countries. Many solutions are proposed to answer these issues concerning the respect of compliance (Werling, K., Carnell, H. and McCormick, D. 2011):

- Medical Affairs should be an independent entity within the company from commercial department. This allows medical team, including MSLS, to have a clearer separation and facilitate management. Hence, the reporting must be done to other department than commercial like R&D or Compliance.
- Funding of MA should not be dependent of commercial objectives or in other words sales driven. Grant review board should besides be composed of members from MA or R&D
- Clear framework for off-label literature dissemination through the establishment of process detailing how the literature could be diffuse (proactively without any request or reactively after a written explicit demand) and which kind of material could be sent.

- Clear guidance for MSLs activities.
- Transparency on every payment or transfer value made by a pharmaceutical company towards a healthcare professional.

In France, in 2011, the “Anti-Gift” and transparency law has been reinforced. This law described two main areas (18):

- Transparency of the links between the pharmaceutical industry and health actors (going to healthcare professionals to every stakeholder working with pharma companies such as students, healthcare institutions or software companies). It requires companies commercializing products covered by the Social Security system to publish advantages granted, conventions and amounts.
- “Anti-gift” law which is a part of the “*Diverses Mesures d’Ordre Social*” (DMOS) law (n° 93-121) adopted in 1993 and reviewed in 2016 with the “Santé” law (19). This law ensures a control of advantage granted to healthcare professionals.

More recently, in October 2020, the “Anti-Gift” law has been updated with even stricter conditions guiding interactions between pharmaceutical industry and healthcare professional (20):

- Students, healthcare associations or public officials implicated in public health policies are now also concerned by the scope of application
- “Benefits” thresholds, that could be research studies funding, remuneration of an expertise or hospitality during professional meetings, have been updated downward.

2.5. Medical Affairs impact measure

Demonstrating Medical Affairs value could be difficult since this department cannot directly quantify their impact on revenue because of the very essence of their activity of guarantor of the diffusion of information. Indeed, most of MA activities are intangible and hence difficult to measure (21). Moreover, finding effective Key Performance Indicator (KPI) is not natural for MA since strict regulatory guidelines that are governing them and could lead to a too consistent separation between them and commercial activities (2,16). Nevertheless, Dietlin et al (2013) (21) and Dias (2014) (22), mentioned the demonstration of value as a key lever of optimization of impact of Medical Affairs (among others: clear defined role of Medical Affairs functions, alignment between MA and brand message and optimization of MSLs utilization). The difficulty is then to establish which metrics Medical Affairs value could be both quantified and qualified. To characterize the measurement of Medical Affairs value, two types of metrics can be defined (23):

- **Outcome-based metrics:** metrics that measures the capacity to achieve a strategic objective. It follows broad metrics that not only consider MA department but could also include external actors. A typical example of this type of metrics could be the change of position of a healthcare professional concerning a practice or a product.
- **Goal-based metrics:** those metrics are the one which evaluate all the intermediary goals that allow to reach the outcome. They are much more precise but need to be aligned with the much broader outcome.

Added to this, a distinction between qualitative and quantitative metrics must be done. Most of the time outcome-based metrics are qualitative in opposition of goal-based metrics that are mostly quantitative (Table II).

Table II : Example of different kinds of qualitative and quantitative metrics in MA (Arbet-Engels et al., 2018) (23)

Qualitative metrics	Quantitative metrics
<ul style="list-style-type: none"> • Internal and external customer feedback (eg, market research, surveys) • Insights captured from investigators, advisors, patients, and other external stakeholders that may inform medical strategy, clinical development, or other internal functions • Changes in formulary decisions or medical policy, or guidelines • External recognition: <ul style="list-style-type: none"> - Credibility for scientific information in therapeutic areas - News coverage - Social media coverage and/or reach - What credible KOLs and HCPs in the field are saying at congresses and in publications • Sentiment analysis for altimetric • Benchmarking to other companies 	<ul style="list-style-type: none"> • Number and type of MSL activities and engagements • Number of accepted publications • Number of symposia or educational opportunities supported • Number of conversations/interactions with KOLs • Number of formulary changes • Number of medical information requests • Patient or investigator recruitment • Number of investigator-initiated trials • Altimetric (to measure publication impact)

Both outcome and goal-based metrics are closely interlinked. The establishment of those metrics should be anticipating prior to the execution of technical tactics to set-up a clear logic between metrics and medical plan to find an alignment. (Figure n°7).

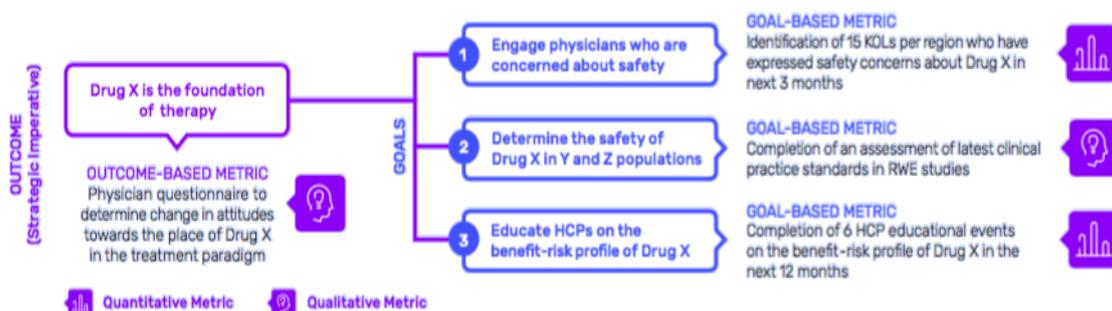


Figure n° 7 : Example of goal- and outcome-oriented metrics aligned with strategic objectives (extracted from Arbet-Engels et al., 2018) (23)

In conclusion, MA has taken a central role into the pharmaceutical companies with many internal and external interlocutors and must manage permanent environmental changes. MA is influenced by those transformations and will have to handle digitalization, embracing patient-centric healthcare, RWE data generation while managing the increase of partnership. Despite having now a clear strategic role, evaluating its added value is still challenging. A part of this issue could be solved by the Artificial Intelligence (AI) with technology becoming a way of quantifying the value of qualitative data (24).

3. Research methodology

The intent of this research part is to demonstrate how and to which extent Medical Affairs can bring benefit within the pharmaceutical industry.

Indeed, even if Medical Affairs Department seems to have a central role, since its activities are about giving a scientific and clinical support, it is complicated to both qualify and quantify the contribution that Medical Affairs bring to the industry. Both quantitative and qualitative value will be explored in the below methodology. The aim is to have a real overview of each lever on which Medical Affairs have an impact. To do so, the methodology is separated in two distinct parts corresponding to the two different metrics allowing evaluating the MA value: qualitative and quantitative metrics. The timeline description of different stages of this study is available in the Appendices part (Appendix 1).

3.1. Qualitative metrics

Firstly, qualitative metrics will allow showing input made by MA that are not numerically measurable. Collecting qualitative measures is essential to show the consideration behind all MA activities and getting more in details of the links MA developed internally. Moreover, the understanding of relationships they support with HealthCare Professionals (HCPs) is as much important as quantitative indicators. For that reason, both internal and external to the pharmaceutical company links will be studied to determine the MA' role and to which extent this role could be considered as a pivot role.

3.1.1. Internal value measurement through links with Marketing department

Demonstrate the internal value is important to highlight if MA got a central role or not. To do so, this project focused on one main department that interacts daily with MA: Marketing department.

Semi-structured interviews are conducted and in order to be as accurate as possible, several French pharmaceutical companies (headquarters or subsidiaries) are interrogated (Astellas Pharma, MSD, Pfizer, Ipsen & one unreported). This type of interview has been chosen for its capacity to lead to a real discussion allowing a more complete content. The aim of the interview is to firstly see the perception Marketing has of the Medical Affairs department; secondly to detail interactions between them and thirdly to understand how Medical Affairs department is collaborating with the Marketing department and in which environment those relationships integrate. Interviews in both Medical Affairs and Marketing departments are planned to spotlight potential inconsistencies on activities, potential strategic role, collaborations opportunities and point of view on the evolution of MA within the pharmaceutical industry between:

- what was described in the literature review and the view both medical and Marketing departments gave of Medical Affairs
- the description Marketing department did about Medical Affairs and the description Medical Affairs did about themselves

In the end, both medical and Marketing departments are interrogated allowing a deep analysis of the comprehension that those departments have from each other's. The duration of each interview varies from 30 minutes to one hour.

The guideline for semi-structured interview consists of four main parts (Figure n°8):

- 1) The interviewee answers questions about his current position (either Marketing or Medical Affairs functions)
- 2) The interviewee is then asked about his point of view of the other part (either Marketing or Medical Affairs functions)
- 3) The interviewee describes their inter-relationships between them and the other part (either Marketing or Medical Affairs functions) listing needs of both departments and what each of the departments brings to each other
- 4) Finally, the fourth part consists on providing perspective describing what are the main challenges, how will this interaction evolve and why?

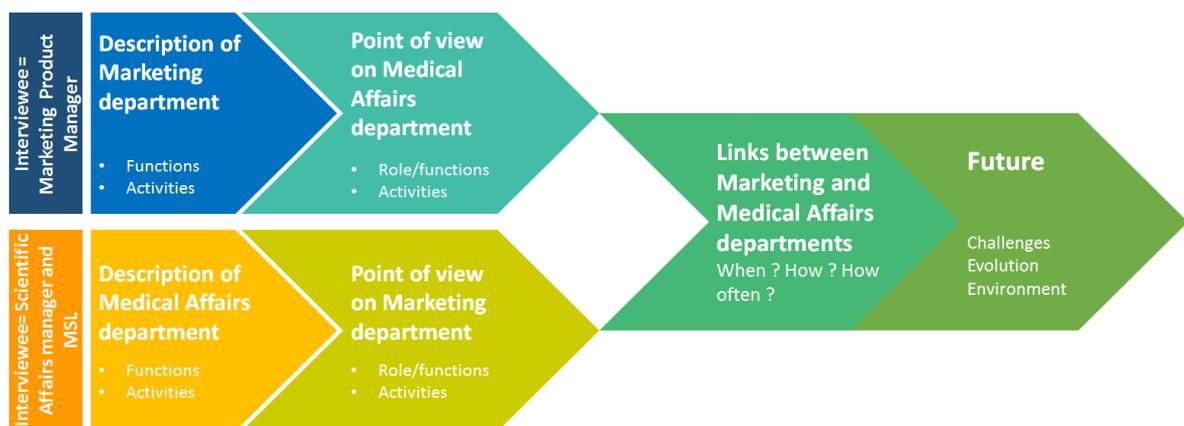


Figure n° 8 : Semi-structured interview guideline for Marketing and Medical Affairs departments

The set of questions asked during the interviews are available in the *Appendix 2*.

3.1.2. External value with healthcare providers

The second step to get an exhaustive overview of Medical Affairs was to have the point of view of external actors. Here, this project focused only on one external stakeholder which was assessed as the most important to study

healthcare providers. Indeed, they have the higher frequency of interactions with MA.

To get the higher rate of response, only key opinion leaders (KOLs) were targeted because of their closest and greater number interactions with Medical Affairs. An online survey format has been chosen since it is one of the less time-consuming method for this type of medical function that does not have much time to spend. For practical reasons, only KOLs from the oncology area have been targeted (oncologist but also each specialty with an oncology specialization). It allowed facilitating the identification of KOLs while keeping a great diversity of therapeutic area since oncology can concern every organ of the human body. In France, the estimated KOLs in the oncology area is around 1200 (oncologists and other specialties with an oncology specialization). With a 10% margin of error and a confidence level of 90%, the expected number of responses was 65. The online survey is sent by email to KOLs selected according to their name's apparition on publications in famous scientific journals and on congress presentations. Indeed, the influence of a HCP is often linked with the frequency of their appearance in scientific publications (and therefore his implication in major clinical trials) and correlated with the number of times this same HCP is involved in international congresses. In this project, frequency of publication and congresses' implication are both required to describe a specific HCP as a KOL.

The survey was oriented specifically on interactions they have with Medical Affairs (MSLs team and headquarter team) and the perception they have about it (the detailed online survey is available in the *Appendix 3*).

Questions were made so that answers also showed if HCPs understand the difference between each department of a pharmaceutical company.

3.2. Quantitative metrics

The quantitative value of MA has been estimated through the analysis of the practical case study of MA implication within a pharmaceutical company in the therapeutic area of prostate cancer. This specific example allows extracting accurate quantitative metrics of the MA impact on this cancer management. Different metrics are analyzed within MA headquarter team and MA field team (Table III). Those metrics are collected retrospectively from 2017 to 2019.

Table III : Different metrics collected during the quantitative analysis

Metrics of the headquarter team collected	Metrics of the field team collected
<ul style="list-style-type: none"> • Number of accepted publications • Number of symposia or educational opportunities supported • Number of donations, Investigator Sponsored Research and collaborative study supported 	<ul style="list-style-type: none"> • Number and type of MSL activities • Number of conversations/interactions with KOLs

To resume, the first part is dedicated to a qualitative analysis with firstly, internal interviews realized with both Medical Affairs and Marketing departments and secondly, external online survey for HCPs. The second part of this study

concerns quantitative data on a concrete case study of the MA involvement into a pharmaceutical company.

3.3. Limitations

Since this project aims to give an overview on how MA brings value to pharmaceutical company, some constraints result from this objective. Indeed, the methodology described below is not entirely exhaustive and some parts could not be analyzed.

For instance, the evaluation of the value through external links has only been studied on one type of stakeholder. HCPs are not the only external actors with which MA interact therefore completing this project by studying other groups, such as patient organizations, health authorities among others, would allow to get a more specific impact's evaluation of MA thanks to their external links. In addition, only KOLs from a specific therapeutic area (oncology) into the HCP's group have been targeted.

Moreover, this methodology focuses on scientific affairs and MSLs teams excluding the medical information sub-department impact. Indeed, even if this sub-department has a lower strategic impact it would have been more accurate to get data from it to complete the entire picture of MA's involvement.

To finish, this study focused only on the Medical Affairs practice in France which may differ in other countries.

3.4. Data analyzing

The integrity of data is presented on a blind way to ensure targeted people to talk freely. This means that data about names or company affiliation of the persons who answer the survey or the interview have not been disclosed.

4. Méthodologie de recherche

Le but de cette partie est de décrire la méthodologie de recherche permettant de démontrer comment et dans quelle mesure les Affaires Médicales peuvent être un avantage au sein de l'industrie pharmaceutique. En effet, même si les Affaires Médicales semblent avoir un rôle central puisque leurs activités consistent à apporter un soutien scientifique et clinique clairement séparé du service commercial, il est compliqué à la fois de qualifier et de quantifier la contribution des Affaires médicales à l'industrie pharmaceutique. L'objectif est d'obtenir une véritable vue d'ensemble des leviers sur lesquels les Affaires Médicales ont un impact. Pour ce faire, la méthodologie est séparée en deux parties distinctes correspondant aux deux différentes mesures permettant d'évaluer la valeur des Affaires Médicales : les paramètres qualitatifs et les paramètres quantitatifs. La description chronologique des différentes étapes de cette étude est disponible dans la partie Annexes (Annexe 1).

4.1. Mesures qualitatives

Premièrement, les mesures qualitatives permettront de montrer la contribution faite par les AM qui ne sont pas mesurables numériquement. La collecte de mesures qualitatives est essentielle pour montrer la prise en compte

de toutes les activités des AM et pour obtenir plus de détails sur les liens que les AM développent en interne. De plus, la compréhension des relations que les AM entretiennent avec les professionnels de la santé (HCP) est tout aussi importante que certains indicateurs quantitatifs. Pour cette raison, les liens tant internes qu'externes à l'entreprise pharmaceutique seront étudiés afin de déterminer le rôle des AM et dans quelle mesure ce rôle peut être considéré comme pivot.

4.1.1. Mesure de la valeur interne au travers des liens avec le département Marketing

Démontrer la valeur interne est important pour mettre en évidence si les AM ont un rôle central ou non. Pour ce faire, ce projet s'est concentré sur un des principaux départements interagissant quotidiennement avec les AM : le département du Marketing Pharmaceutique.

Des entretiens semi-structurés ont été réalisés et afin d'être le plus précis possible, plusieurs laboratoires pharmaceutiques français (siège social ou filiales) ont été interrogés (Astellas Pharma, MSD, Pfizer, Ipsen & un non rapporté). Ce type d'entretien a été choisi pour sa capacité à conduire à une véritable discussion permettant un contenu plus complet. Le but de l'entretien était d'abord de voir la perception Marketing du département des Affaires Médicales ; puis de détailler les interactions existantes entre eux et pour finir de comprendre comment le service des Affaires Médicales soutient le travail du service Marketing et dans quel environnement ces relations s'intègrent.

Des entretiens au sein des départements des Affaires Médicales et du Marketing ont également été planifiés afin de mettre en lumière d'éventuelles

incohérences sur les activités, le rôle stratégique potentiel, les opportunités de collaborations et le point de vue sur l'évolution des AM au sein de l'industrie pharmaceutique entre :

- ce qui a été décrit dans la revue de la littérature et le point de vue des Affaires Médicales et du Marketing
- la description que le service Marketing a faite des Affaires Médicales et la description que les Affaires Médicales ont fait d'elles-mêmes

Finalement, les départements médicaux et marketing ont été interrogés, permettant une analyse approfondie de la compréhension que ces départements se font l'un de l'autre. La durée de chaque entretien variait de 30 minutes à une heure.

Le guide pour l'entretien semi-structuré se décompose en quatre parties principales (Figure n°8):

1) La personne interrogée répond à des questions sur son poste actuel (soit des fonctions Marketing, soit des Affaires Médicales).

2) La personne interrogée est ensuite questionnée sur son point de vue de l'autre département que le sien (soit les fonctions Marketing, soit les Affaires Médicales).

3) La personne interrogée décrit ses relations avec l'autre département que le sien (soit les fonctions Marketing ou les affaires médicales) énumérant les besoins des deux départements et ce que chacun des départements apporte l'un à l'autre.

4) Enfin, la quatrième partie consiste à fournir une perspective décrivant quels sont les principaux défis, comment cette interaction pourrait-elle évoluer et pourquoi.

4.1.2. Valeur externe avec les professionnels de santé

Afin d'obtenir une vue d'ensemble exhaustive des Affaires Médicales, la deuxième étape permet le recueil du point de vue des acteurs externes. Ce projet se concentre uniquement sur une partie prenante externe qui a été évaluée comme la plus importante : les médecins. En effet, ils ont la plus haute fréquence d'interactions avec les AM.

Afin d'obtenir un taux de réponse élevé, seuls les leaders d'opinion (KOL) ont été ciblés en raison de leurs interactions plus étroites et plus nombreuses avec les Affaires Médicales. Le format d'une enquête en ligne a été choisi car il s'agit de l'une des méthodes les moins chronophages permettant ainsi un taux de réponse élevé. Pour des raisons pratiques, seuls les KOL du domaine oncologie ont été ciblés (oncologues médicaux mais aussi toute autre spécialité avec une compétence en oncologie). Cela a permis de faciliter l'identification des KOLs tout en conservant une grande diversité de domaines thérapeutiques puisque l'oncologie peut concerner tous les organes du corps humain. En France, les KOLs estimés dans le domaine de l'oncologie sont d'environ 1200 (oncologues et autres spécialités avec une spécialisation en oncologie). Avec une marge d'erreur de 10% et un niveau de confiance de 90%, le nombre attendu de réponses était de 65. Les KOLs à qui l'enquête en ligne a été envoyée par courriel sont sélectionnés selon l'apparition de leur nom sur des publications dans des revues scientifiques renommées et sur des

présentations de congrès. En effet, l'influence d'un médecin est souvent liée à la fréquence de son apparition dans des publications scientifiques (et donc à son implication dans des essais cliniques) et est corrélée avec le nombre de fois que ce même professionnel de santé est impliqué dans des congrès internationaux. Dans ce projet, les deux critères précédemment cités (fréquence de publication et implication dans les congrès) étaient nécessaires pour définir un médecin comme étant un KOL.

L'enquête était spécifiquement orientée sur les interactions que les professionnels de santé entretiennent avec les Affaires Médicales (équipe MSL et équipe du siège) et la perception qu'ils en ont (Annexe 3). Des questions ont été posées afin que les réponses montrent également si les professionnels de santé comprennent la différence entre chaque département d'une entreprise pharmaceutique.

4.2. Mesures quantitatives

La valeur quantitative des AM a été estimée par l'étude du cas pratique de l'implication des Affaires Médicales dans une entreprise pharmaceutique dans l'aire thérapeutique du cancer de la prostate. Cet exemple spécifique permet d'extraire des mesures quantitatives précises de l'impact des AM dans la prise en charge de ce cancer. Différentes mesures sont analysées au sein de l'équipe des AM du siège et de l'équipe des AM terrain (Tableau IV). Ces métriques sont collectées rétrospectivement sur la période de 2017 à 2019.

Table IV : Différents paramètres collectés lors de l'analyse quantitative

Paramètres de l'équipe du siège collectés	Paramètres de l'équipe de terrain collectés
<ul style="list-style-type: none"> • Nombre de publications acceptées • Nombre de colloques ou opportunités éducatives soutenus • Nombre de dons, recherche parrainée par un chercheur et étude collaborative soutenue 	<ul style="list-style-type: none"> • Nombre et type d'activités MSL • Nombre de conversations / interactions avec les KOL

Pour résumer, la première partie est consacrée à une analyse qualitative avec d'une part, des entretiens internes réalisés avec les départements des Affaires Médicales et du Marketing et d'autre part, une enquête externe pour les professionnels de santé. La deuxième partie de cette étude concerne des données quantitatives grâce à une étude de cas concrète de l'implication des AM dans une entreprise pharmaceutique.

4.3. Limites

Étant donné que ce projet vise à donner un aperçu de la manière dont les AM apportent de la valeur à l'entreprise pharmaceutique dans leur ensemble, certaines limites découlent de cet objectif. En effet, la méthodologie décrite ci-dessous n'est pas entièrement exhaustive et certaines parties n'ont pu être analysées.

Par exemple, l'évaluation de la valeur qualitative externe n'a été étudiée que sur un seul type d'acteur. Les professionnels de santé ne sont pas les

seuls acteurs externes avec lesquels les AM interagissent, donc compléter ce projet en étudiant d'autres groupes, tels que les patients, les associations, les autorités sanitaires entre autres, permettrait d'obtenir une évaluation plus précise de l'impact des AM au travers de leurs liens externes. De plus, seuls les KOL d'un domaine thérapeutique particulier (oncologie) dans le groupe des professionnels de la santé ont été ciblés.

Cette méthodologie se concentre sur les Affaires Médicales et les équipes MSL sans prendre en compte l'impact du sous-département d'Information Médicale. En effet, même si ce sous-département a un impact stratégique moindre, il aurait été plus précis d'obtenir des données afin de compléter le profil complet de l'implication des AM.

Pour finir, cette étude s'est concentrée uniquement sur la pratique des Affaires Médicales en France qui peut différer dans d'autres pays.

4.4. Analyse des données

L'intégralité des données est présentée de manière anonyme pour garantir aux personnes ciblées de pouvoir parler librement. Cela signifie que les données sur les noms ou la société affiliée des personnes qui répondent à l'enquête ou à l'entretien n'ont pas été divulguées.

5. Results

5.1. Qualitative value: Internal and external links and perception of MA

5.1.1. Internal links between MA and Marketing departments

5.1.1.1. Marketing department description by Marketing themselves and by Medical Affairs

This study gathered fourteen semi-structured interviews which lasted between thirty minutes and one hour each following the guideline shown in Figure n°8. Respondents were Product Managers for the Marketing department and Medical Advisors and MSLs for the Medical Affairs department. Overall, seven product managers, three MSLs and four Medical Advisors have been interviewed. Companies and other respondents' characteristics are listed in the Table V. The objectives of this study are to describe the perception of Marketing and Medical Affairs on Medical Affairs department, to detail interactions between them and to contrast all those links into the current environment. Interviews will provide the opportunity to define if there are potential inconsistencies between the opinions of these two departments.

Table V : Interview respondents characteristics

Company		Profile	
Name	Number of respondents	Type	Number of respondents
Astellas Pharma	9	Product Manager	7
Ipsen	2	Medical Advisor	4
Pfizer	1	MSL	3
MSD	1		
Unreported	1		
Total	14	Total	14

The following tables gathered main ideas communicated during interviews (terminology used can be slightly different since the aim of this table is to highlight key ideas cited by respondents). The purpose of those tables is to compare the Marketing and Medical Affairs point of view on what are the main missions of Marketing and Medical Affairs departments to characterize their relationship.

Table VI : Description of Marketing department role according to Marketing and medical respondents*

	Marketing Interviews	Medical Interviews
Main ideas on Marketing department	Number of times cited (n total = 7)	Number of times cited (n total = 7)
OPERATIONAL PART	3	1
-promotional documents, promotional campaign, communication	6	6
-marketing operations (symposia, events with Marketing lead)	4	4
-sales force training	2	0
-congress	2	2
-competitive intelligence	1	1
STRATEGY PART	5	6
KOL Management:	3	1
-event implication	2	0
-partnerships	2	1
Sales forecast	4	0
Communication	1	3
Internal strategy diffusion for alignment	1	0

OTHERS		
-Care pathway optimization	4	2
-Medication valorization as part of indications and for the best patient benefice	0	1

*Color code:

Green: alignment between marketing and medical point of view on marketing activities (≤ 1)

Red: important differences between marketing and medical point of view on marketing activities (≥ 2)

In every interview made, three parts came out when respondents where ask to describe the Marketing department (Table VI):

- **Operational part:**

The operational activities of the Marketing department are the first thing respondents thought about (both Marketing and Medical Affairs). Indeed, results show that the most frequent response when product managers were asked “what are they main mission?” was to provide promotional documents for sales force by quoting it six times for each department. The second important operational activity for respondents was the project management of marketing operations such as symposia during congress or event on the company initiative among others. For the two previous activities, creation of promotional documents and project management, Marketing and Medical Affairs were aligned in terms of number of responses. However, the following point reveal differences between Marketing and Medical Affairs perception: Marketing quoted twice the sales force training whereas none of the Medical Affairs respondent thought about this point. Finally, two other ideas stood out with a lower proportion but aligned between both departments: congress participation

and competitive intelligence by identifying key competitors and following their strategy.

- **Strategic part:**

The marketing strategic implication into the pharmaceutical industry gets a high proportion of response since 5 Marketing respondents upon 7 mentioned it and 6 Medical Affairs respondents upon 7 talked about this activity. Globally, this idea came out into the discussion as the second highest frequent response and was among the first answers given. Into this strategic part, the first main idea for Marketing respondents was the KOL Management quoted 3 times. This point includes the event implication of KOLs (who, where, when and for which subject) but also partnerships. The second important activity for Marketing respondents was the sales forecasting (quoted four times). On the opposite, Medical Affairs responses are not aligned with the two previous points (KOL Management and sales forecast) since almost none of the Medical Affairs respondents mentioned it. Another divergence is that Medical Affairs respondents consider the communication as an important activity (3 times quoted) whereas Marketing only cited once.

- **Others:**

Four product managers described their function as focused on care pathway and not on product directly in order to help HCPs to support them, standardize the management of disease and allow them to share between them. In that case, their mission is to identify HCPs issues and create project trying to find solution for these issues. Only two Medical Affairs mentioned this idea.

5.1.1.2. Medical Affairs department description by Medical Affairs themselves and by Marketing

Table VII : Description of Medical Affairs department role according to marketing and medical respondents*

	Medical Interviews	Marketing Interviews
Main ideas on medical department	Number of times cited (n total = 7)	Number of times cited (n total = 7)
INTRINSIC CHARACTERISTICS		
-Communication guarantor	7	3
-Environment, pathology and products associated expertise	4	3
-Literature monitoring	3	0
EXTERNAL ROLE		
KOL Management:	4	6
-Network	4	4
-Meetings	3	2
-Clinical study/ research projects	5	5
Health authorities	1	0
Patient associations	1	0
Learned societies	1	0

INTERNAL ROLE		
Medical strategy	1	2
Medical operations:	6	2
-Congress	3	2
-Advisory board	3	4
Pharmacovigilance	3	1
Medical information	2	0
Market Access	3	2
Marketing collaboration	2	6
Internal training (sales force or others)	2	4
Regulatory affairs	1	2
Tool creation for MSL	0	1
OTHERS		
-Management	1	0
-Data generation, Life Cycle	2	2
Management		

*Color code:

Green: alignment between marketing and medical point of view on marketing activities (≤ 1)

Red: important differences between marketing and medical point of view on marketing activities (≥ 2)

In the fourteen interviews realized, when respondents were asked to describe what the Medical Affairs department does daily, their answers could be organized in four main parts (Table VII):

- **Intrinsic characteristics**

In that part, intrinsic characteristics could be defined as what made Medical Affairs who they are. Three characteristics came out. First, the term

“scientific guarantor” stood out for each Medical Affairs respondent interviewed whereas only 3 Marketing respondents mentioned it. Secondly, both departments agreed on the scientific expertise of Medical Affairs department (4 and 3 times quoted for Medical Affairs and Marketing respondents respectively). Finally, literature monitoring was only noticed in Medical Affairs interviews.

- **External role**

The most frequent response concerning the external role of Medical Affairs department was the KOL Management. Nevertheless, the department which quoted the most this idea was Marketing respondents (6 times) and not Medical Affairs (4 times). That observation might show an overexpression of the Medical Affairs role on the KOL Management that is in reality lower or it might reveal an underestimation of Medical Affairs for their implication on KOL Management.

- **Internal role**

Marketing respondents make their relationship with Medical Affairs department a priority, while the opposite does not seem to be the case. This may be due to the questionnaire which is presented as in the context of writing an analysis on the role of MA but still, 6 Marketing respondents upon 7 noticed the collaborative role of Medical Affairs with Marketing whereas only 2 upon 7 Medical Affairs respondents did. The same observation can be done with the training role of Medical Affairs which seems more important for Marketing department (quoted 4 times) than for Medical Affairs (quoted 2 times). On the opposite, Medical Affairs highlighted their role for medical operations 6 times against only 2 times for Marketing respondents. To finish, some internal links seem to be unrecognized by Marketing department. Indeed, Medical Affairs

described internal links with Pharmacovigilance and Medical Information (3 and 2 times respectively) that Marketing didn't point out. The low rate of answer concerning medical strategic role (either by Medical Affairs or Marketing respondents) has to be noticed even if at this stage of the interview it was just general questions on main missions.

- **Others**

Two ideas came out into this part and were roughly aligned in terms of number of responses between both departments: management and data generation.

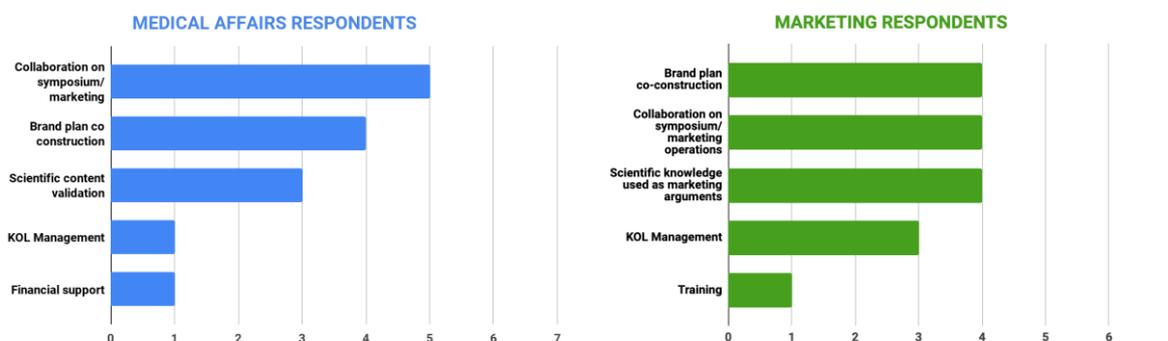
5.1.1.3. Links between those two departments

Comparison between Marketing and Medical Affairs point of view on collaborations opportunities

When comparing, Medical Affairs answers on what opportunities they must collaborate with Marketing department to Marketing answers on the same question, some differences appeared but also alignments emerged (Figure n°9). Indeed, both Medical Affairs and Marketing respondents agree on their collaboration work on brand plan co-construction (5 and 4 times quoted respectively) and collaboration on symposia/Marketing operations (4 times quoted for each groups). On the opposite, these two departments do not seem to have the same point of view on the use of the scientific expertise of Medical Affairs talents: for Medical Affairs, this expertise is a competency allowing the validation of marketing documents whereas for Marketing, this high scientific knowledge is a way to create marketing arguments. Moreover, Marketing

respondents answered with a higher frequency that Medical Affairs and Marketing collaborate on KOL Management (3 times quoted for Marketing against only once for Medical Affairs). Marketing detailed by saying that Medical Affairs have a greater relationship with HCPs allowing choosing the right physician for the right operation, including for their marketing operations.

Figure n° 9 : Comparison of Medical Affairs and Marketing point of view on the collaboration's opportunities



Relationship characterization

In view of these results, it seems important, to differentiate the supporting role from the strategic role for each department in order to characterize this relationship and to bring to light if this relationship is balanced or unidirectional. To achieve this goal, the following direct question was asked during the interview: in your opinion, Medical Affairs would have a support or strategic role into a pharmaceutical company? Answers are presented in the following table:

Table VIII : Medical Affairs role: support versus support and strategic

Medical Affairs role	MEDICAL AFFAIRS RESPONDENTS (n = 7)	MARKETING RESPONDENTS (n= 7)
SUPPORT	0	1
BOTH STRATEGIC AND SUPPORT	7	6

Results are unanimous, for both departments, Medical Affairs clearly have a strategic role in addition to its historical support role: all the Medical Affairs respondents and 6 upon 7 Marketing respondents declared that the Medical Affairs role is both strategic and support (Table VIII).

Concerning the frequency of their collaboration, everybody agrees that it is daily interactions between Marketing and Medical Affairs on head office, and some describe this relation as an “in continuous collaboration” (Appendix 4). Nevertheless, it is not the case for the medical field team, which interacts at a lower frequency with Marketing (monthly or even less frequently).

Respondents were also asked if they perceived challenges into this relationship including a potential competition between them. At first sight, the answer was unanimously that they do not feel any competition between them (every answer was in this sense n = 13) but rather that they work together. Here are some key words respondents said during interviews when answering the previous question: “work team”; “collaboration” (three times quoted);

“intelligently”; “same objective” (two times quoted); “synergy”; “alignment”; “complementary”(two times quoted); “relationships of trust”.

Nevertheless, when arguing their answers, some distortions appeared as shown with the following citations: “sometimes confrontation between commercial interests and medical willing”; “the scientific part outweighs the commercial part and it could be the reason of conflicts”; “the conciliation between promotional marketing message and fair, clear Medical Affairs message can be the source of discords” and “competition appears when someone exceeds its role”. Sometimes Medical Affairs estimate themselves as “more noble”. In some company, some rivalry can exist since Medical Affairs took many projects that were before belonging to Marketing: “everything about patients associations or HCPs relationships became Medical Affairs projects”. Another respondent talks about “positive competition”. All those remarks are qualified by the fact that it could happen, but it is not the majority of case and those issues are highly dependent on company and on people themselves (this was noted by four Marketing respondents and by four medical respondents)

Perspective:

This section aims to set this relationship between MA and Marketing against the current context with three major parts: challenges surrounding those links, past changes that have already been observed and finally the future of this relationship. For the following results, answers from respondents are directly cited. If an idea is mentioned many times, the number of times is put in brackets.

On the **MARKETING** point of view, main **challenges** perceived are listed below:

- Nowadays, there is less and less communication around the product but more and more around the care pathway (n=3). This trend could lead to a more important place of Medical Affairs with a different role of giving not scientific information on a precise point but on the global management of a disease (real world data, quality of life data, taking into consideration global efficiency and not only efficacy).
- Medical Affairs is not anymore only a support role but more an advisory role for Marketing department (n=1).
- No challenge (n=1): it is a complementary relationship where both departments have their own role. The Medical Affairs have a scientific contribution specifically whereas Marketing on the opposite allow to step back and take the overall management of the disease into consideration.
- Challenges are highly dependent on each company (people working in and internal rules (n=4)).
- The limit between commercial and medical lead is sometimes unclear and not well defined (n=3). Here the challenge is to know who does what to avoid duplicates or a worst final quality.
- Lack of human resources, lack of time to talk about real questions together which could impact the quality of projects (n=3).
- Not always the same vision on the interpretation of data (n=1). This issue is highly dependent on medical profiles who are more or less strict regarding scientific results meanings.

- A too drastic separation of Medical Affairs versus Marketing that can reflect a certain hypocrisy and impede an efficient communication (n=1).

In addition, Marketing respondents have already seen some **changes** since the beginning of their career:

- The sales force has decreased (n=1).
- Marketing is evolving from a product centered work into a care pathway optimization (n=1). In this new way of thinking, Medical Affairs have a different role that still concern scientific issue but on a wider aspect.
- Changes depend on internal rules and hence on companies (n=1). For instance, in some company, Medical Affairs are now included into the local strategy. Before, MA were only implicated into the global strategy that could lead to differences in objectives between Medical Affairs that reported globally and Marketing that reported locally.
- Due to several scandal, regulations are increasingly tougher and obliged pharmaceutical companies to increase their compliance rules which led to the development of Medical Affairs department (n=1).

Marketing respondents have several ideas on the possible **future** of those both departments and relationship:

- According respondents, the field teams would be more impacted by changes with a potential progressive replacement of sales rep by MSLS (n=4).
- One respondent raised the possibility of Marketing disappearance with everything done with scientific information and hence with Medical

Affairs. This respondent mentioned, besides, a development of “hybrid” profiles between the research of Marketing need and scientific need. For instance, a new profession emerged: a project manager half on the field to collect locally issues and develop marketing in this regard. On the opposite one respondent thinks “the strategy will always be more leaded by Marketing” and hence, that this department could never be replaced.

- The technology development is also raised as a reason of diminution of sales headcount: ”there will be fewer and fewer marketing resources concerning sales headcount due to the emergence of digitalization”(n=1).
- The current health model changes lead to a real transition (n=1):
 - The transformation from medication prescribed by an office-based practice to the hospital market is another trend that could give a higher importance for Medical Affairs. Indeed, this trend influences the role of Medical Affairs since hospital market concerns diseases with an important scientific actuality and hence a high need of data generation managed by Medical Affairs.
 - The shift from global medication markets to more specialized markets (less patients and higher price) that are asking for a more important scientific expertise.

Considering now the **MEDICAL AFFAIRS** respondents point of view, two main **challenges** came out:

- Frontiers between Medical Affairs and Marketing are unclear (n=2). For instance, is the medical education a Medical Affairs or marketing activity?

Since medical and marketing often work in tandem in the head office, there is a real need to be clear on each other's scopes in order to be synergistic and to be able to define "Who does what?". A respondent raised awareness on this limit and potential drifts with, for instance, Marketing leading meetings with HCPs organizing by a third party which is the same as disguised professional meetings. On the opposite, "Medical Affairs must not transform itself into Marketing or Marketing must not do data generation".

- Despite the additional regulatory and compliance rules (n=2), one challenge would be to know how to work into this framework without seeing it as a constraint but as a guide.

Medical Affairs also felt some **changes** since they have been working in this department:

- Medical Affairs department has, for some years, its own medical projects and is not only dedicated to give a scientific input (n=2). It was before only driven by Marketing with a medical support which is not anymore true since Medical Affairs have their own strategic plan. One respondent said: "the Medical Affairs department has a real weight it didn't have before". Those changes could be explained by "general events such as mentalities evolution, sanitary crisis, new laws (Loi Bertrand), macroeconomics events (financial resources, evolution of healthcare system)".
- More regulations to separate promotional from non-promotional activities lead some companies to give a more important role to Medical Affairs

(n=2). Those regulations forced pharmaceutical companies to develop projects with real scientific and non-promotional objectives. For a respondent, “sales reps have less and less liberty”. One respondent suggests that bigger companies are the first doing this shift and that smaller companies still have a strong presence of Marketing department.

- There is a change of perspective especially from HCPs because diseases treated are more complex (n=2).
- MSL teams are expanding rapidly (n=2). One respondent explained that in three years MSL headcount goes from one team to two now and continue to grow. Another said that five years ago MSL team didn't exist at all.
- Medical Affairs talents have changed from medical doctor only to several scientific profiles (PhD, pharmacist...).

Concerning the potential evolution in the **future**, Medical Affairs respondents evocated the following ideas:

- The profession of medical sales rep is doomed to disappear (n=2). This potential change could also lead to a restructuring of product manager profession since they are “the source of sales rep strategy”.
- Future is driven by physicians (n=1): one respondent said “physicians are those who make the pharmaceutical industry change”.
- The regulatory pathway governing the interactions conditions between HCPs and pharmaceutical industry could evolve and become even more strict until no interactions would be allowed (n=1).
- Potential set up of Medical Affairs specific training (n=1).

To conclude on the internal links between Medical Affairs and Marketing departments, these results show a global alignment but with major inconsistencies concerning the perception of Medical Affairs department. Considering the perception of Marketing department, both Marketing and Medical Affairs respondents are quite aligned. Differences found into those interviews concern mainly the strategic work of Marketing department where medical respondents show a lack of information on some marketing activities (sales forecast or KOL management) and on the opposite, medical respondents guess a communication activity that Marketing respondents do not raised. Concerning the perception of Medical department, results reveal a real underestimation of both medical intrinsic characteristics and internal roles by the Marketing departments. Indeed, Marketing respondents seem not to understand the role of scientific guarantor and underestimate the number of internal stakeholders with whom Medical Affairs interact. Outcomes show a good line-up concerning collaboration opportunities between those two departments such as brand plan co-construction or collaboration on symposia/marketing operations. Medical and Marketing respondents agree that Medical Affairs is a department with both support and strategic functions.

5.1.2. External links with medical Key Opinion Leaders

Medical Affairs department is highly implicated into building strong links with HCPs and hence with medical KOLs. Considering recommendations from previous interviews, not only international KOLs have been interrogated but the

target has been enlarged to every KOLs even with only a local influence. In the end, a total of 474 KOLs has been emailed.

A total of 69 responses has been recorded. The global response rate is 14,55%. Since the targeted population was estimated to 1200 KOLs in oncology, the final sample of 69 KOLs responses lead to an analysis with a 95% level of confidence and a 8,94% margin of error. This number of responses was not expected in the methodology and enhances the power of the study. Of these responses, two were unsustainable since it was empty. Some other responses are not complete but kept into this analysis. The number of respondents for each question is specified in figure/table titles.

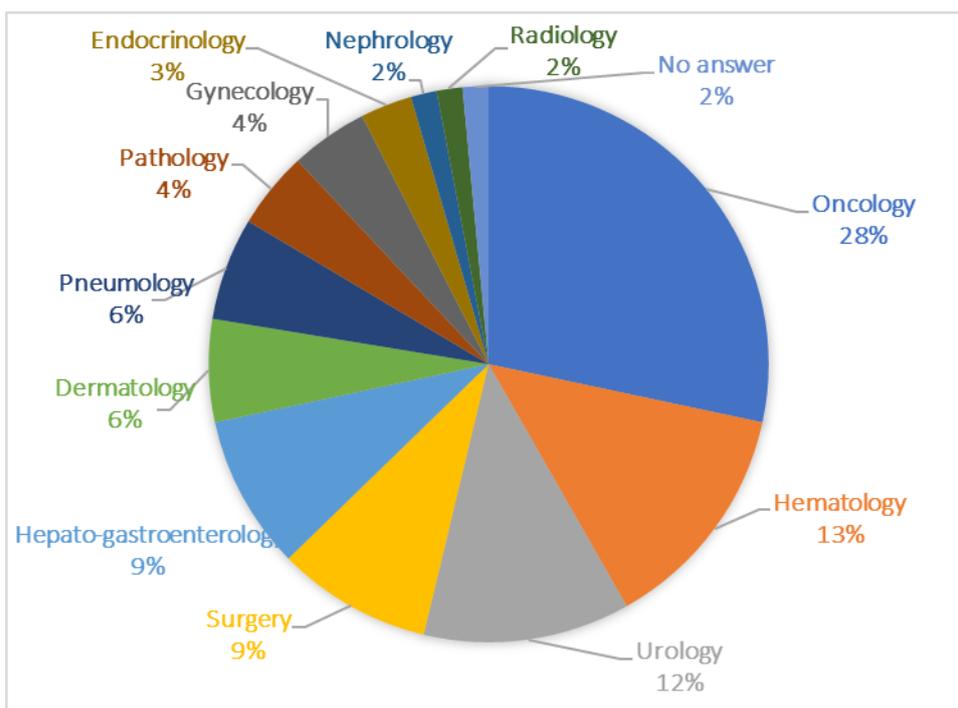


Figure n° 10 : Medical specialty distribution for survey respondents (n=67)

As shown in Figure n°10 and described in the methodology section, oncology was the first target of this survey with classical specialties such as

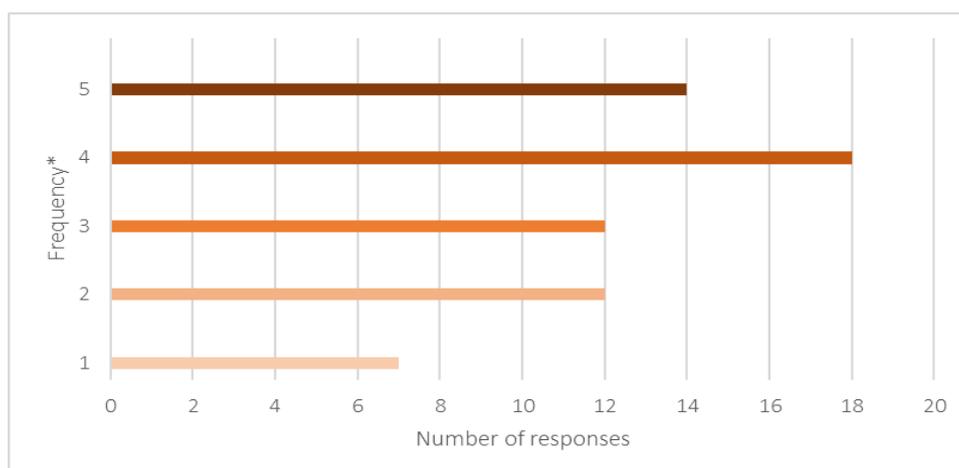
oncologists or pathologists. Several other specialties found in this graph are oncology declensions (respondents of this survey were hematologists, urologists, surgeon, hepato-gastroenterologists, dermatologists, pneumologists, gynecologists specialized in oncology). Endocrinologists, nephrologists and radiologists were non targeted respondents but since this target was set-up only for practical reasons, those responses were kept.

The results of this survey are separated in two parts:

- Global results of all responses by questions.
- Subgroup survey results by respondent degree of influence for specific questions. This subgroup study intends to determine if relationships between HCPs and Medical Affairs department could differ according to the degree of influence.

5.1.2.1. Global survey results

Overall, 90% of the panel know the Medical Affairs department of a pharmaceutical industry (n=60) (Appendix 5).



* The frequency is defined as: 1 = infrequently to 5 = very frequently

Figure n° 11 : At what frequency do you interact with Medical Affairs department? (n=63)

The average frequency at which the panel interacts with Medical Affairs is 3,31 upon 5. The most frequent answer is 4 upon 5 (n=18). Globally, Figure n°11, shows that more than two third of the 63 respondents interacts frequently (3) to very frequently (5) with Medical Affairs department.

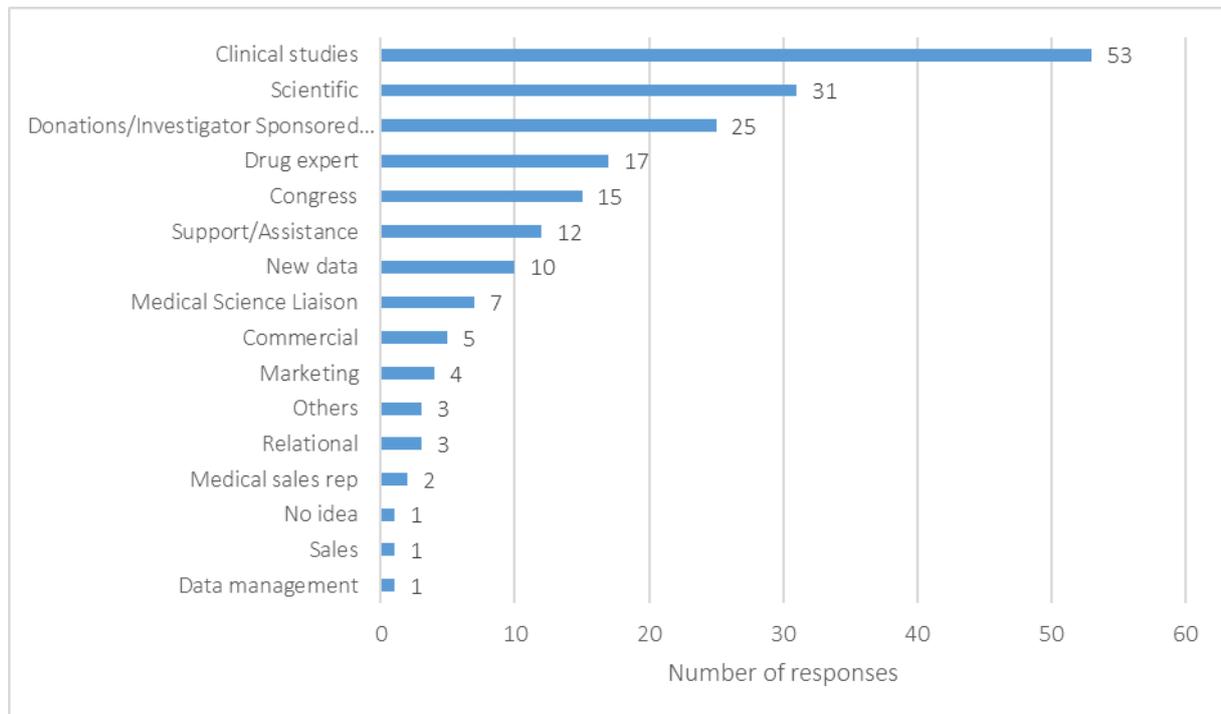


Figure n° 12 : In your perception, what are the three proposals that best represent the Medical Affairs department? (n=65)

In the panel's perception, the three words representing best the Medical Affairs department are: Clinical studies (n=53); Scientific (n=31); Donations/Investigator Sponsored Research/Collaborative study (n=25) (Figure n°12). Three words that don't represent at all Medical Affairs were included in this list in order to highlight the well or wrong understanding of this department by the panel: commercial, marketing and sales. Those three words were chosen 5, 4 and 1 times respectively and show a low misunderstanding. Since 65 respondents answered this question and only 60 declared that they know

Medical Affairs department, this 5 respondents' gap could have been an explanation. But, by seeking by respondents, it shows that KOLs answering one of those three words were KOLs declaring to know the Medical Affairs department.

88% of the panel have already been in contact with headquarters teams of the Medical Affairs department (n=57) (Appendix 6).

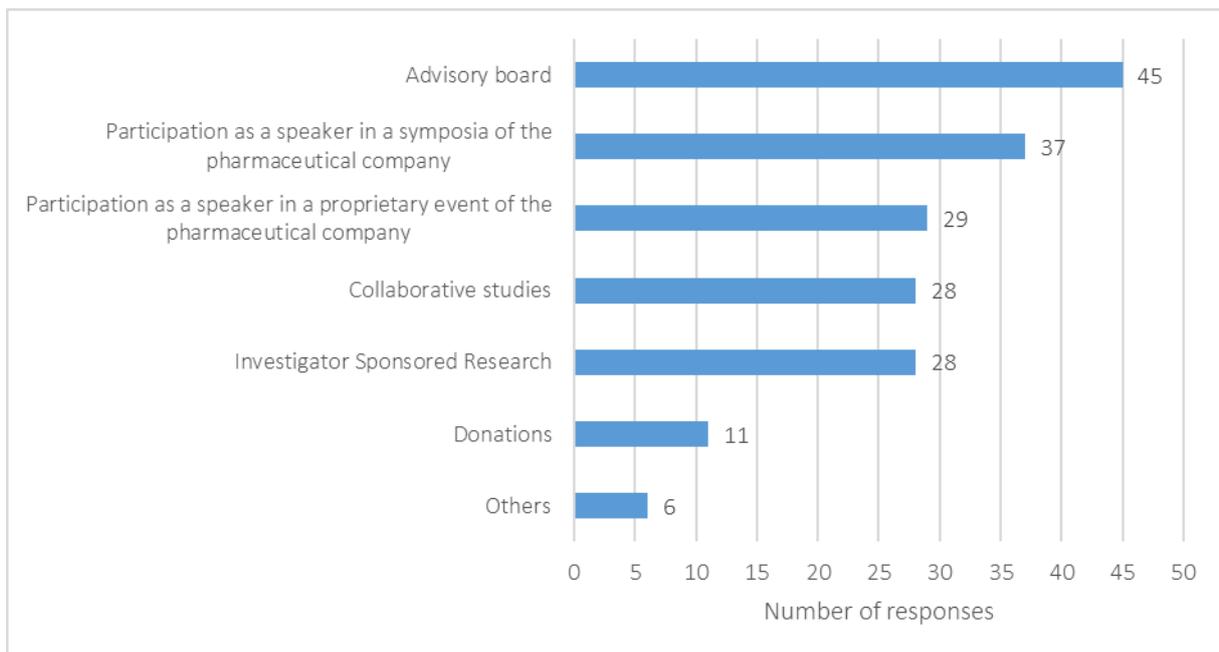


Figure n° 13 : What have been your collaborations with the headquarters teams of the Medical Affairs department of a pharmaceutical company? (n=61)

Concerning the collaboration types between the panel and headquarters teams of MA department, the most frequent responses are advisory board (n=45), participation as a speaker in a symposium of the pharmaceutical company (n=37) and participation as a speaker in an event on behalf of the company (n=29) (Figure n°13). In this collaboration opportunities some profits at the end the pharmaceutical companies (advisory board, speaker in symposia, speaker in an event on the company initiative) and other benefits the KOL

(collaborative studies, Investigator Sponsored Research, Donations). Those results show that the most frequent answers were in the first category with a higher benefit for pharmaceutical companies than for KOLs.

Thereon, a specific question of this survey was intended to characterize the balance in this collaboration and the potential unidirectionality (Figure n°14). The results of this question show that 72% of the panel consider the collaboration as balanced. However, there is still a quarter of the panel who affirms to bring more to the pharmaceutical company than the Medical Affairs bring them. On the opposite, only two respondents (3%) are considering that Medical Affairs bring them more than they bring to pharmaceutical company.

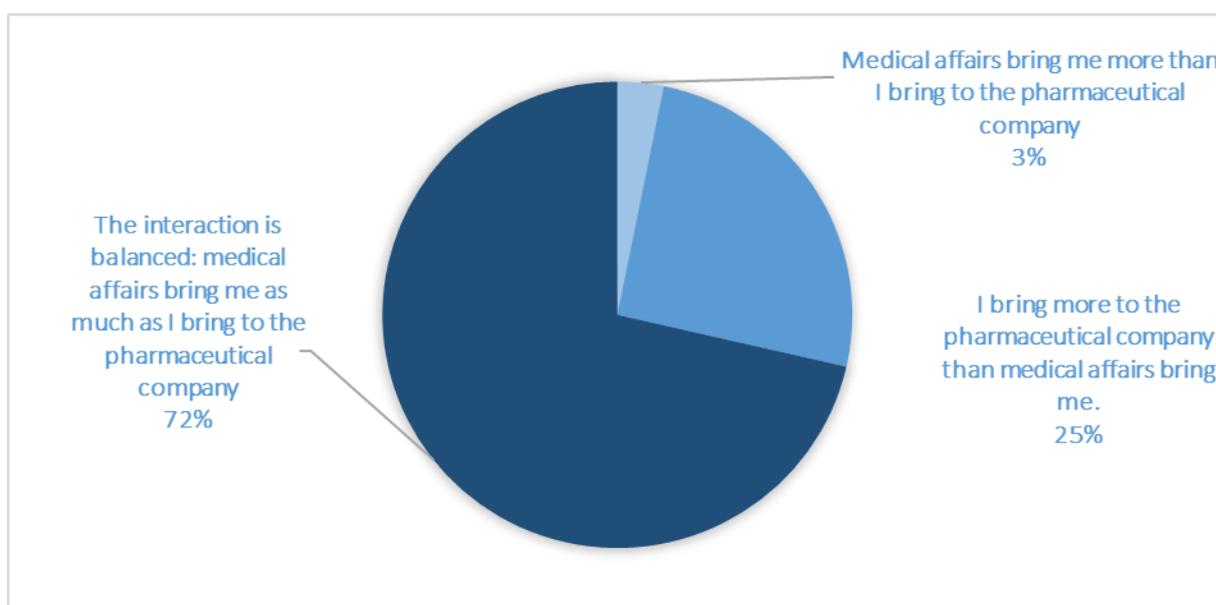


Figure n° 14 : Do you think that the Medical Affairs of a pharmaceutical company bring you more than what you bring to it or vice versa? (n=63)

Considering now the field teams of MA department, around 77% of the panel has already been in contact with MSL (n=49) (Appendix 6). Comparing

with headquarters teams, less KOLs of the panel interacts with MSLs than with headquarters teams (88%).

The perception of the importance of MSLs intervention for the panel's daily practice fluctuates a lot (Appendix 8). Around 45% of the panel, estimate MSLs' role as moderately important or important for their daily practice (n=29). On the opposite, there are around 41% of respondents who either do not see the interest of MSL or estimate their role as not very important for their daily practice (n=26). Finally, a significant part has never had the opportunity to have MSL intervention (n=10; 16%).

An open question was asked about differences they perceive between MSLs and sales reps. Answers have been summarized into the following table:

Table IX : Differences between MSL and sales rep on the KOL perception

		How do you differentiate the role of MSLs in comparison of the sales representatives' role? (n=41)
Differences (n=29)	MSL	<ul style="list-style-type: none"> - More knowledge of the product - Can go deeper into results (pre-approval) - Higher scientific expertise level (n=3) - Scientific value, quality discussion - Off label communication (n=3) - Partnership discussion - Medico-scientific

		<ul style="list-style-type: none"> - Aware of ongoing clinical trials - More collaborative, scientific approach - A bit more expertise and less commercial - More scientifically relevance - Medical expertise on the subject - Scientific aspect and no product aspect - More relevant - Continuity of the MSL action - No marketing - Freer speech, projects - Scientific background, higher discussion level - More purposeful scientific contribution - Scientific support - No promotion, scientific discussion - Privileged interlocutor - Medical discussion and not commercial - Scientific information/pharmacovigilance - Higher quality of data information
	<p>Sales rep</p>	<ul style="list-style-type: none"> - Sales - Basic information
<p>Not clear difference (n=4)</p>		<ul style="list-style-type: none"> - Unclear (n=2) - Very unclear - Difficulty to appreciate MSL role

No difference (n=5)	<ul style="list-style-type: none"> - No difference, both give useful information - Both useless to date - Not much - Useless as it is (for both MSL and sales rep) - Slight difference
Others (n=3)	<ul style="list-style-type: none"> - Depends on companies - Don't know (n=2)

To summarize, Table IX shows that most of the panel can see a difference between MSLs and sales reps (n=29/41). The main differences are that MSLs have a better scientific expertise, can discuss about off-label/pre-approval data and are less commercial whereas sales reps share basic information and have a promotional activity. However, around 10% of the panel (n=4) cannot explain the differences between those two jobs and around 12% of respondents (n=5) don't see any difference.

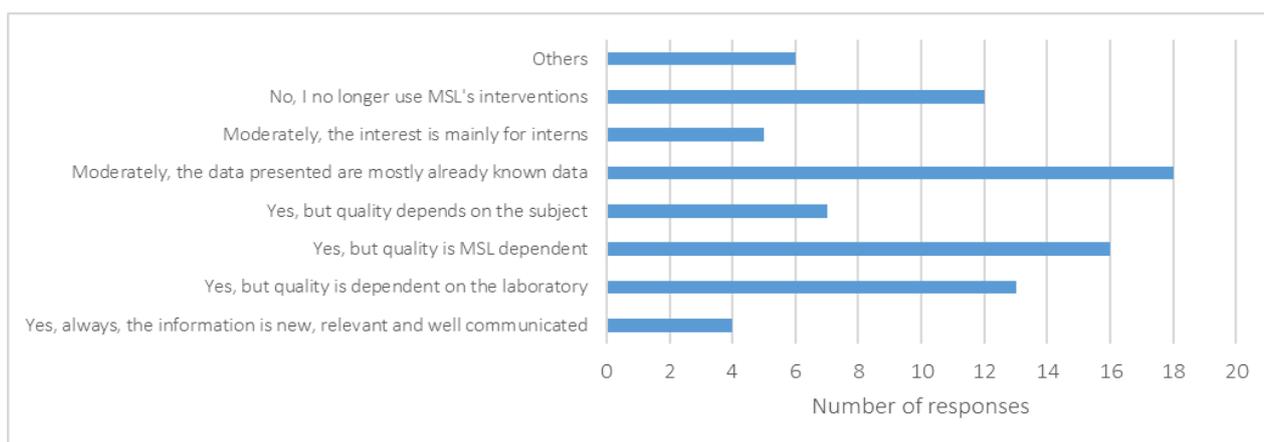
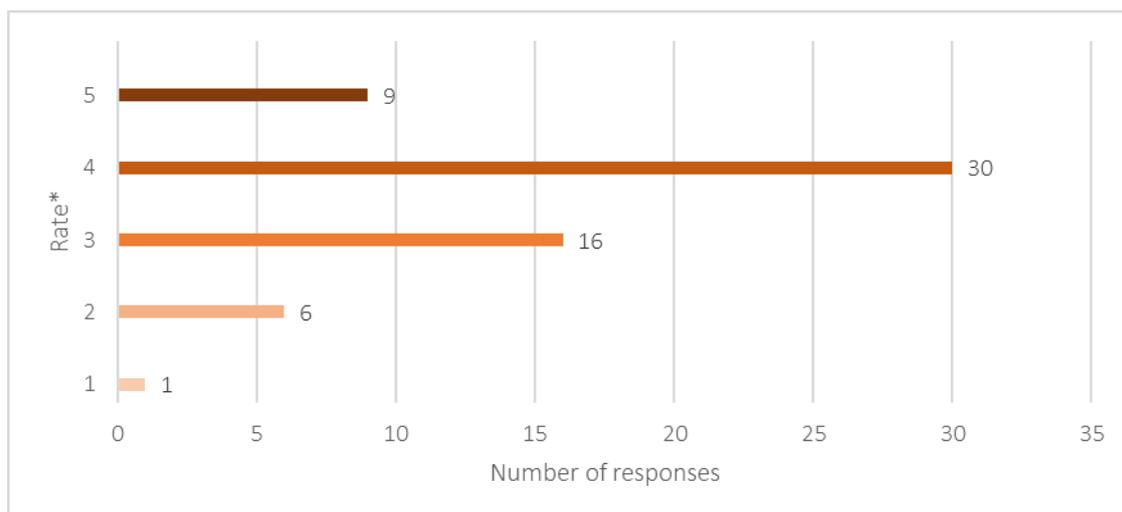


Figure n° 15 : Do you appreciate MSL's intervention in your hospital department? (n=62)

Panel's appreciation of MSL's intervention varies considerably depending on respondents (Figure n°15). The first largest part of the panel (58%) appreciates MSL's intervention but thinks it depends on either the MSL (n=16), the laboratory (n=13) or the subject (n=7). A second major part (37%) moderately appreciate MSL's intervention because of already known content (n=18) or find it useful only for interns (n=5). 19% of respondents do not appreciate MSL's activity and on the opposite, around 6% always appreciate MSL's intervention.

Around 77% of the panel discern Medical Affairs headquarters team from field team of a pharmaceutical company (Appendix 9).



*Rate defined as: 1= no service, utility and support to 5: important service, utility and support

Figure n° 16 : What would be the global rate of the Medical Affairs service, utility, and support? (n=62)

The global average rate of the MA service, utility, and support is 3,65 upon 5 and 89% of the panel rate MA above or equal to 3 upon 5 (Figure n°16).

5.1.2.2. Subgroups survey results

One question of the survey was made to obtain KOLs subgroups by degree of influence: how often do you intervene on international congress? (1 = infrequently to 5 = very frequently). According to the answers KOLs have been assigned to three different subgroups (Appendix 10):

- Major KOL if the respondent's intervention frequency as a speaker on international congress was equal to 5 (n=18).
- Moderate KOL if the respondent's intervention frequency as a speaker on international congress was between 3 and 4 (n=23).
- Minor KOL if the respondent's intervention frequency as a speaker on international congress was below or equal to 2 (n=26).

Table X : Subgroup analysis according to the degree of influence

Questions	Whole responses	Major KOL	Moderate KOL	Minor KOL
1. Do you know the Medical Affairs department of a pharmaceutical industry? (%)				
-Yes	90	89	91	88
-No	10	11	9	12
2. At what frequency do you interact with Medical Affairs department? (Between 1 to 5)				
-Average score	3,32	3,12	3,36	3,33

3.In your perception, what are the three proposals that best represent the Medical Affairs Department? (%)				
-Clinical studies	82	83	86	75
-Scientific	48	56	55	33
-Drug expert	26	28	32	17
-Donations/Investigator Sponsored Studies/Collaborative studies	38	39	32	46
-Congress	23	17	23	21
-Commercial	8	6	5	4
-New data	15	22	14	8
-Support/assistance	18	11	18	17
-Relational	5	6	5	4
-Data Management	2	0	0	4
-Sales	2	0	5	0
-Medical sales rep	3	11	0	0
-Medical Science Liaison	11	11	9	12
-Marketing	6	6	9	0
4.Have you ever been in contact with the headquarters teams of the Medical Affairs department of a pharmaceutical company? (%)				
-Yes	88	89	87	87
-No	8	11	13	0
-No opinion given	4	0	0	13
5.What have been your collaborations				

with the headquarters teams of the Medical Affairs department of a pharmaceutical company? (%)				
-Donations	18	12	23	18
-Investigator Sponsored Studies	46	50	41	50
-Collaborative studies	46	44	55	36
-Participation as a speaker in a proprietary event on the pharmaceutical company initiative	48	62	32	55
-Participation as a speaker in a symposium of the pharmaceutical company	61	62	55	64
-Advisory board	74	75	68	82
6.Do you think that the Medical Affairs of a pharmaceutical company bring you more than what you bring to it or vice versa? (%)				
-Medical Affairs bring me more than I bring to the pharmaceutical company	3	0	5	4
-I bring more to the pharmaceutical company than Medical Affairs bring me	25	41	23	17
-The interaction is balanced: Medical Affairs bring me as much as I bring to the pharmaceutical company	72	59	72	79

<p>7.Can you distinguish between the Marketing department teams and the Medical Affairs department teams?(%)</p> <p>-Yes, the distinction is clear: these two departments do not interact in the same way with me at all</p> <p>-No, for me, they do the same job</p> <p>-I understand that they do not come from the same department but do not see any difference in our collaborations</p>	<p>72</p> <p>6</p> <p>22</p>	<p>71</p> <p>18</p> <p>11</p>	<p>79</p> <p>4</p> <p>17</p>	<p>66</p> <p>4</p> <p>30</p>
<p>8.Have you ever been in contact with the field teams (MSLs) of the Medical Affairs department of a pharmaceutical company? (%)</p> <p>-Yes</p> <p>-No</p> <p>-No opinion given</p>	<p>77</p> <p>12</p> <p>11</p>	<p>82</p> <p>18</p> <p>0</p>	<p>67</p> <p>17</p> <p>17</p>	<p>87</p> <p>0</p> <p>13</p>
<p>9.How do you perceive the role of MSLs in your daily practice? (%)</p> <p>-Very important</p> <p>-Important</p> <p>-Moderately important</p> <p>-Not very important</p> <p>-I don't see what their intervention brings</p> <p>-I've never had the opportunity to have a MSL intervention</p>	<p>2</p> <p>17</p> <p>25</p> <p>28</p> <p>12</p> <p>16</p>	<p>6</p> <p>18</p> <p>24</p> <p>29</p> <p>6</p> <p>12</p>	<p>0</p> <p>13</p> <p>30</p> <p>22</p> <p>13</p> <p>22</p>	<p>0</p> <p>17</p> <p>22</p> <p>35</p> <p>17</p> <p>9</p>

10.Can you differentiate between the Medical Affairs headquarters teams and field teams of a pharmaceutical company? (%)				
-Yes	77	81	83	68
-No	16	19	13	18
-No opinion given	7	0	4	14
11.What would be the global rate of the Medical Affairs service, utility and support? (Between 1 to 5)				
-Average rate	3,65	3,75	3,43	3,72

Overall, subgroups show homogeneous results for different questions. Nevertheless, some specific differences could be noticed (Table X, bold numbers). Questions 3 showed that the need between those three subgroups does not seem to be the same. Indeed, when major KOLs group is asking for new data (22%), moderate and minor KOLs groups are searching for support/assistance by MA (18% and 17% respectively). Another inclination, that shows question 6 of this subgroup's analysis, is that major KOLs seem more likely to think they bring more to the pharmaceutical company than the opposite (41%) compared to moderate and minor KOLs groups (23% and 17% respectively). On the opposite, the collaboration is more balanced for those moderate and minor KOLs groups (72% and 79% respectively) compared to major KOLs group (59%). The few KOLs thinking that MA bring them more than they bring to the pharmaceutical company are in moderate and minor KOLs subgroups. Moreover, in question 7, a higher proportion of major KOLs group

does not distinguish Marketing department teams from Medical Affairs department teams (18% for major KOLs against 4% for moderate and minor KOLs).

About question 8, moderate KOLs group shows a fewer proportion that is in contact with MSLs (67%) as well as this group has the highest proportion of KOLs that never had the opportunity to have a MSL intervention (22% in question 9) in comparison to the other two subgroups. Concerning question 10, minor KOLs subgroup seems to be less likely to differentiate MA headquarters teams from field team (68%). Finally, the average global rate of MA service, utility and support is higher for major and minor KOLs subgroups than for moderate KOLs subgroup.

To resume key findings of the survey characterizing external links of MA with external KOLs, a majority of KOLs interrogated has already been in contact with MA and collaborations are first for the benefit of the pharmaceutical company (KOLs bringing their expertise for Advisory Board or as a speaker in a scientific meeting) and secondly for the benefit of KOL research programs (collaboration on clinical studies). However, KOLs panel estimates that this collaboration is balanced. KOLs well differentiate MSL activity from sales rep and MSL from headquarters MA teams. Overall, KOLs estimate global MA service, utility and support at 3,65 upon 5. KOLs subgroups analysis depending on their degree of influence show aligned overall outcomes. Nevertheless, those results highlight that subgroups have different needs from MA depending on the degree of influence: major KOLs prefer new data sharing whereas minor KOLs express a support need.

5.2. Quantitative value: Value of MA through the practical case study of prostate cancer

After qualitative value through internal interactions with Marketing department and external links with HCPs has been studied, this following part will now concern quantitative results. Metrics listed in methodology from both headquarter team and field team will be described. As a practical case study, the aim of this quantitative value evaluation is to show concretely as part of the management of a disease, the implication of Medical Affairs department. Hence, those results are extracted from Medical Affairs teams from a pharmaceutical company and more specifically from activities around prostate cancer.

5.2.1. Head office teams

As headquarter team, MA' specific activities (excluding activities linked with other department internally) are mostly centered on operations. These operations could concern publications work, support for research alongside the HCPs or pharmaceutical company operations with a MA lead (symposia, advisory board or educational opportunities). The number of those three types of operations have been quantified since 2017 according to Core Medical Plan reports given by the pharmaceutical company. However, those metrics do not take into consideration MA activities around interactions with other internal departments.

5.2.1.1. Publications

Table XI : Number of approved Medical Affairs publications at a global and local level between 2017 and 2019 concerning prostate cancer products

Tactic Type	Number		
	2017	2018	2019
Publications from Global functions	113	79	125
Publications from local team (France)	0	1	

■: Data not available

As Table XI shows, publication activity highly depends on Global functions. Almost 100% of publications come from Global functions each year.

5.2.1.2. Support for research

Table XII : Number of approved Medical Affairs supports for research in France between 2017 and 2019 concerning prostate cancer products

Tactic Type	Number		
	2017	2018	2019
Donations	10	10	3
Investigated Sponsor Study (ISR)	1	0	0

According to Table XII, number of donations and ISR is not constant according to the year.

5.2.1.3. Medical Affairs operations

Table XIII : Number of approved Medical Affairs operations in France between 2017 and 2019 concerning prostate cancer products

Tactic Type	Number		
	2017	2018	2019
Medical tools	3	1	
Advisory Board	2	2	
Symposia	0	0	2

The number of symposia is currently very low (Table XIII) because symposia are almost all with a commercial lead. Nevertheless, it does not mean that MA have no activity on it.

5.2.2. Field teams (MSLs) in France

Metrics to measure the value of the field team are different from the one used for headquarters team. Indeed, at a first sight, MSL activities seem easier to evaluate since one part of their function is to deliver information to HCPs and that number of conversations/interactions is easily quantifiable. However, as for headquarter teams, it does not completely represent their value and, for instance, insights reporting or collaborators training are difficult to evaluate numerically.

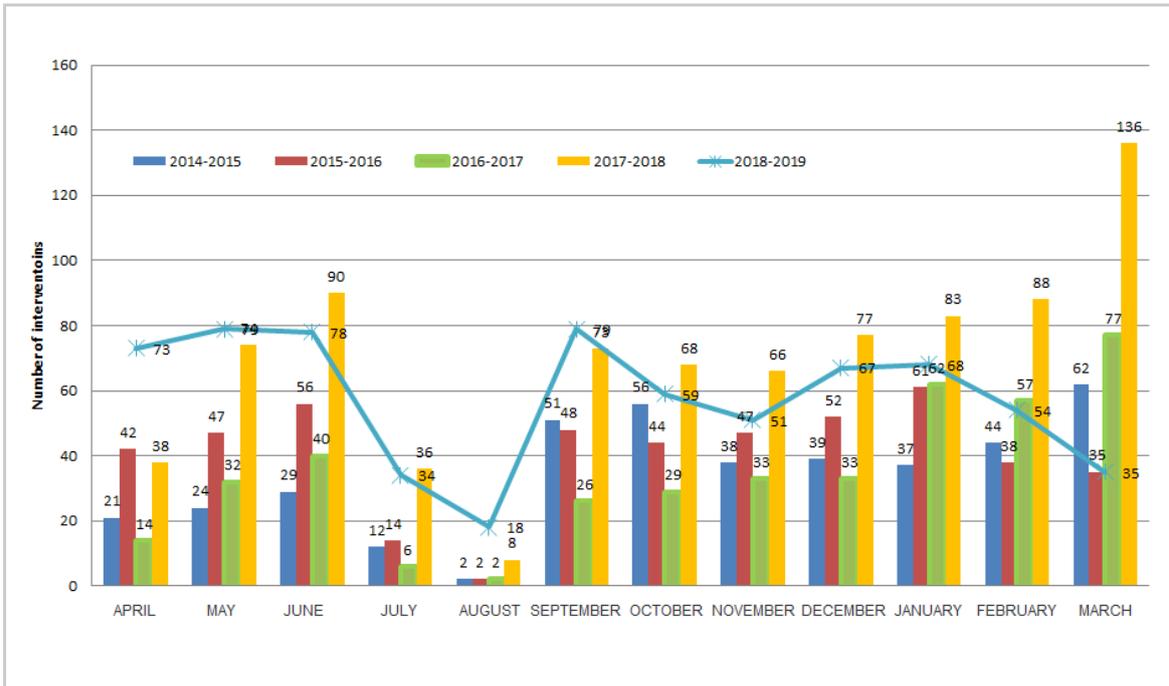


Figure n° 17 : Number of MSL's interventions for a pharmaceutical company by year

MSL's interventions to healthcare professionals are fluctuating both depending on months of the year and depending from year to year.

First, the graph on Figure n°17 shows a similar trend of activity volume according to months of the year. Indeed, the activity increases from April to June and falls during the summer (July and August). From September to December, the activity is roughly constant. The period from January to March is uncertain with marked increase some years and sharp decrease for other years. The graph does not allow to conclude if there are months with higher activity.

Second, the graph shows important difference of activity volume according to fiscal year. Delta of total volume activity can variate from 842 interventions in 2017/2018 to 379 in 2014/2015 (more than double).

Considering now the specific oncology area of this same pharmaceutical company dedicated to prostate cancer, the volume activity follows the same trend as the global France MSL's activity (Appendix 11).

As shown in Appendix 12, MSL's intervention with HCPs are most of the time staffs (n=222) or face/face (n=223). A small proportion concerns congress intervention.

To conclude on quantitative outcomes, findings from head office team and field team are coming from only one pharmaceutical company what makes interpretation difficult. Further studies on several companies should be done to conclude on quantitative value of MA.

6. Discussion

In this qualitative and quantitative value and strategic role analysis of Medical Affairs, the aim was to understand the advantage of this department and to find a way to estimate its value within the pharmaceutical industry.

6.1. Advantages of Medical Affairs

6.1.1. A unique expertise essential into a pharmaceutical company

First, this study outcomes confirmed that the main advantage of Medical Affairs department is its unique scientific expertise within the pharmaceutical industry.

This need of specific medical expertise was already described in the literature (Wolin, Ayers and Chan (2001) and Geete, D. and Kurne, D. (2017))

because of the evolution of markets which become more specialized with diseases needing a higher scientific level of understanding. The interview supports this idea with a respondent explaining that past global medication markets are currently evolving into specialized markets that are asking for a more important scientific expertise.

This essential scientific expertise, constantly updated by Medical Affairs talents, is the cornerstone of this department and explain why MA are essential. Thanks to this expertise capacity, Medical Affairs are described as the scientific communication guarantor of a pharmaceutical company (Table VII). Hence, this high specialized knowledge allows them to be the privileged interlocutor both with commercial department but also with Key Opinion Leaders.

Firstly, interviews with marketing product managers showed that this expertise is non-substitutable and hence, that Marketing Department needs it. Even if marketing profiles have mostly scientific background, the heart of their position is not to be aware of the scientific environment. Consequently, Marketing teams need Medical Affairs on many levels (Table VII). On an operational level, Marketing needs the scientific validation of the content of their promotional documents and of the content of symposia or any operation with a Marketing lead (Figure n°18). Taking into consideration the strategic level, Medical Affairs have a more important role for Marketing teams since MA collaborate with them on (Figure n°18 and Table VII): the KOL Management (selection for event, mapping, interactions between KOLs...); the creation of marketing arguments for their promotional campaign using scientific data (which clinical study results could be used, why and how) and the construction of their brand plan (competitive intelligence on future clinical studies and hence

potential future indications for both competitors and the company itself, KOL opinion on the disease management).

Table XIV : Collaboration opportunities between Medical Affairs and Marketing: strategic role versus supporting role

	Collaborations items	Number of times quoted for both departments (n=14)
Medical Affairs strategic role for the benefit of Marketing	<ul style="list-style-type: none"> - Scientific knowledge used as marketing arguments - KOL Management - Brand plan co-construction 	<p>4</p> <p>4</p> <p>8</p>
Medical Affairs collaboration role for the benefit of Marketing	<ul style="list-style-type: none"> - Scientific content validation - Collaboration on symposia/marketing operations 	<p>3</p> <p>9</p>
Marketing strategic role for the benefit of Medical Affairs	<ul style="list-style-type: none"> - Brand plan co-construction - Collaboration on symposia/marketing operations 	<p>8</p> <p>9</p>
Marketing collaboration role for the benefit of Medical Affairs	<ul style="list-style-type: none"> - Financial support 	<p>1</p>

Even if results clearly showed the strong collaboration between the Marketing and the Medical Affairs, outcomes also reveal that those both departments are not completely aware of what each other does. Indeed, Table VI and Table VII highlighted some differences between the perception of the department and the reality. For instance, there is an important gap between what Medical Affairs described as the internal role of MA and what Marketing did: Marketing mostly noticed their interaction with MA and less raised internal links between MA and other departments such as Pharmacovigilance and Medical Information. On the opposite, MA did not talk about sales forecast and only few about KOL Management whereas for Marketing these notions were often cited as a main activity of their department. This analysis indicated that the role of MA (and more particularly its scientific knowledge on product and environment) is primordial for Marketing but it still exists a lack of information between both departments that could allow an even greater synergy. Marketing and Medical Affairs are two departments with two distinct roles, but a real need of collaboration noticed during interviews (cf. Relationship characterization). Outcomes are not the same between Medical Affairs operations that can handle the data part since they can talk about off-label but without any promotional rights and marketing operations that are not allowed to develop off-label but can cover the promotional part. The key of success is based on the good separation of these two functions with a clear frontier and a good communication. It is not already true that every pharmaceutical company found the right limit between commercial and medical. Pharmaceutical industry is currently in a restructuring phase concerning the adoption of the right limit between medical and

commercial activities. This transition phase is crucial to avoid useless competition that could emerge from too ambiguous boundaries.

Moreover, this unique medical expertise within the pharmaceutical industry is also a way to get privileged links with HCPs. This study focused on KOLs. The survey outcomes confirmed the benefit of this scientific expertise for pharmaceutical companies. Indeed, this expertise allows the Medical Affairs department to be well differentiated from commercial: the three proposals that best represent the MA department for the panel are about scientific matters (Clinical Studies, Scientific, Donations/Investigator Sponsored Research/Collaborative study) and only few chose commercial or sales answers; the open question (Table IX) showed that, for the panel, MSLs have a better scientific knowledge than sales rep ; and lastly 72% of the panel distinguish the Marketing department from the MA (Table X, point 7). Moreover, through this knowledge, MA get a privileged way to be in touch with KOLs since around 88% and 77% of the panel declared they already have been in contact with headquarter and field teams of Medical Affairs respectively (Appendices 6 and 7). KOLs answers also proved that MA clinical study expertise is a way of collaboration. Indeed, within the panel, around the half has been in contact with headquarters team to collaborate on clinical research project whether for collaborative studies or ISR (Figure n°13). Although, the scientific expertise is a differentiation advantage, the survey also supports the hypothesis that often, KOLs do not distinguish different industrial players (commercial, Marketing, Medical Affairs from headquarters or based on field...). Point 7 on Table X shows that still 28% of the panel either don't distinguish Marketing from MA teams or understand that those teams are not from the same department but

don't see any difference in their collaborations. Moreover, Table IX also highlights the blurred frontier between sales rep and MSL for some of the respondents (9 upon 41) who are declaring either that they do not see any difference between those two functions or that the difference is unclear. Finally, and in a new way, the subgroup analysis shows that point of view on collaborations between the panel and MA of pharmaceutical companies is highly dependent on their influence degree (Table X). The more influential the KOL is, and the more this KOL thinks he brings more to the pharmaceutical company than the opposite. Another outcome supports this idea that KOLs could get the feeling to be more useful for the pharmaceutical company than the pharmaceutical company could be for them: the most frequent panel's answers on the opportunities to collaborate with MA were in the category of collaborations that profits at the end the pharmaceutical industry (advisory board, speaker in symposia, speaker in events on behalf of the company). This outcome could be discussed by the fact that being a speaker on a national or international congress is also a way to develop their influence and is a benefit for KOLs. Nevertheless, overall, Figure n°14 shows that 72% of the panel finds their interaction balanced. At the end, the overall feeling is that KOLs are well aware of their interdependence (for pharmaceutical company to get insights and for KOLs to develop their influence via congress presentation or through clinical support for research by pharmaceutical industry) but they emphasized more the pharmaceutical industry dependency on KOLs than the opposite.

To finish on the major advantage that scientific expertise gives to Medical Affairs department, by allowing privileged interaction with KOLs, Medical Affairs also become the link between HCPs and other departments internally. Hence,

they are often associated with the KOL Management as shown on Table VI, VII and Figure n°18. Table VII also reveals that MA do not seem aware of this role since they fewer quoted this idea than Marketing. Even if Marketing also estimated KOL Management as one of their activity, it is not the same type of KOL Management. Medical Affairs have the capacity to know which expert is the best in which scientific subject and, through their field team, MA can have an idea on the regional network of each HCPs.

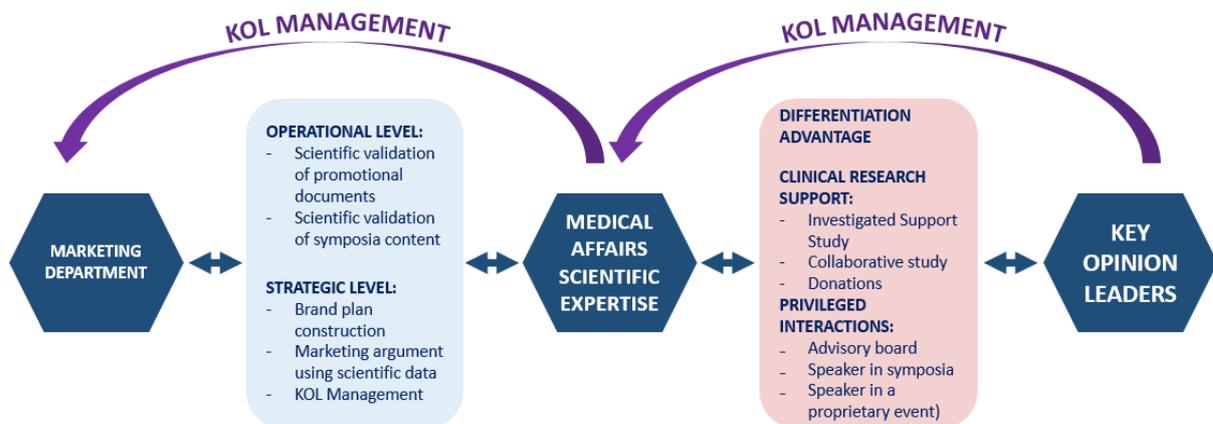


Figure n° 18 : Medical Affairs scientific expertise: a real competitive advantage

6.1.2. A rapid evolution of MA situation forming part of external and internal environment

The past and current development of the MA situation into the pharmaceutical industry highly depended on the external and internal evolution of environment. This fact was already found in the literature and this study confirmed it and specified in which terms the environment influences the MA status in France.

Previous decades have been marked by a real shift first of health market models but also of the regulatory framework. Firstly, the increased importance and development of MA is the direct consequence of models' evolution. Indeed, as the interview results showed, (cf. Perspective results) the past health model is going through transition from the medication prescribed by an office-based practice to the hospital market. During past decades, pharmaceuticals markets were mostly about medication prescribed on a high scale by general practitioner but since the normalization of generic medication, other markets had to develop and markets that are more specialized emerged. Those markets concern now more hospital market with management of diseases that had before no therapeutic options or niche markets with orphan diseases. In both cases, the scientific progress allows the discovery of new drugs but as the science evolves, the complexity of those diseases and their management also increased. The evolution of MA was, hence, inevitable to fill this need of scientific expertise on the side of pharmaceutical industry first to be able to become the link between HCPs and pharmaceutical companies but also to be the privileged interlocutor internally for scientific matters. Indeed, since models evolved, Marketing communication also changed and as the interviews demonstrated, product manager communication is more and more focused on care pathway and not only product. As a result of this trend, MA have a greater role to play concerning its interaction with Marketing that is increasingly looking for disease management ways of communication and hence need MA expertise on the disease environment and potential needs.

Along with the evolution model described above but still external to pharmaceutical industry itself, the mindset evolution, the higher public scrutiny

and several sanitary crises led to tougher regulatory laws and hence tighter compliance rules internally. It is also an outcome found both in the literature review and in the interview analysis from both Marketing and Medical Affairs respondents. In France, the DMOS law as well as the transparency obligation of links between the pharmaceutical industry and HCPs described in the Code de la Santé Publique (CSP) are the main regulatory framework. In regard of this laws, compliance departments of pharmaceutical companies adapt their work to be at least as strict as the law. One of the major actions for most pharmaceutical companies was to choose to separate clearly commercial department from Medical Affairs department. Nevertheless, interviews outcomes gave an important additional information on this separation. Indeed, respondents highlighted the fact that this sudden and rapid separation has led to a certain ambiguity and noticed it as one of the main challenge for companies to clearly define the limit between those two departments in order to improve their efficiency which seems not to be always the case. Interviews also showed that, this undefined limit could lead to rivalry which impacts their collaborative work. The separation that appears to be simple to set-up theoretically is, in practice not easy and the good balance is difficult to find. The good limit could be the right balance to both satisfy internal compliance rules while keeping the optimal capacity to stay competitive. The latter means to find a limit allowing collaboration between Marketing and Medical Affairs to valorize both competencies at the right level. One key point for this success would be the communication by gaining awareness on each other's objectives, strengths, and weaknesses together with suppressing competition.

Finally, on a field point of view, those external environmental changes lead to a restructuration of field teams as interviews and surveys showed. As a matter of fact, the assumption made at the beginning of this project was confirmed as sales force is slowly replaced by MSLs. Respondents were unanimous on that point and survey outcomes confirmed that HCPs are searching for a higher degree of scientific knowledge in order to collaborate with pharmaceutical industry. This does not however mean that this is the end of sales rep. Indeed, even if they are fewer in number, they acquired a different role of coordinator between every pharmaceutical stakeholder interacting with HCPs and HCPs themselves. This trend even leads to an original outcome of this study analysis with the suggestion of disappearance of Marketing in favor of development of MA department and combined functions.

The previous environmental changes that have induced the quick development of Medical Affairs can also explain the evolution of strategic role that MA play into the pharmaceutical industry. From now on, outcomes from the interviews support the hypothesis that MA endorse a strategic function in addition to their support activities. Table VIII demonstrates that both Medical Affairs respondents and Marketing product managers agree to point out that MA have a strategic role. The explanation of this increasing strategic role is directly deriving from the specific irreplaceable expertise of this department integrated into this moving environment. MA is implicated in each step of a drug development (Figure n°4): on pre-approval on clinical studies development in collaboration with clinical studies department; market access by giving strategic clinical data to use in their dossier; marketing authorization including TUA (Temporary Use Authorization) and on post-approval on the safety follow-up of

the drug with pharmacovigilance and medical information departments; marketing communication by being the source of scientific data that could help marketing arguments not forgetting its primordial interaction with external players on pre and post-approval first with HCPs but also with health authorities or patient associations. Hence, it has a global strategic vision that is important for both individual departments but also globally for the entire pharmaceutical company.

The increasing strategic role of MA is a fact but outcomes showed it is still highly dependent on companies (cf. Perspective results). Indeed, the interviewees unanimously explained that interaction between MA and Marketing department were dependent on people but also on internal rules. The good communication and collaboration are directly based on the way the leadership management team defines the limits of both departments but also on a local scale, the way individuals perceive this boundary. KOL survey, on Figure n°15, displays that quality of MSL's intervention is dependent on individuals and on laboratory which prove that the place given to MA influences the final impact on targets.

To conclude, pharmaceutical companies need to find the right place for MA while integrating environmental changes in order to optimize their efficiency and develop their strategic role.

6.1.3. Value estimation of Medical Affairs: the added value is difficult to quantify

As seen in the previous part, Medical Affairs have a clear intrinsic advantage linked with their scientific expertise empowered environmental changes. Nevertheless, demonstrate the value of this department is still a challenge. As shown in the literature, there are some metrics available (Arbet-Engels et al., 2018) but still the interpretation of these data is very complex. Indeed, the quantitative study of this project has revealed that finding metrics is possible but does not allow to infer the added value of Medical Affairs department. On the headquarter point of view and for this prostate cancer case study, the data found isn't reflecting the real work and the real added value. Indeed, as shown in Tables XI and XII, publications are mostly leading by Global functions and the support for research is highly fluctuating according to the year. The first explanation is that, as a subsidiary where operations are mostly with a Marketing lead, it is difficult to show quantitatively their activity. Moreover, as the previous results illustrated, the added value is not on quantitative facts but on the MA capacity to give insights through their scientific/environmental knowledge on disease management and hence their capacity to be in collaboration with most of the departments and with external stakeholders. Henceforth, taking under consideration field-based teams, it is easier to get data since their activity is more quantifiable (interactions with HCPs) but again, the interpretation is impossible and does not give any clue on the pertinence of their value. It is not the quantity that brings the added value of MSL. Nevertheless, the study suggests that the activity is fluctuating depending on the year, and it may exist a link between the lifecycle of a drug and the MSL

activity. A wider research on several drugs at different development stages could be an interesting complementary study to explore this hypothesis.

Numbers do not allow quantifying another important benefit in which MA play a role: the company's image and reputation. Even if outcomes from interviews didn't identify this point, the survey outcomes, and in particular Figure n°16, brought to the fore the important average rate of the Medical Affairs service, utility and support (3,65 upon 5) and suggest that MA highly participate to improve the reputation of a pharmaceutical company. A complementary study on MA implication into the pharmaceutical company reputation should be done to complete those results.

6.2. Recommendations

6.2.1. Links between Medical Affairs and Marketing

Outcomes from the interviews showed a global alignment between MA and Marketing departments but also a lack of communication. The way a company defines interactions modalities between those two departments is crucial. A complete separation would be a mistake because both departments are complementary. Alignment of those departments is a key of success for a brand. Indeed, MA is the source of scientific argument on efficacy, safety but also on Quality of Life (QoL) for a drug. On the opposite, Marketing sets up the brand guideline and defines the communication that other departments follow. Their functions are also complementary all along the life cycle of a drug. On pre-approval, MA have a greater strategic role since promotion is not allowed at this stage. Hence, scientific presence on congress and more generally the clinical development depends on MA. On post approval, communication takes

place and the strategic role of Marketing increases. Considering the above, the key of success is not how to separate them but rather how facilitate their communication to enhance their collaboration.

Results also highlight that scientific expertise allowed MA to emerge in the pharmaceutical industry through a support role. Nevertheless, needed MA skills keep growing to become broader with not only scientific background but also business acumen. Hence, MA and Marketing functions are currently in a restructuring phase with a redefinition of roles. Given the tighter regulations, it is not unlikely that with time, roles will be reversed and that MA become more strategic than Marketing. Marketing will then get a support role with for instance communication support creation and sales monitoring.

6.2.2. Estimation of Medical Affairs value

Because of the higher strategic role described above, the pharmaceutical industry will intend to quantify more their activity. However, this department value is difficult to estimate and it will be a major challenge in the coming years to find relevant metrics that allow an accurate value estimation while avoiding the complexification of MA functions that are already often overworked. Apart from being as less as possible time consuming, the setting up of metric chosen should not be obstacles for daily work and development of MA. An example is that, it should not impede MA in their operations. Too much control could lead to drifts that can be detrimental for the entire pharmaceutical company. Nevertheless, since digitalization is now part of the current practice of MA, using new technologies to improve the quantification of a qualitative work through the integration of IA could be a piece of the overall solution.

6.2.3. Links between HCPs and Medical Affairs and more generally with the pharmaceutical industry

Outcomes showed that links between pharmaceutical companies and HCPs are first, slowly moving from commercial functions to Medical Affairs functions and second, that those links are bidirectional. Nevertheless, links benefiting from KOLs input will be potentially prohibited in the coming years and only support for research will remain possible. It could reinforce the strategic role of MA that will become the only interlocutor with HCPs.

6.2.4. Global recommendations for the future growth of Medical Affairs

Considering this whole study, to improve the future growth of Medical Affairs, main challenges will be:

- To enhance communication between MA and Marketing department by defining clear limits for what function is doing what. The improvement of collaboration will also go through the training of MA and Marketing employees on what are the specific activities of each departments to allow a better understanding of their skills, constraints, weaknesses and strengths.
- To integrate ways to measure MA benefit without impinge on their efficacy. Good metrics are metrics that do not change the daily MA work by complicating the process but rather metrics that are integrated into their activities. Qualitative metrics better represent MA value than quantitative metrics and IA could be a solution to quantify the value of these qualitative contribution.

- To anticipate potential changes of interactions modalities with HCPs by reinforcing, as of now, their links with HCPs concerning support for research. A potential tightening of interactions conditions with HCPs could happen but the support for research will remain one of the last ways of interaction with physicians. Hence, the place a company takes concerning support for research for HCPs is crucial. Moreover, MA interlocutors are diversifying and MA activity will increasingly be focused on the disease management in a global scale involving new stakeholders such as patient organizations or access providers.

6.3. Limitations

This study aimed to demonstrate the potential strategic role of Medical Affairs and to learn how estimate the value of this department. Outcomes gave a lot of information on those two points. However, this project would have been improved if key missing data had been completed. To give the most comprehensive strategic profile of MA, every internal interaction with other departments cited in Figure n°4 could have been studied. Time constraints forced this study to focus on only one department. However, the choice of this particular department was well-considered and Marketing was estimated as the department that has the highest number of interaction with MA. Moreover, still about internal interviews, the lack of high-ranking or top management respondents is a limitation of this study since it seems that the importance of MA within a pharmaceutical company is highly dependent on top management decision positioning.

The strategic role of MA is also explaining by its external interactions. However, here, only interactions with KOLs have been targeted. A complementary study on overall HCPs and not only KOLs but also on other external stakeholders such as health authorities and patient associations should be considered. Focusing on the oncology field is also a limitation of the survey since oncology area, and its high innovation degree, is probably not the least knowledgeable about MA. Hence, this survey should be completed with other therapeutic area.

CONCLUSION

THESE SOUTENUE PAR : Célia PICARD

TITRE :

LES AFFAIRES MÉDICALES : LEUR RÔLE ET LEUR VALEUR AJOUTÉE AU SEIN DE L'INDUSTRIE PHARMACEUTIQUE

Les Affaires Médicales (AM) sont actuellement confrontées à un réel changement. S'appuyant sur leur expertise scientifique qui les a conduits à la croisée de l'innovation et des connaissances, les AM, qui n'étaient autrefois qu'un département support, jouent désormais un rôle stratégique dans l'industrie pharmaceutique. Grâce à leur double expertise médicale et scientifique, les AM sont devenues l'interface privilégiée entre le laboratoire pharmaceutique et les parties prenantes externes. Au sein du laboratoire pharmaceutique, les AM ont pris une position centrale entre toutes les fonctions internes grâce notamment à leur aptitude à maîtriser la gestion des données, leur communication scientifique et leur gestion des leaders d'opinion. Ainsi, les AM sont devenues incontournables pour des départements tels que le Marketing, l'Accès au Marché, la Pharmacovigilance, l'Information Médicale, les Affaires Réglementaires ou la Formation.

L'environnement mouvant qui régit l'industrie pharmaceutique et les changements qui en découlent ont conduit les AM à conquérir une position stratégique au sein de cette industrie. Ce travail met en lumière les principaux facteurs qui ont favorisé la propulsion des AM en première ligne. D'une part,

l'évolution du modèle de santé menant à une science médicale plus complexe a amené un nouveau besoin d'expertise spécifique dans l'industrie pharmaceutique. D'autre part, le renforcement du cadre réglementaire accompagné de règles de conformité plus strictes ont précipité les AM au premier plan de par leur caractère non promotionnel.

En raison de cette mutation rapide, l'un des défis majeurs auxquels les AM sont actuellement confrontées, et que cette étude a mis en évidence, est de trouver le bon positionnement au sein de l'industrie pharmaceutique. En effet, utiliser des facteurs externes, tels que la réglementation ou les règles de conformité, comme guide et non comme contrainte en établissant la bonne frontière entre les activités médicales et commerciales est un critère important de réussite pour le futur de ce département. Trouver un cadre de gouvernance médicale solide et un soutien organisationnel sont des défis majeurs pour les AM (25).

En outre, cette étude a également démontré que malgré l'importance indéniable des AM, la quantification de sa valeur reste une tâche difficile et sa marge de progression reste importante. En effet, obtenir des données quantitatives est possible mais leur interprétation est très complexe car les chiffres ne reflètent pas directement leur impact sur l'activité de la société pharmaceutique. L'apport des AM sur la réputation et son influence sur l'utilisation finale d'un médicament sont difficiles à mesurer.

Le rôle des AM continue d'être modelé par de nouveaux changements qui s'ajoutent aux évolutions externes précédemment citées. Jusqu'en 2025, les AM devraient renforcer davantage leur rôle stratégique. Pour ce faire, les AM doivent développer les compétences suivantes (26) : orientation sur le patient,

digitalisation, collecte d'information, génération de données de vraie vie et engagement de nouveaux experts externes. L'orientation patient est désormais un revirement incontournable pour l'industrie pharmaceutique. Il est important de la prendre en compte dès la conception des études cliniques ou même dans les relations avec les associations de patients pour lesquelles les AM ont un rôle fondamental. La collecte d'information est un défi majeur qui a déjà commencé avec le besoin croissant de preuves de vraie vie (*Real World Evidence*) de la part des autorités institutionnelles et sanitaires du circuit réglementaire du médicament. Les AM seront l'un des acteurs clés de la génération de données de vraie vie notamment à travers la création d'une nouvelle fonction nommée '*Health Economics and Outcomes Research*' (HEOR) qui se situe à la frontière de l'accès au marché et des Affaires Médicales. Grâce à leur niveau de connaissances scientifiques élevé, leur maîtrise de la gestion des données et leur connaissance des parties prenantes externes, les équipes des Affaires Médicales ont la capacité de rechercher les preuves nécessaires pour soutenir l'ensemble du cycle de vie d'un médicament et d'optimiser les résultats pour les patients (26). Enfin, alors que l'industrie pharmaceutique veut éviter les conflits d'intérêts des leaders d'opinion externes qui s'expriment en leur nom, une nouvelle tendance potentielle pourrait apparaître au cours des prochaines années suivant laquelle les AM seront amenées à remplir ce rôle d'orateur (26). Les réglementations sur les modalités d'interactions entre l'industrie pharmaceutique et les professionnels de santé pourraient devenir encore plus strictes dans les années à venir. Les premières collaborations impactées seront d'abord celles où les professionnels de santé

sont sollicités par le laboratoire pharmaceutique à intervenir en leur nom. Cette probabilité doit être anticipée par les entreprises pharmaceutiques.

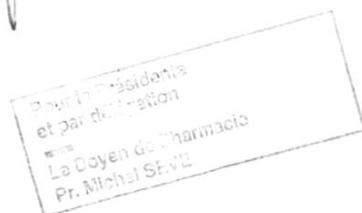
Pour conclure, l'importance des AM continue de croître dans un environnement mouvant. Les AM ont déjà su s'adapter à ces évolutions pour devenir un véritable acteur stratégique au sein de l'industrie pharmaceutique. Néanmoins, de nouveaux changements apparaîtront et pour que ces changements renforcent les AM, ces dernières ont besoin :

- de confirmer leur position d'acteur stratégique en améliorant la communication avec les autres services et en intégrant des moyens de mesurer les bénéfices des AM sans empiéter sur leur efficacité.
- d'anticiper les évolutions potentielles des modalités d'interactions avec les professionnels de santé en renforçant dès à présent leurs collaborations en matière de soutien à la recherche.

VU ET PERMIS D'IMPRIMER

Grenoble, le : 23/08/21

**LE DOYEN,
Michel SEVE**



**LE DIRECTEUR DE THESE,
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ANNEXES

Appendix 1 : Study timeline

Tasks	Execution periods
Subject identification and title	1st May 2019 - 15 June 2019
Bibliographic search	15 June 2019 - 15 January 2021
Preparation of all the methodology tools: survey, guideline for interviews, quantitative data extraction on headquarters- and field- team activity	1st August 2019 - 15 August 2019
Target identification for: <ul style="list-style-type: none">- Internal collaborators- KOLs	15 August 2019 - 15 September 2019
Quantitative data analysis	15 August 2019 - 15 September 2019
Sending of the survey to KOLs	16 September 2019
Interviews realization	15 September 2019 - 30 September 2019
Analyzing surveys, interviews responses	1st October 2019- 15 October 2019
Writing of the report	1st October 2019 - 15 November 2020

Appendix 2 : Set of questions asked during the interviews for both Marketing and Medical Affairs departments

- 1) Current position description
 - a) What is your position? What are your main missions/activities?
- 2) Point of view on Medical Affairs/Marketing department
 - a) In your point view, what could be the best definition of Medical Affairs/Marketing? What are, for you, their missions/activities?
- 3) Relationships between Marketing and MA departments
 - a) In which occasion do you collaborate with MA/MKT?
 - b) Can you describe how the collaboration works? (Meetings, calls, approvals, review, opinion....)
 - c) How often? (Is it a daily, weekly or monthly collaboration)
 - d) Does MA is aligning with your Marketing strategy? If yes, how?
 - e) How would you describe your relationship with MA?
 - f) How would you characterize MA/MKT role for MKT/MA? (support, strategic...)
 - g) What do you think are the main challenges in the future for this relationship?
- 4) Perspective
 - a) What do you think will be the main challenges in the future for this relationship?
 - b) Do you think environment changes influenced or will influence this relationship?
 - c) Did you see an evolution into this relationship since you work in Marketing department?

Appendix 3 : Healthcare Professional online survey

“Les "Affaires Médicales" sont décrites comme les garants de la qualité, de la fiabilité et de la justesse de l'information scientifique diffusée au sein du laboratoire pharmaceutique et auprès d'acteurs externes (autorité de santé, professionnels de santé, patients...) Les Affaires Médicales se consacrent donc à l'interaction avec les professionnels de la santé incluant à la fois les médecins impliqués dans des études cliniques faisant intervenir un/des médicaments du laboratoire ou des médecins qui utilisent simplement un/des médicaments du laboratoire dans leur pratique courante.

Ce questionnaire a pour but de caractériser ces interactions entre professionnels de santé (plus particulièrement les KOLs) et Affaires Médicales des laboratoires pharmaceutiques. Il s'inscrit dans une analyse plus globale visant à décrire le rôle de ce département.

Je remercie par avance l'ensemble des professionnels de santé prenant le temps de répondre à ces quelques questions. La durée de l'enquête est estimée à 6 min.”

1. HCP qualification:

- 1.1. *What is your medical specialty?*
- 1.2. *How often do you intervene on international congress?*
 - 1.2.1. *As a speaker?*
 - 1.2.2. *As an attendee?*
 - 1.2.3. *As an author in an oral presentation or poster?*

2. Knowledge on Medical Affairs as a whole:

- 2.1. *Do you know what the Medical Affairs department of a pharmaceutical company is?*
- 2.2. *If yes, since how many years Medical Affairs department has been interacting with you?*
- 2.3. *If yes, what represents Medical Affairs in your perception? (3 key words)*

3. Links with headquarters team:

- 3.1. *Have you ever been in touch with Medical Affairs' headquarters team?*
- 3.2. *If yes, what kind of collaborations did you have with Medical Affairs headquarters team? (Clinical study, advisory board, donation...)*
- 3.3. *Would you say Medical Affairs brings you more than you bring to them or the contrary?*
- 3.4. *Can you perceive the difference between Marketing department team and Medical Affairs department teams?*

4. Links with field team:

- 4.1. *Have you ever been in touch with MSLs?*
- 4.2. *How do you perceive the role of MSLs in your daily practice? (Very important, important, moderately important, not very important, I don't see what their intervention brings, I've never had the opportunity to have a MSL intervention)*
- 4.3. *How do you differentiate the role of MSLs in comparison of the sales representatives' role?*
- 4.4. *Do you appreciate to get MSLs intervention? Why?*
- 4.5. *Can you perceive the differences between headquarters and field teams?*

5. Conclusion:

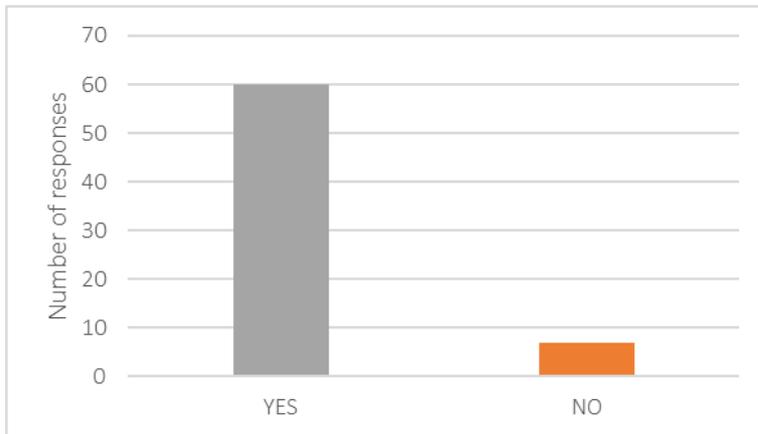
- 5.1. *What would be the global rate of the Medical Affairs service, utility and support?*

Appendix 4 : The frequency interaction between Medical Affairs and Marketing teams

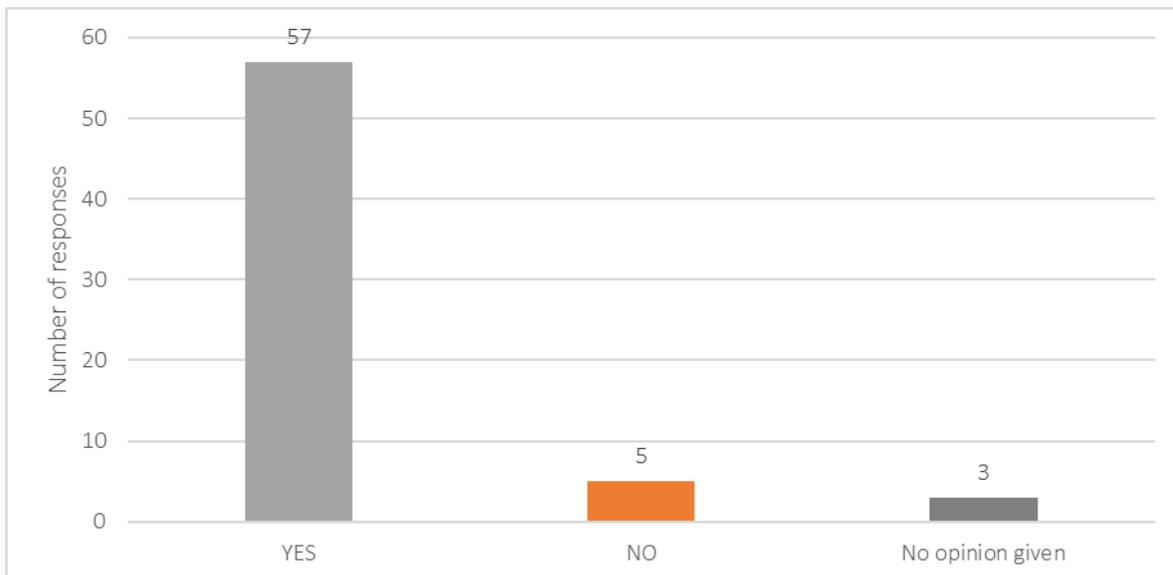
	Medical Affairs Head team (n=4)	Medical Affairs Field team (n=3)	Marketing (n=6)
Frequency	-Daily (4) -Weekly -Monthly -More	-Daily -Weekly -Monthly (2) -More (1)	-Daily/several times a week (6) -Weekly -More
Complementary terms used	“In continuous” “Permanent”	“no many interactions” “aleatory”	“at a minimum monthly” “daily or several times a week”

NB: the overall size of Marketing respondents is not seven because one of them didn't have Medical Advisor and couldn't respond this question

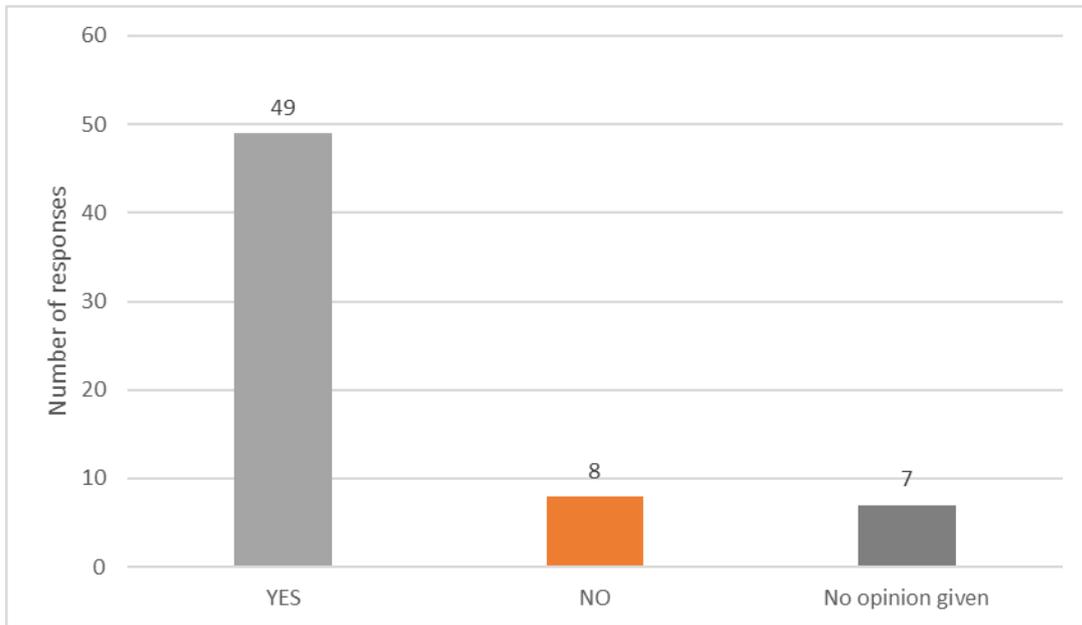
Appendix 5 : Do you know the Medical Affairs department of a pharmaceutical industry? (n=67)



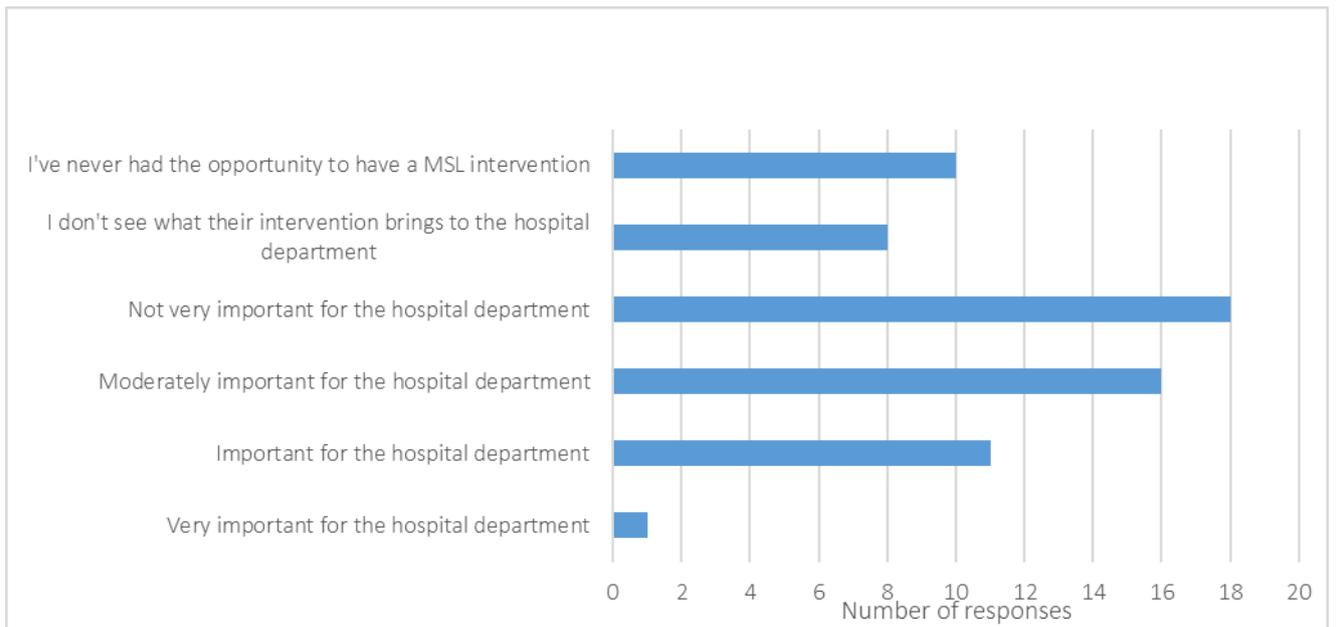
Appendix 6 : Have you ever been in contact with the headquarters teams of the Medical Affairs department of a pharmaceutical company? (n=65)



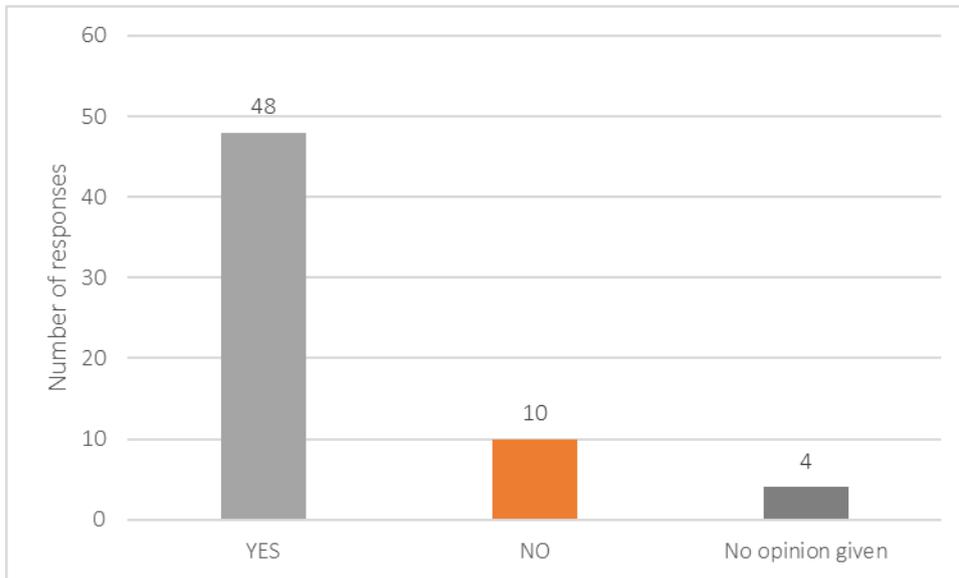
Appendix 7 : Have you ever been in contact with the field teams (MSLs) of the Medical Affairs department of a pharmaceutical company? (n=64)



Appendix 8 : How do you perceive the role of MSLs in your daily practice (n=64)



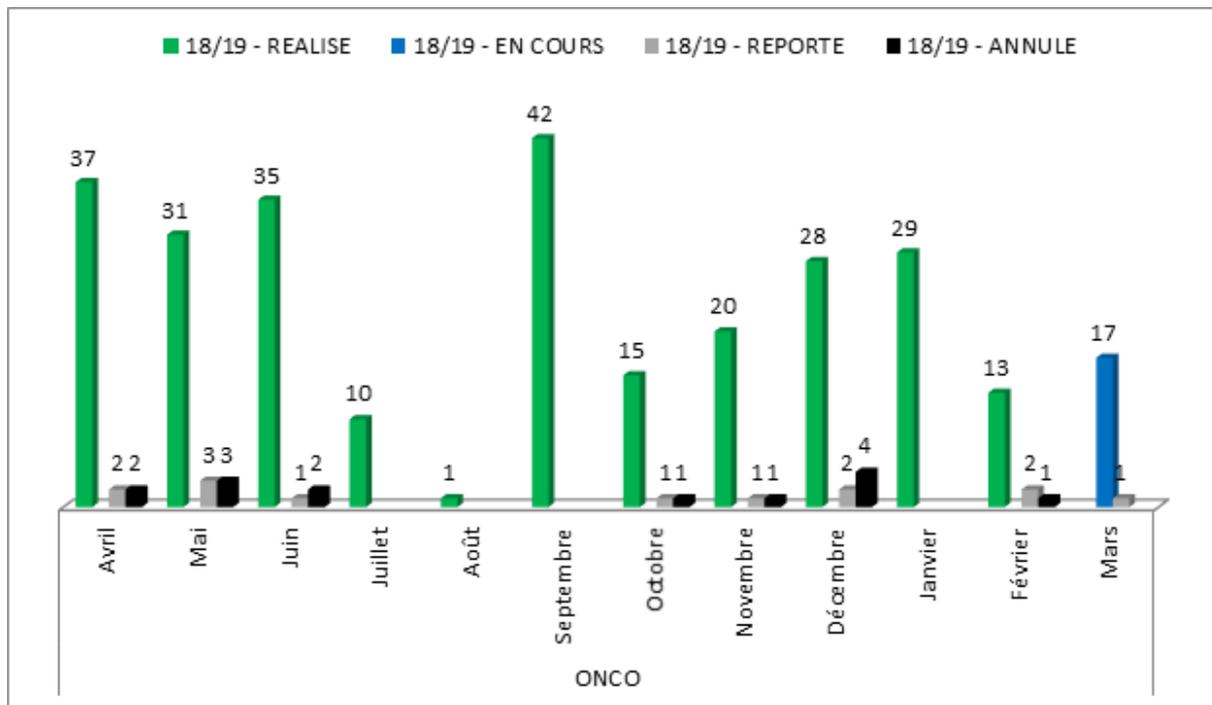
Appendix 9 : Can you differentiate between the Medical Affairs headquarters teams and field teams of a pharmaceutical company? (n=62)



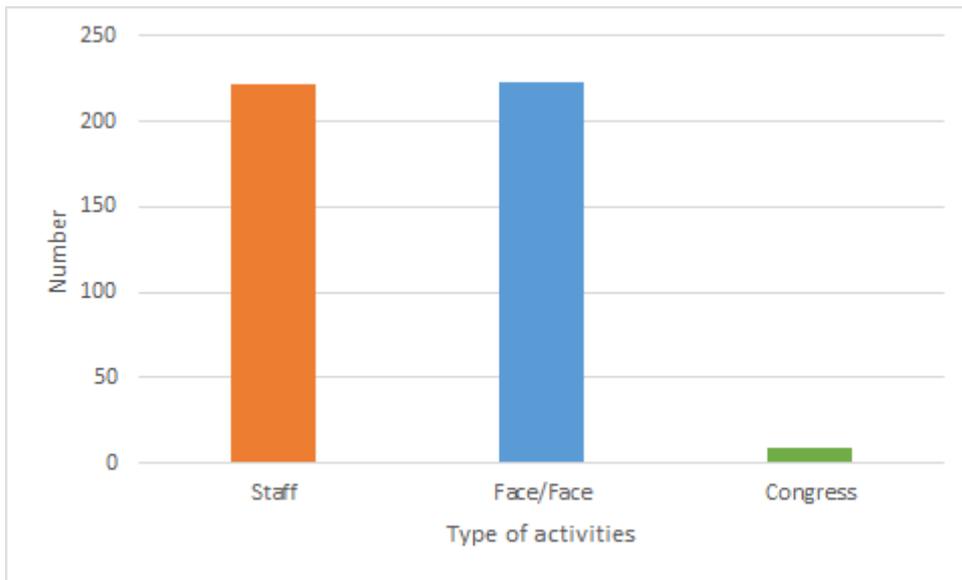
Appendix 10 : Subgroup distribution

	How often do you intervene on international congress as a speaker? (1 = infrequently to 5 = very frequently)		
	Below or equal to 2	Between 3 and 4	Equal to 5
Headcount	26	23	18
Group affiliation	MINOR KOL	MODERATE KOL	MAJOR KOL

Appendix 11 : Number of interventions in the oncology area for the French subsidiary of a pharmaceutical company for the 2018/2019 fiscal year



Appendix 12 : Number and type of MSL interventions for 2018/2019 fiscal year





Serment de Galien



« Je jure en présence des Maîtres de la Faculté, des Conseillers de l'Ordre des Pharmaciens et de mes condisciples :

D'honorer ceux qui m'ont instruit(e) dans les préceptes de mon art et de leur témoigner ma reconnaissance en restant fidèle à leur enseignement.

D'exercer, dans l'intérêt de la santé publique, ma profession avec conscience et de respecter non seulement la législation en vigueur, mais aussi les règles de l'honneur, de la probité et du désintéressement.

De ne jamais oublier ma responsabilité et mes devoirs envers le malade et sa dignité humaine ; en aucun cas, je ne consentirai à utiliser mes connaissances et mon état pour corrompre les mœurs et favoriser des actes criminels.

Que les hommes m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert(e) d'opprobre et méprisé(e) de mes confrères si j'y manque ».

Célia PICARD

LES AFFAIRES MÉDICALES : LEUR RÔLE ET LEUR VALEUR AJOUTÉE AU SEIN DE L'INDUSTRIE PHARMACEUTIQUE

RÉSUMÉ :

Ce projet vise à décrire le rôle actuel du département des Affaires Médicales (AM) ainsi que ses différents liens avec les acteurs externes et internes via la réalisation d'une revue bibliographique dans le but de mettre en évidence son rôle stratégique croissant face aux changements environnementaux majeurs des dernières décennies et en expliquant comment les AM peuvent devenir un réel avantage pour l'industrie pharmaceutique en estimant leur valeur actuelle et future grâce à la réalisation d'entretiens, d'une enquête en ligne auprès de médecins et d'un cas pratique.

Les données qualitatives ont montré que l'avantage distinctif des AM est son expertise scientifique unique au sein de l'industrie pharmaceutique à la fois en interne avec le département Marketing ou en externe auprès des professionnels de santé. Cette étude a également démontré que la valeur ajoutée quantitative des AM est difficile à estimer.

Les AM ont su prendre une place centrale dans l'industrie pharmaceutique. De nouvelles transformations environnementales influenceront le rôle des AM comme la digitalisation, l'orientation patient ou la génération de données de vraie vie tout en multipliant ses interlocuteurs. L'évaluation de sa valeur ajoutée reste un défi qui pourra être en partie solutionnée par l'intelligence artificielle.

MOTS CLÉS : Affaires Médicales ; Rôle ; Industrie Pharmaceutique ; Valeur

FILIÈRE : Industrie