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Contribuição dos Assuntos Médicos para uma gestão eficiente na Indústria Farmacêutica

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Dissertação apresentada à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Doutor na vertente de Ciências e Tecnologias da Saúde, realizada sob a orientação científica do Professor Doutor José Manuel Calheiros, Professor Catedrático da Universidade da Beira Interior, do Professor Doutor Luís Almeida, Professor Afiliado da Universidade do Porto e da Professora Ana Paula Mecheiro de Almeida Martins Silvestre Correia, Professora Associada da Universidade de Lisboa.

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keywords

Medical Affairs, Customers, Pharmaceutical Industry, National, Multinational, Health Care Professionals, Clinical Research & Development, Clinical Trials, Key Performance Indicators, Marketing, Multichannel Marketing, EMA, APIFARMA, INFARMED, Regulatory Authorities.

abstract

During the last decade the pharmaceutical industry (PI) operations became far more complex due to several structural and organizational changes, new legislation and pharmacoeconomic constraints. The role of Medical Affairs (MA) has been increasingly important and the interactions between PI and healthcare professionals (HCP) are currently much more based on science, than in marketing or commercial arguments. This thesis provides an in-depth description of the MA function, maps key areas of activity, challenges processes and opportunities, based on the feedback collected from PI professionals, HCP, regulatory authorities, payers and patient´s associations, while suggesting metrics to evaluate the activity and impact of such actions. To collect insights from these sources two questionnaires were sent to 400 pharmaceutical industry professionals and to 197 customers, addressing the most relevant topics of the MA contribution to strategic and operational activities, while identifying areas where there was greater perceived value of their activity. There were 169 responders to the first survey (colleagues), while 40 answers to the second one (customers). The importance of the MA on the overall results of the company was very high rated and, its contribution to strategic activities was seen as essential for the support of product launch, improvement of therapeutic adherence and partnerships with Patient's Associations. Higher scores were also given to operational activities such as medical awareness/education and symposia preparation, internal training and advisory board management. A great deal of medical effort was also spent in content creation, preparation and review of materials, in medicine related responses, presentations, reimbursement dossiers, safety risk management, internal cross functional meetings, as well as, in dealing with customers. Digital and multichannel medical labor was still rated low, while the contribution for mobile applications and similar devices gained some interest. The number of medicines considered reasonable for a Medical Affairs professional to be responsible for, was two through three. Customer facing activity was found to be reasonable up to ten customers per medical full time equivalent (FTE). MA efficiency was considered to be better exercised if office based rather than home based, while clinical research was considered to be more efficient if performed by company resources than by clinical research organizations (CRO).

For these colleagues, the most important driver for clinical research in our country was said to be interest/perceived value while, long approval timelines, lack of resources and low curriculum vitae impact were identified as major roadblocks. The customer's experience with clinical trials was greater than with investigator initiated research (IIR) or other non-interventional studies. When recruiting a Medical Affairs person, the characteristics perceived as most relevant were: a problem solving attitude, flexibility, pro-activeness and competency. The most important factors impacting Medical Affairs retention were: opportunities for personal development, recognition and work conditions. The contribution of the Medical Affairs to the reputation and credibility of the pharmaceutical industry was very highly rated. Looking at the future, most colleagues forsee a greater involvement of MA in pharmaceutical opperations. The impact of the implementation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) disclosure code of ethics and transparency governing the relations between pharma industry and HCP was considered to be high, while the pharmaceutical image was assessed as good. In the future, the majority of customers foresee greater Medical Affairs involvement, while patients as well as citizens, will have a greater participation on the decision making process of their own health. At the end, set of MA metrics on volume and impact is also suggested.

palavras-chave

Medical Affairs, Assuntos Médicos, Clientes, Indústria Farmacêutica, Profissionais de Saúde, Investigação e Desenvolvimento, Ensaios Clínicos, Indicadores de Desempenho, Marketing, Marketing Multicanal, EMA, APIFARMA, INFARMED, Autoridades Regulamentares.

resumo

Durante a última década, a gestão das operações na indústria farmacêutica (PI) tornou-se mais complexa devido a várias mudanças estruturais e organizacionais das empresas, a nova legislação e às restrições orçamentais a nível nacional e internacional. O papel dos Assuntos Médicos/Medical Affairs (MA) tem vindo a ser cada vez mais importante e as interações entre empresas farmacêuticas e os profissionais de saúde (HCP), muito mais baseadas em ciência, do que em argumentos comerciais ou de marketing. Esta tese fornece uma descrição detalhada da função MA, mapeia as principais áreas de actividade, problemas, desafios e oportunidades, com base na informação recolhida junto de profissionais da indústria farmacêutica, HCP, autoridades regulamentares, pagadores e associações de doentes, ao mesmo tempo sugerindo métricas, para avaliar a actividade e o impacto de tais ações. Para recolha de dados elaborámos dois questionários que, foram enviados por email a 400 profissionais da indústria farmacêutica e a 197 clientes, abordando os tópicos mais relevantes da contribuição de MA para as atividades estratégicas e operacionais, identificando as áreas onde existe um maior valor percebido dessa acção. Foram recebidas 169 respostas ao primeiro inquérito (colegas) enquanto que 40 respostas ao segundo inquérito (clientes). Os resultados obtidos permitem concluir que a contribuição dos MA para os resultados globais da empresa e para as estratégias definidas foi muito alta, sendo essencial para o apoio ao lançamento dos medicamentos, melhoria da adesão terapêutica e colaboração com as associações de doentes. Foram igualmente salientadas as atividades operacionais, como as relacionadas com materiais educacionais e de actualização, preparação de simpósios, treino interno e de consultoria. Um grande esforço médico é igualmente investido na criação de conteúdos, preparação e revisão de materiais, bem como, nas respostas relacionadas com os medicamentos, planos de gestão de risco, contribuição para dossiês de reembolso, em reuniões internas de alinhamento e na interacção com clientes. O contributo médico para as actividades digitais e multicanal foi ainda classificado como pouco relevante, enquanto que, as aplicações móveis registaram interesse. O número de medicamentos considerado razoável para um profissional de MA ter sob sua responsabilidade foi de dois a três, enquanto que o número de clientes a acompanhar deveria rondar os dez. A eficiência destes profissionais foi considerada melhor se exercida a partir do escritório do que do domicílio, enquanto que, a investigação clínica foi considerada mais eficiente se realizada pelos recursos da empresa vs recursos contratados (CRO).

Para estes colegas, alguns dos factores determinantes para a investigação clínica no nosso país foram: o interesse na investigação e valor percebido dessa participação, enquanto que, os longos tempos de aprovação, a falta de recursos e o baixo impacto no curriculum vitae, constituíram alguns dos principais obstáculos. A experiência dos clientes com os ensaios clínicos é maior do que com os estudos de iniciativa do investigador (IIR), ou outros estudos não-intervencionais (NIS). Ao recrutar um profissional para Assuntos Médicos/Medical Affairs, as características percebidas como mais relevantes foram: uma atitude visando a solução de problemas, flexibilidade, pró-atividade e competência. Os factores mais relevantes referidos como impactantes na retenção destes profissionais foram: as oportunidades de desenvolvimento pessoal, o reconhecimento e as condições de trabalho. A contribuição dos Assuntos Médicos/Medical Affairs para a reputação e credibilidade da indústria farmacêutica foi altamente reconhecida, prevendo no futuro um ainda maior envolvimento médico nas empresas. O impacto da implementação do Código de Ética e Transparência da Federação Europeia da Indústria Farmacêutica e Associações (EFPIA), que rege as relações entre a indústria farmacêutica com os profissionais de saúde, foi considerado elevado; enquanto que a sua imagem foi avaliada como boa. No futuro, prevê-se um envolvimento maior dos Assuntos Médicos/Medical Affairs nas operações da indústria farmacêutica, dos doentes e dos cidadãos, no processo de decisão sobre a sua saúde. No final sugerem-se um conjunto de métricas sobre a actividade de MA em termos de volume e de impacto.

Foreword

I moved to the Pharmaceutical Industry (PI) after a relatively long medical career in Hospitals, Primary Care Health Centers and at the General-Directorate of Health. At the time, I thought I had the knowledge and attributes to perform competently the Medical Director function.

I recognize now that I knew little about the Medical Affairs (MA) job characteristics, the regulatory environment, the complexity of the actions and the reach of such a role. Time, day-to-day management, personal experience and the support of some colleagues, allowed me to progressively consolidate this knowledge and eventually, to become an expert on this field.

My purpose was to investigate the importance of this role and associated responsibilities, seen from the perspective of the colleagues working at the Pharmaceutical Industry, as well as the customers we serve. Questionnaires were addressed to these two target populations, inquiring on major activities and areas where MA can contribute efficiently to bring the best treatment options and services to Health Care Professionals (HCPs) and patients, while ensuring compliance and maintaining a trustful relationship.

Therefore, the structure of this thesis comprises:

- An Introduction to the Medical Affairs function.
- Results of a questionnaire sent to Professionals working for the Pharmaceutical Industry.
- Results of a questionnaire sent to Customers.
- Discussion and conclusions of the analyses performed to both of them.
- A set of metrics useful to evaluate the MA activity and impact.

After devoting more than 20 years to MA, I'm absolutely convinced that what we do is fundamental to the Pharma Industry's activity and to the population as a whole. Calling the reader's attention to the characteristics of this function, how it is valued by the market, the environmental challenges, the opportunities and how to provide an increasingly efficient service to our customers, might also be useful for those already working in pharma, as well as, to newcomers to Medical Affairs.

Lisbon, June 5th 2018

José Augusto Aleixo Dias

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LIST OF ACRONYMS

AMPIF – Association of Portuguese Physicians of the Pharmaceutical Industry

APIFARMA – Portuguese Association of the Pharmaceutical Industry

APs – Alliance Partners

AUC – Area Under the Curve

BU – Business Unit

CRO – Clinical Research Organization

CEGEDIM – Technology & Services Group

EC – European Commission

EFPIA- European Federation of Pharmaceutical Industries and Associations

EMA – European Medicines Agency

EU – European Union

FDA – Food and Drug Administration

FTE – Full Time Equivalent

GDP – Growth Domestic Product

HCP – Health Care Professional

HR – Human Resources

IIR - Investigator Initiated Research

INFARMED – National Authority of Medicines and Health Products

IMS – Pharmaceutical Market Consulting Group

IT – Information Technology

KAM – Key Account Manager

KOL – Key Opinion Leader

KPIs – Key Performance Indicators

MA – Medical Affairs

MAs – Medical Advisors

MD – Medical Director

MI – Medical Information

MKT - Marketing

MLs – Medical Leaders

MM – Medical Manager

MMM – Multichannel Marketing Manager

MSR – Medical & Scientific Relations

MSL – Medical & Scientific Liaisons

NHS – National Health Service

MTL – Medical Team Lead

Pharma – Pharmaceutical Industry

PI – Pharmaceutical Industry

R&D – Research & Development

SOP – Standard Operating Procedure

SMART – Specific, Measurable, Attainable, Relevant and Time bound

After the start of this doctoral program in 2014, I had the chance to publish a number of scientific papers and opinion articles, make several presentations and participate in conferences and round tables on the topic of Medical Affairs and Medical Affairs related activities. These are being described below according to type and in chronological descending order:

Papers more recently published (2014-2018)

1 Dias JA. Sobre Doações na Indústria Farmacêutica. Revista da Ordem dos Médicos. 2016; nº 172: 97.

2 Dias JA. Santos A. Assuntos Médicos – Uma ponte entre a investigação e a prática clínica. Revista da Ordem dos Médicos. 2015; nº163: 54-59.

3 Dias JA. Duarte P. BIG Data Opportunities in Health Care - How can Medical Affairs contribute. Revista Portuguesa de Farmacoterapia. 2015; Vol. 7 (4): 230-236.

4 Dias, JA. Medical Affairs Efficiency in Pharma – A pragmatic approach to success. Revista Portuguesa de Farmacoterapia. 2014; Vol.6 (4): 221-232.

Collaboration in papers published (2014-2018)

5 Pereira A, Escoval A, Dias JA. (Expert collaboration) Ensaios Clínicos em Portugal - Consensos e Compromissos. APIFARMA/ENSP-UNL Report. 2016: 1-11.

Presentations, conferences and debates (2014-2018)

6 Dias JA. The quantified self is alive and well; eHealth Summit, Lisboa, 2018, 22 Março.

7 Dias JA. O Papel das Associações de Doentes na melhoria da literacia em saúde; Associação Portuguesa Associação Portuguesa para o Desenvolvimento Hospitalar (APDH). 2017; November 23rd.

8 Dias JA. Instituto de Saúde Pública da Universidade do Porto (ISPUP) – Uma carreira Médica na Indústria Farmacêutica. ISPUP. Porto, 2016; December 19th.

9 Dias JA. Inovação em Saúde. Experiências internacionais, nacionais e locais; 6º Congresso Internacional dos Hospitais; Associação Portuguesa Associação Portuguesa para o Desenvolvimento Hospitalar (APDH). Lisboa, 2016; November 25th.

10 Dias JA. Faculdade de Farmácia da Universidade de Coimbra (FFUC). Painel Investigação Clínica em Doenças Raras. Ensaios Clínicos em Medicamentos Órfãos. FFUC. Coimbra, 2016; November 11th.

11 Dias JA. Escola Nacional de Saúde Pública (ENSP). Think Tank Ensaios Clínicos em Portugal: Consensos e Compromissos. ENSP. Lisboa, 2016; September 30th.

12 Dias JA. Portugal Biotechnology Industry Organization (P-BIO). Semana Europeia da Biotecnologia em Portugal – Moderation and debate of the study: Roadmap do Desenvolvimento Clínico. Biocant. Cantanhede, 2016; September 28th.

13 Dias JA. Associação Medicina Farmacêutica Portuguesa (AMPIF). Comunicação, a arte de ser entendido. Portuguese Order of Physicians. Lisbon, 2016; July 13th.

14 Dias JA. Health Cluster Portugal: Ensaios Clínicos, oportunidades de melhoria. Hospital Braga. Braga, 2016; April 13th.

15 Dias JA, Santos A. Training Program in Pharmaceutical Medicine. Medical Affairs: From therory to practice. Advisory Boards: Shaping theory and practice. INFARMED. Lisboa, 2015; April 24th.

16 Dias JA, Marcelino, C. Comemoração dos 75 anos da Associação Portuguesa da Indústria Farmacêutica (APIFARMA): Dia da Porta Aberta da Inovação Biofarmacêutica – Casos de sucesso de colaboração Empresas Farmacêuticas & Associação para a Investigação Biomédica em Luz e Imagem (AIBILI). Coimbra, 2014; May 20th.

Occasional Teaching activities (2014-2018):

17 Dias JA. Centro de Estudos Superiores da Indústria Farmacêutica (CESIF). Master em Monitorização de Ensaios Clínicos e Medical Affairs. Big Data in Healthcare – Opportunities for Medical Affairs. Lisboa, 2018; May 28th.

18 Dias JA. Centro de Estudos Superiores da Indústria Farmacêutica (CESIF). Medical Affairs Training Course: Medical Governance. Lisboa, 2017; April 5th.

19 Dias JA. Instituto de Higiene e Medicina Tropical (IHMT). Curso de Especialização em Saúde Pública: Desafios e Oportunidades do Big Data nos Cuidados de Saúde. Lisboa, 2016; July 12th.

20 Dias JA. Centro de Estudos Superiores da Indústria Farmacêutica (CESIF) – Mestrado em Monitorização de Ensaios Clínicos e Medical Affairs: The Importance of Data Generation; Interventional and Non-interventional Studies. Lisboa, 2016; March 2nd.

21 Dias JA. Training Program in Pharmaceutical Medicine - Healthcare Marketplace (responsible for the module). University of Aveiro. Aveiro, 2015; March 26-28th.

22 Dias JA. Training Program in Pharmaceutical Medicine - Healthcare Marketplace (responsible for the module). University of Aveiro. Aveiro, 2014; May 8-10th.

23 Dias JA. Training Program in Pharmaceutical Medicine - Risk Management Systems. University of Aveiro. Aveiro, 2014; February 21st.

Institutional related activities:

24 Portuguese Order of Physicians - President of the Competence in Pharmaceutical Medicine: 2015 to date.

25 Associação para a Investigação Biomédica em Luz e Imagem (AIBILI) – Member of the General Assembly, 2013 to date.

26 Instituto de Higiene e Medicina Tropical (IHMT) – Invited Member of de Advisory Council, 2015 to date.

"A lot of new discoveries are often at the interface between different fields."

Paul-Peter Tak

CHAPTER I – PHARMACEUTICAL INDUSTRY TRENDS

1.1- The Pharmaceutical Industry and Medical Affairs

The Pharmaceutical Industry (PI) is a strategic sector for the health and the country economy, translating in innovation, qualified work and health gains. The economic pressure related to the European recession in recent years seriously affected the health sector, leading to substantial reductions in investments (-27.2%) and manpower[1]. The number of pharma companies in Portugal dropped from 130 (2010) to 122 (2013) and 121 (2016)[2], while the number of professionals experienced an 18.5% cut overall and 21.1% in multinational companies. Cuts were primarily focused on sales force and some other supporting functions, whereas in Medical one sees stabilization or even an increased demand. These environmental changes together with the recognition of the value of Medical Affairs (MA) in communicating the clinical value of medicines and devices, understanding customer's needs, capturing insights, identifying opportunities, while ensuring compliance and transparency, raised more focus and interest in this function.

Pharmaceutical companies dispute the most well prepared and qualified professionals. This role requires, among other skills: strong understanding of scientific issues and clinical research, fluency in foreign languages, ethics, transparency, knowledge about country codes and standard operating procedures (SOP), adherence to safety standards and reporting, agility in establishing and maintaining relationships while responding to customer needs. Investigators, key opinion leaders (KOL) and prescribers, they all recognize the Medical function as of paramount importance, contributing to improve patient access, disease awareness and patient outcomes.

Working predominantly in the field close to the customer, is a natural strategic evolution of the traditional MA role, demonstrating value, business alignment, integration, governance and transparency, which are essential pillars in building customer partnerships and trust. Customers such as patients, regulators, health administrators and other healthcare professionals (HCP), expect pharmaceutical companies to deliver not only medicines but a continuum of care, ranging from disease awareness, prevention, diagnosis and treatment of marked health value.

1.2- Challenging the decision making process at pharma

The majority of the companies still exercise a top-down approach but, increasingly, they listen from stakeholders and local affiliates which are the best strategies to implement. The majority of the decision making is derived from the executive level (40.0%); technology

decision making is driven primarily by executive management (34%), business, sales and marketing (28.0%) and IT (24.0%)[3]. Medical should contribute to strategic decisions both at product and management level. The Medical Affairs' view and scientific advice should be independent from commercial, although in line with the market characteristics and company interests.

In recent years the medical segment has been progressively recognized by pharma, through the added value they incorporate in the decision making process. Their knowledge about the therapeutic areas involved, the product characteristics, the potential alternatives available in the market, the patient profiles, the medical thinking while prescribing, the economic and legislative environment and the safety and compliance patterns, justify this recognition.

1.3- Innovative Medicines are crucial to the quality of care provided

The National Health Service (NHS) is universal and has predominantly free access, supported by a high number of qualified healthcare professionals; it provides access to innovation and shows fairly good results versus investments. Pharmacologic innovation was responsible for 75.0% of the life gains in life expectancy achieved during the first decade of this century. Access to innovative medicines is critical for the impact on results, namely in what regards disease prevention, early diagnosis and treatment[4]. However, only a limited number of medicines are approved for reimbursement each year in Portugal (Fig. 1), despite some recent positive changes.

More than 50% of the drugs approved by EMA are reimbursed	↑	France Germany Italy	Spain UK Belgium	Denmark Greece Luxembourg	
Between 40% and 50% of the drugs approved by EMA are reimbursed	↕		Bulgaria Czech Republic	Slovakia Slovenia	
Less than 40% of the drugs approved by EMA are reimbursed	↓	Austria Croatia Cyprus Estonia	Finland Hungary Ireland	Latvia Lithuania Norway	Poland Portugal Romania

Figure 1 – Reimbursement of innovative drugs approved by European Medicines Agency (EMA) - ***(adapted from Wikman, J – 2016)***

Time to price approval (667 days) is one of the longest in Europe, well above the European average (435 days) and 5.6 times longer than the shortest time (Denmark: 120 days) as shown in (Fig. 2)[5].

Medical Affairs can contribute to a much quicker approval process by gathering scientific evidence from Epidemiologic studies, Clinical Trials, Real World Data, Pharmacoeconomic studies and competitive data that will be included in the submission dossiers, providing the best evidence possible of the added value of the medicine being submitted. Authorities have to do also their part being more efficient in managing this process.

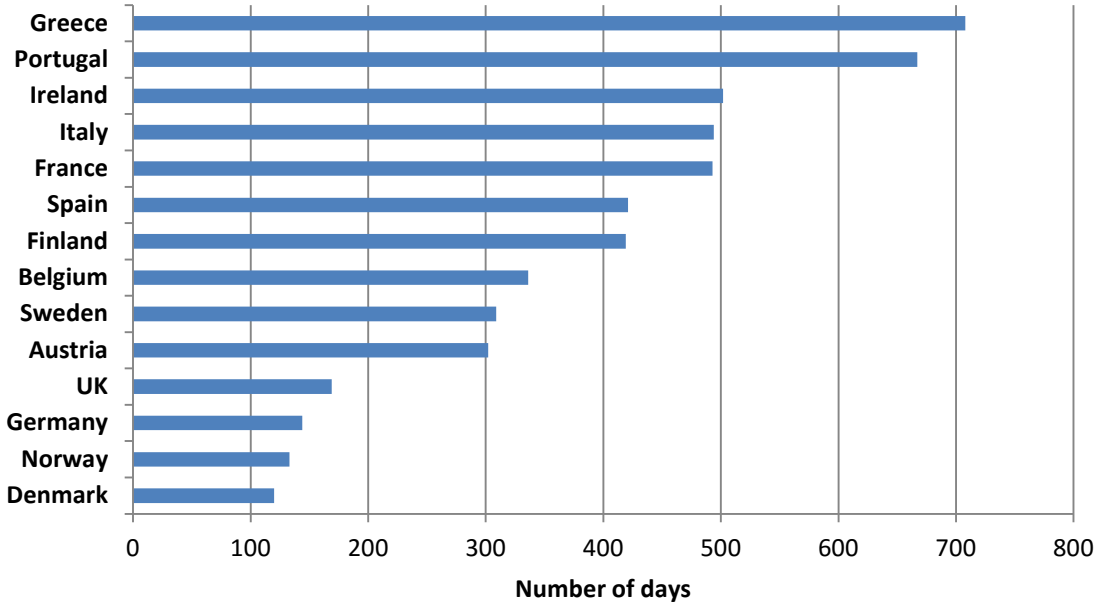

Figure 2 – Time to pricing for innovative drugs in EU countries *(adapted from Wikman, J – 2016)*

1.4- Clinical Research is key to understand in depth the disease characteristics and treatment options

Traditionally, research and development (R&D) in pharma has been a secret activity conducted within the walls of R&D. In recent years, the external collaboration with universities, other pharma companies, consultants, health providers and payers, have expanded it. By breaking internal silos and enhancing collaboration with external partners,

pharmaceutical companies can extend their knowledge and data networks. Due to the disinvestment in R&D in Europe and in Portugal in recent years[6], it is difficult to show an attractive study recruitment record (Fig. 3).

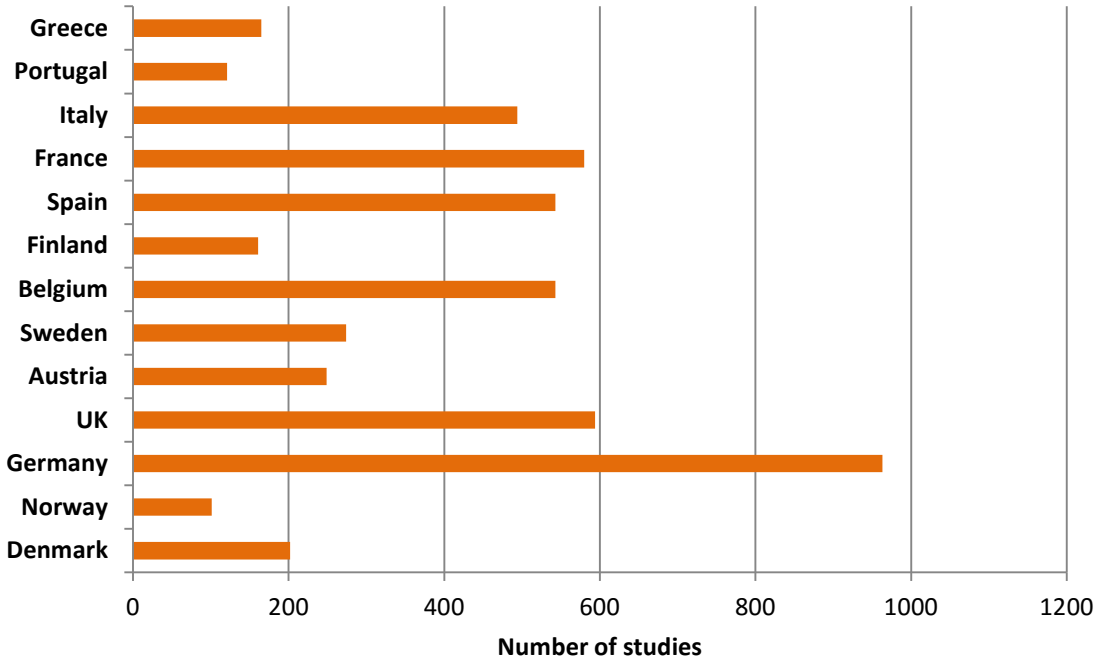

Figure 3 –Clinical studies in EU *(adapted from EFPIA – 2012)*

There was a decline of studies submitted to INFARMED from 160 in 2006 to 88 in 2011, showing some marginal improvement since then, with 137 submissions in 2017[7]. The European Commission (EC) classifies the Pharmaceutical Industry as a strategic sector for the European economy[8], while politicians and some HCPs at the country level are apparently embedded with the same spirit[9]; however we need to act decisively to attract these investments and scientific knowledge and showcase[10]. The new regulation of the European Parliament[11] also reinforces this strategy.

1.5- Moving from R&D to commercialization

Bringing a new pharmaceutical product to market is usually a long process and a challenge for either big or small biotech companies, who need to make early decisions regarding their investigational compounds. There is no real equivalent to Medical Affairs in

biotechnology, yet it plays an ever-increasing and important role in that industry as well[12]. The traditional pharma model includes two main pillars: an R&D organization in charge of developing new products and, a commercial organization in charge of marketing and selling those products. The bridge between development and commercialization is provided by Medical Affairs during the various phases: pre-launch (drug development, clinical research, KOL mapping, competitors characteristics, reimbursement dossiers), launch (awareness, competitive advantage, prescribers feedback), as well as during post-launch (public acceptance, dosage management, compliance/adherence, pharmacovigilance, willingness to pay, etc).

1.6- Customers expect pharmaceutical companies to deliver not only medicines but a continuum of care – Medical Affairs drive this effort

The current pharmaceutical model is still based, in some companies, around the efficacy, safety and cost of medicines, but one can see a shift towards a more valued-based and patient-centric approach, increased external partnerships and the outsourcing of non-strategic activities (Fig. 4)[13].

What changes to the commercial business model is your company taking?	December 2013	March 2015	Change
Increased focus on market access strategies	54%	50%	-4%
Shift to a more patient-centric approach	37%	41%	**4%**
Redefining the role of the sales force	46%	37%	-9%
Utilizing multichannel engagement strategy	N/A	34%	N/A
Increased focus on Key Opinion Leaders	41%	29%	-12%
Developing external therapeutic partnerships	18%	25%	**7%**
Increased use of digital channels	27%	23%	-4%
Increased focus on marketing	28%	22%	-6%
Increased focus on Medical Science Liaisons	N/A	19%	N/A
Outsourcing of non-strategic activities	10%	14%	**4%**
No changes at this time	N/A	6%	N/A

Figure 4 – Changes in the pharmaceutical business model: 2013 – 2015 ***(adapted from IMS Health, 2015)***

Pharma needs to be close to the customers, understand their needs, capturing insights, communicating and responding timely and appropriately. Medical Affairs are the best resources to manage expectations and to respond to this challenge.

The increasing collaboration with Patients' Associations are mostly done through Medical Affairs and are decisively contributing to improve disease awareness, early diagnosis, treatment compliance, transparency and trust.

1.7- Consolidating a more patient-centric approach

Pharmaceutical companies need to understand the customers' point of view, their most critical needs and challenges, so that they can provide adequate and pragmatic support to Patients' Associations. Effective communication channels, clarity of the message, available and adequate contents and capability to respond in due time, are critical for the success of these partnerships. As shown in the previous figure, a more customer-centric approach has been experienced in recent years, but it still needs improvement. For Medical Affairs, having the patient at the center of the system means having the patient in mind in everything we do. It translates in allowing Patients' Associations and Caregivers to contribute in almost every stage of the development process, starting from the study design, protocol conception of studies - namely in what concerns determining more judicious endpoints, data analysis, and outcomes. In addition to the HCPs, and payers, these groups play an important role and should be considered as such. Support homecare initiatives, provide digital education and tools tailored to patient's needs, and contribute to secure the supply chain[14] is very important. But, it also means helping these customers to improve health literacy, education in operational areas, access, networking, and to have a stronger voice near legislators and regulators. On a transparent win/win basis, Patients' Associations can also be helpful to pharma in sharing information (e.g. clinical trials, pharmacovigilance, co-creation of materials), improving disease awareness, contribute to early diagnosis, excel treatment compliance and evaluating impact.

1.8- Developing a multichannel engagement strategy

Health professionals are increasingly involved in clinical discussions through digital platforms. However, when communicating with their patients, they still use the traditional face-to-face, phone-calls, short messaging services or emails. New technologies, namely

those based on devices and smart phones, will monitor more closely patient´s parameters in the future, reducing or eliminating interviewer influence or inappropriate measurements. Communication tools will get more interactive, allowing health professionals to receive the information they need, when they need it. Medical Affairs will play a role in this customized management of the information, improving awareness and recommending the right tools when appropriate. While helping to overcome patient's barriers, this needs to be done in full respect for privacy laws and patient adherence.

1.9- Measuring impact while striving for continuous improvement and reputation

The Medical Affairs resources are always scarce and one needs to make pragmatic evaluations of activity and impact. Which activities matter? As Rory O'Connor said:

"*The true measure of medical performance is impact*"[15].

All external surveys available from pharma companies as well as from independent institutions, appreciated with a very high rank the contribution of Medical Affairs to scientific and business operations[16]. It is hard to gain trust because it takes time, requires consistent performance, compliance with standards, scientific rigor, transparency, quality of the services provided and an adequate communication. However, the level of trust of the general public to the Pharma Industry is not high[17]. To change this perception MA need to assess everything MA do, by promoting responsibility and accountability at all levels.

"In strategy it is important to see distant things as if they were close and to take a distanced view of close things".

Miyamoto Musashi

CHAPTER II – The Medical Affairs Function

2.1- What do the Medical Affairs do?

In the Pharmaceutical Industry's Medical Affairs professionals are bound to create, demonstrate and communicate the clinical value of medicines and devices under their responsibility, to listen and understand customers' needs, identify opportunities and respond adequately, ensuring compliance and transparency, whilst maintaining the primacy of patient's best interests. This activity covers a broad spectrum of specific tasks and associated interactions, both at internal and external levels. In recent customer surveys, investigators, KOL and prescribers, they all recognize the Medical function as of paramount importance, both in Portugal and abroad[13,14].

These MA professionals are a source of accurate and up-to-date scientific information, contributing for Medical Education, Clinical and Research Grants efforts. They also provide information on support services designed to improve patient access, disease awareness and outcomes. The MA role is performed by Medical Directors (MDs), Medical Advisors (MAs), Medical Leads (MLs) Medical & Scientific Liaisons (MSLs), Medical & Scientific Relations (MSRs) and functions alike.

The Medical Affairs represent the medical voice within the Pharmaceutical Industry. Depending on the company structure, it covers: management of medical activity associated with products (medicines or devices), clinical research and production, drug safety, compliance with regulatory requirements and internal SOPs, medical information, access, communication and customer management. The business structure varies, depending on size, type and number of products. The vast majority of Medical Affairs professionals are physicians, pharmacists or biologists. Most small businesses have at least one MA professional. Medium and large companies frequently have their resources organized in a Medical Department or, split the MA resources across different business units, reporting directly or indirectly to the MD.

The Medical Director is usually the responsible for the scientific service requested by law[18]. Along with the Technical Direction, the MD represents the face of the company in its regulatory, safety and compliance relations with the health authorities. In a traditional model, the MD reports to the General Director and sits in the board of directors. More recently, and mainly to secure independence from the commercial line, some MDs report directly to their Medical structure at regional level and indirectly to their General Director in Portugal. Reporting to the Medical Director one may find Medical Team Leads (MTLs) in companies that hold a large portfolio of products but in general, these are MAs, MSRs or MSLs, which are in charge of a specific portfolio of products and customers. It is up to MA

to grant a good management of these portfolios while ensuring a set of internal training activities, research support and customer management. Its greatest value is based on the scientific knowledge of the products and therapeutic areas where they operate, transmitting these to HCPs while cultivating internal and external relationships with key parts. These skills consolidate the sharing of experiences at medium and long-term, contributing decisively to a sound relationship, which is essential in building trust.

The information provided by Medical Affairs need to be: adequate, accurate, balanced and provided in a timely manner, not expecting anything in return. The service provided aims to complement the added value of the portfolio of medicines which are publically available. In the launch preparation of a new product, the action of MA begins a few years before, with the review of existing literature and publications, identifying local sources of information on the incidence and prevalence of disease, contacting the main opinion leaders and researchers, as well as specialized centers, listing potential therapeutic gaps and alternatives. It is followed by a long and systematic work collecting, interpreting and analyzing data, which will lead to the preparation of the market to receive the new medicine/device. During the launch phase, the rapid dissemination of information and collection of early market experience is critical to design, differentiate and position the product properly. This is also applicable to the launch of a new indication, where the process is similar but usually less demanding. In addition to these activities, MA also interact with a large number of functions or platforms, such as: Production, Marketing, Commercial, Quality of Products, Quality of Processes, Access, Communication (internal and external), Finance, Distribution, Logistics, Human Resources, Information Technology and Legal (Fig. 5).

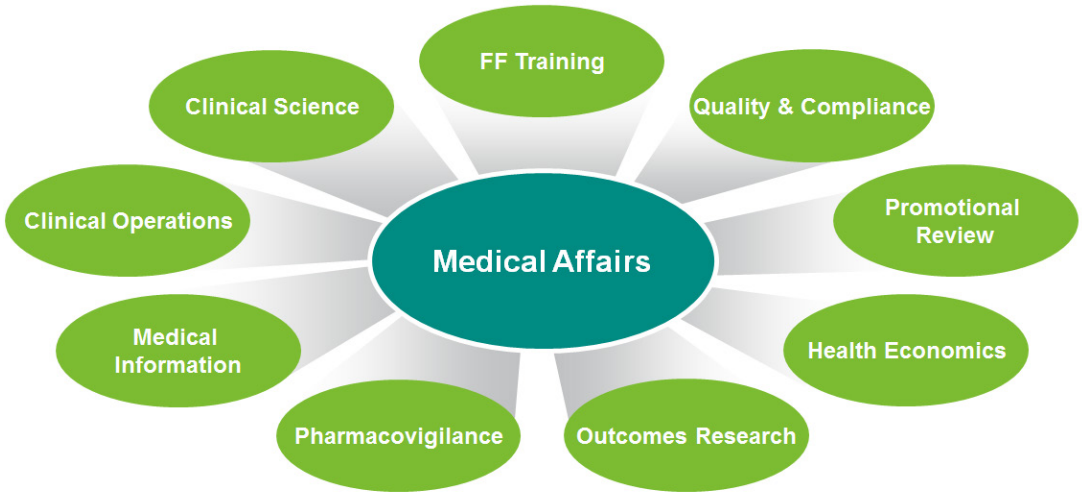

Figure 5 – Medical Affairs scope of activities

2.2- Important determinants of the MA function

- *A compelling Mission and Vision*
- *A strategic contribution to business*
- *A well-defined consistent and coherent strategy*
- *An efficient business operating model*
- *An adequate structure adapted to the country needs*
- *Clearly defined Medical governance and Leadership*
- *A specific Medical Affairs' budget*
- *Effective collaboration and coordination of stakeholder's management*
- *People's management*
- *Efficient systems and processes*
- *A set of pragmatic metrics*
- *A continuous improvement mindset*

2.2.1- A compelling Mission and Vision

Most companies are bound to mission statements and values. They state them, they write them everywhere: on people's objectives, on paper walls, corridors, elevators, stands, cards, leaflets, etc.… but these are not kept into the people's heart and mind, unless they really understand, live and fight for what they believe worthwhile doing. There needs to be a clear alignment between what companies say and do, each and every day. The scrutiny made by colleagues is permanent and sets the mood for the actions taken, as well as for the pride and devotion to their profession, especially in difficult times. This is extremely important not only to reach objectives but for personal satisfaction and sense of ownership. To have these principles embedded, companies need to make a good use of the competency they have in-house, working efficiently, while maintaining attractiveness, recognizing and rewarding accordingly. The decision on how to design the MA mission has to do with the core business of the company, its portfolio and the operations maintained in a specific region or country.

2.2.2- A strategic contribution to business

Medical should contribute to business decisions both at strategic and at product management level, through cross-functional teams, together with Regulatory, Safety, Marketing, Sales, Medical Information (MI) and Key Account Managers (KAMs), Legal, Multichannel and other supporting functions. The MA ability to interpret and translate scientific information into commercial insights, credibly communicate scientific data to HCPs and, supporting publications, provides it with a unique position in the business.

Historically, companies have narrowly defined the set of activities that Medical was responsible for, but the current understanding naturally leads to an increasing number of activities that Medical undertakes, in order to create added value for the business[19]

These activities tend to be common across organizations, but the precise mix of responsibilities will vary depending on the nature of the company's portfolio and its business needs. Clinical, regulatory and reimbursement hurdles continue to increase the cost of drug development and its risk profile. Some companies are joining resources, through acquisitions, mergers and alliances. These combinations would enhance the innovative and established portfolios in key markets[20].Tightening regulation where Medical Affairs plays a paramount role as gatekeepers, compliance reviewers and scientific ambassadors to customers to date, their contribution in some cases, still remains below its potential. A model that recognizes the Medical appropriately and compliantly integrated with the sales, marketing and other functions will ensure companies to maximize the value of their products and of the services provided.

2.2.3- A well-defined, consistent and coherent strategy

Medical Affairs success requires a well-defined strategy, consistency on the direction to be followed, focus on critical actions where people are required to apply their efforts and a coherent attitude regarding the objectives, mission and values. Has the company made key strategic choices on issues such as priority assets and partnering? Has it created a compelling overarching story about the drug being launched?[21] Pharma companies should not enter a new therapeutic area, invest significant resources to develop new medicines, work hard to become a player in that particular field, train people, establish relations, launch products, and suddenly divest or close that specific business area. What will internal and external customers think?

Under these circumstances, credibility and trust become fragile. Similarly, companies should not create a new internal structure (unit or function), attract colleagues to apply, allow them to develop a business purpose, create operational plans, invest their personal life on this endeavor, and then change it, or close it, soon afterwards. One should not enter highly competitive areas without a minimum level of investment for adequate development but also, to sustain these products against competition, in a way that product's value can be defended. In some companies, Medical still plays a limited role in strategy development, often receiving it from the commercial line. In most of them, Medical attends meetings during the development of the brand strategy, but tends to play a less intervenient role.

As things evolve, we believe that Medical will act as a critical source of information and decision support, since companies try to differentiate themselves in such a highly competitive market. In order to do so, Medical must become proactive during strategy development. This role is crucial as Medical will convey knowledge about physicians, patients and competitors, that will materially impact a given brand's strategy. Medical can contribute to a more robust strategy formulation process by collecting and generating information on the epidemiology of the disease, characteristics of the available treatment options and differentiating factors, guidelines, local norms and prescribing patterns, patient's preferences and compliance, insights from KOLs and other critical stakeholders.

2.2.4- An efficient business operating model

Efficiency is the cornerstone of success in pharma. Organizations realize the benefits of improving their MA function, making it more visible through customer facing interactions, because Medical touches all aspects of the business, including development, sales, marketing, and government affairs.

2.2.4.1- What is the most efficient business model?

The business operating model is mainly driven by the size and reach of the company. In small pharmaceutical companies, the senior Medical function, usually the Medical Director, reports to the General Manager and takes part of the local administration board. In multinational companies with a large portfolio of products, this "country model" has evolved to a matrix structure of business units (BUs), where the local Medical Director or Medical Lead reports to the regional structure through the global Medical line,

maintaining the MA responsibility within or across BUs. There are also mixtures of these models in place. A matrix organization tends to be less agile in the decision making process, once there are several layers to overcome in order to reach a final decision.

2.2.4.2- Which level of decisions should be taken centrally, regionally or locally?

Strategic and operational MA decisions should be taken at all levels. The key drivers here are: alignment, accountability and pragmatism. Aligned with the company's strategy, the MA function at the local level should have autonomy to take their own decisions, following approved operating plans and objectives. Autonomy and delegation are certainly topics worthwhile underlining. These are extremely important because they bring the accountability and responsibility down to the lowest levels of the organization, fostering people's involvement, excelling opportunities and providing everyone with the sense that they have their own share of contribution for the company's results. In the current environment, forecasts and operating plans for five or ten years are not easy to make. Therefore, there should be flexibility to adapt and update them, as new critical factors arise.

This does not mean that these forecasts should not be made. They are obviously needed but, they should be timely prepared, based on objective parameters that real matter for an effective discussion, leaving out a great amount of frequently irrelevant and time consuming materials, such as long sets of slides and pictures. Unless a real urgent and unexpected event occurs, the approved plans should be respected, monitored and accomplished. Changing these plans too frequently creates a sense of instability, which is not favorable to performance and business.

2.2.5- An adequate structure adapted to the country needs

The responsibility of managing the scientific evidence belongs, by nature, to the Medical role. In addition to the MA contribution to strategy, insights and development, the scientific dialogue with physicians, payers and governmental officials is critical. Their contribution to health care does not resume to a specific medicine profile, but it also comprises disease awareness, early diagnosis and treatment options of conditions for which, some health professionals and managers are frequently not fully updated. There are several ways the MA can contribute on this matter such as group presentations and

research involvement (clinical trials, investigator initiated research, collection of real life data, etc.).

They make suggestions for its content, invite speakers, and support attendance to these meetings while organizing advisory boards, webinars and WebEx's on specific disease management or guidelines. MA contribution for the development of digital tools has also been of primary importance, namely in the domains of information sharing and patient disease management. The local MA structure has to be able to cope with research and development if innovation is core in the company's operations. Making structural changes is useful to adapt to an evolving environment. But, change what? When? Changes should be driven by efficiency, added value (responding to an unmet medical need) and return of investment.

2.2.5.1- Should Medical resources be concentrated or decentralized?

To our understanding it depends on where the business is. Where are the customers Medical has to interact with? At a local level, assuming that these customers are randomly distributed across the country, the operations can be centralized in one office, if the average time of transport follows within a 3-4 hour time frame. This will allow for a better coordination within the team and across other functions. If the customers are concentrated in specific areas, not near the base office, the decentralized approach could be more convenient (e.g. clinical research mainly conducted in localized settings). The multinational coordination should remain at global or regional level. However, the level of interaction and the understanding of the country specific archetype need to be well understood and balanced.

2.2.5.2- Should Medical operate from a local office, home based, or virtual?

Costs and efficiency have boosted the outsourcing of some Medical related functions or moved them to a field-based model. Instead of operating from the office, these resources work from home, although there is an expectation that some days will still be spent at the office. The debate on this is going on. The set of customers that the Medical function has to manage, the type of interactions required and the support provided, clearly shows that a substantial part of MA work is done in the field. However, there are also internal customers to meet and alignment to be ensured, particularly with Marketing, Regulatory, KAMs, Sales, Access, Med info, Legal, Digital, etc. These are much more efficiently

organized and impactful if driven *on site* than through teleconferences or webinars. Temporary field based job is certainly needed for offshore based personnel, or Medical functions responsible for the coordination of a number of multinational sites. Some of these virtual assignments work mainly though teleconferences, videoconferences and WebEx's and are also becoming more and more frequent. Again, the best solution should be the one that best matches the support to the company's operations.

2.2.5.3- Should some Medical competencies be outsourced?

If the MA competency within the company is good enough to address the challenges and keep the rest of the organization compliant, generating real competitive advantage at a reasonable cost, than the investment in these talents should be kept, providing a genuine edge over their peers. However, this poses a challenge for most industry players; as the function grew and shifted its focus, companies did not always ensured they had the right talent in place to meet new demands.

What they frequently need is leaders who can effectively engage with multiple stakeholders and senior colleagues. Finding and developing these leaders, and ensuring effective succession planning, is not easy. Instead, pharmaceutical companies should first identify distinctive strengths and potential within their existing MA teams and then build, or fill out, a team with complementary strengths across multiple dimensions[22]. One of the problems with outsourcing is the fact that a third party is representing your organization. Therefore, the relationships that a company has created with their customers along the years, while building confidence and trust, have now a different intervenient partner. This partner can be representing the company "A" today and tomorrow company "B". Most of the Medical related functions are outsourced to Clinical Research Organizations (CROs). CROs have evolved from providing transactional support for specific projects, to becoming strategic partners to pharmaceutical companies. The effectiveness of CROs to manage working relationships with sites has slipped during the past years, with the average CRO falling below performance expectations in several critical areas including study monitoring and project support - "*Relationships are a cornerstone for all of our strategies going forward*"[23]. In addition, the rotation rate is high among these third party providers meaning that a KOL might have to deal with different persons for a single project or study.

2.2.5.4- How many MA resources?

In Portugal, about fifteen years ago, some companies had only one dedicated full time equivalent (FTE), usually the MD and, in some cases, as a part-time job. In order to address the changing dynamics of the market requirements, pharmaceutical companies have increased their number of Medical staff, especially during the last decade. These highly skilled Medical professionals train their sales force appropriately, and provide added value to physicians, payers and patients. According to the law[24], a pharma company operating in Portugal has to have its own technical director and a scientific responsible person; however, this person is not always the MD, as we believe it should. Therefore, in our view, this should be the minimum that a company should have as a Medical resource resident in the country. Depending on the company's portfolio, a set of other Medical functions should be added.

2.2.5.5- What should be it span of control?

How many products should be under a MA responsibility? In a medium/large pharmaceutical company, while ten years ago a medical advisor could be responsible for an average of ten products; now, most of medics with recent launched products might deal with one to three, depending on the life cycle stage of the product portfolio.

For a product in pre-launch phase with an important market potential, a minimum of 0.5 Medical FTEs are required to support the Medical activities during the 1.5 years before launch. During the launch, one or two full dedicated FTEs might be needed, and during the following two years, depending on the prevalence of the disease and approved indications, these resources might need to be reinforced.

2.2.5.6- How many customers should they manage?

Medical Affairs usually manage products from a certain therapeutic area and the scientific relations with HCPs of those particular areas. Among these, there is a set of more relevant investigators and KOLs, to whom they regularly provide updated information, ask for advice, discuss ideas, support programs and educational initiatives, congresses, etc. In order to be effective in this role and provide a service of quality, the number of customers to deal with might vary between 15 during the launch period, through 30 if one is dealing with well-known and established medicine. A balanced customer distribution per Medical FTE is of the highest importance, especially if this function is dealing with more than one

product, so that adequate priorities can be established. Balanced decisions need also to be taken when a particular event is taking place or the life cycle of the product requires it. If a product safety or efficacy issue is raised, then the authorities, as well as prescribers and other relevant customers need to be immediately informed and, a Medical task force might have to be considered, irrespectively of their usual areas of focus. One should not forget how to properly exit certain therapeutic areas, maintaining a residual but certainly important relationship with these customers.

2.2.6- A clearly defined Medical governance mandate and leadership

Medical governance within pharma is a systematic approach to maintain and improve the quality of the services provided to customers and patients. Organizations must control and proactively manage medical issues to ensure that the patient safety and the medicines are protected[25]. It is also vital that an organization has oversight of local operations, while ensuring that global medical standards are consistently applied and issues are properly addressed, and corrective actions are taken in due time. There are two fundamental components in Medical governance: Strategic and Operational. From a strategic point of view, it makes recommendations and helps the decision process and the approach alignment to customers. From an operational point of view, it contributes to the plan of each product or therapeutic area, being responsible for performing themselves tasks accordingly. It is essential to ensure good practice processes and products to ensure the effectiveness and safety of drugs that are offered, safeguarding that any problem detected in a timely manner will be accompanied by appropriate corrective action.

The Medical Board represents the company in its institutional relations with the authorities, medical societies, research centers, academia, associations and related entities. In addition to ensuring the scientific component, it must also communicate internally and externally aspects related to new results generated by research that develops or support, identify and exploit the opportunities and optimize the management of Medical resources, seeking to retain the talent, giving them development opportunities and stimulating their external exposure.

2.2.6.1 - Research & Development

The R&D model is changing dramatically and becoming more collaborative across companies. It was also recognized that it was becoming harder to win an approval by the Food and Drug Administration (FDA) or the European Medicines Agency (EMA), and in addition, there was little to show for the billions invested. As a result, of that and also due to a higher influence of patients' associations, both the pharma companies and the authorities are finding new ways to foster accelerated approvals and priority reviews[26,27]**.** New drugs, namely for patients with serious conditions and where there is an unmet need, can go through a fast track approval in the US whereas in Europe, a pilot process on adaptive licensing is being explored since May 2014. This is not only relevant because it can speed the approval process, but also because most of the decisions are to be taken jointly by the authorities and pharma. This is new and quite relevant to strengthen the collaboration between these parties, hopefully improving the treatment options to patients.

Some companies have been rolling out their own development strategies, while others are outsourcing partially or completely R&D to alliance partners (APs) which act in name of the company. Apparently, this strategy is paying off in large countries with lot of sites and resources on the field. However, this process has dramatically reduced the R&D investments in small countries like in Portugal[28], potential reasons being:

- high competition between countries to gain access to multinational studies
- limited number of sites fulfilling the highest standards now required
- complexity of the protocols proposed for feasibility
- scarce number of patients available to meet the inclusion or exclusion criteria, namely due to their previous or ongoing treatment status or comparators used
- administration boards requesting upfront payments which are not required in other countries and might infringe companies SOP
- number of resources deployed by contractors at the country level (frequently operating from outside the country)
- limited knowledge of the site potential, concurrent investigations ongoing there and Investigator's characteristics
- unmatched opinion between the company and CROs regarding which sites/investigators to involve
- monitors' high rotation rate

Due to the disinvestment in R&D in Europe and in Portugal in recent years[29], currently it is difficult to show an attractive recruitment record. The European Commission classifies the Pharmaceutical Industry as a strategic sector for the European economy[8], politicians and some HCPs at the country level are apparently embedded with the same spirit[9]; however, we need to act decisively to attract these investments and scientific knowledge and showcase. The new upcoming regulation of the European Parliament[11] also reinforces this strategy.

2.2.6.2 - Risk Management

Risk Management involves having robust systems in place to understand, monitor and minimize the risks to patients and staff and, to learn from mistakes. This includes:

- compliance with processes, laws, guidelines and protocols
- reporting adverse events, product quality issues and complaints in a timely manner
- promoting a blame-free culture to encourage everyone to report problems and mistakes
- learning from mistakes/near-misses and introduce corrections, appropriately and timely

2.2.6.3 - Compliance

Compliance means: acting according to the rules. In pharma, all colleagues ranging from the highest levels of management to the most junior employees, are expected to take ownership and compliance, performing all tasks with integrity. Companies continuously scrutinize internal practices and have put in place procedures for taking immediate action when any potential violation is identified[30]. This is ensured through:

- written policies and procedures (SOPs)
- oversight of MA related activities
- effective training and education
- efficient lines of communication
- internal monitoring and auditing
- enforcement through discipline pursuant to published guidelines
- prompt response and corrective action of potential problems

2.2.6.4 - Adverse Events management

All company's employees or third parties that the company contracts, who become aware of any product safety issue, lack of efficacy or misuse are required to be reported as described in the internal SOPs and local laws. Medication errors, occupational exposure or off-label use whether or not there are any associated adverse events[31].

As a precautionary measure, all information captured accidentally or directly reported to MA, is required to be expeditely sent to the company safety officer. Having a proper pharmacovigilance in place is of capital importance. The safety officer and the safety team need to train all new recruited personnel, timely update all colleagues on new procedures, regularly evaluate the number of reports received, check them for accuracy and follow-up them until the issue is closed. Quality reviews as well as internal and external audits are essential to assess accomplishment of these tasks[32].

2.2.6.5 - Quality of processes

The aim of the audit process is to ensure that Medical, Regulatory, Safety and Quality related activities are continuously monitored and that potential gaps or deficiencies in relation to standards are identified and promptly corrected. This comprises:

- having a country quality plan in place
- awareness of the most important laws and SOPs
- ensuring regular quality reviews and audits
- understanding of each colleague reporting responsibilities
- balancing processes reducing bureaucracy
- delegation of duties and empowerment

Always strive to be *inspection ready*. Colleagues are trained to do their jobs and are always updating their training to keep current with revised SOPs, systems upgrades or regulatory changes[33].

2.2.6.6 - Product Quality Issues and Complaints

The primary objective of the quality & compliance team is to ensure all products in the market meet quality according to local regulations and company standards. Medical

device complaints and product complaints must also be forwarded as product safety reports whether or not there are any associated adverse events.

- ***A medical device complaint*** is any written or oral expression of dissatisfaction relative to the appearance, identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device or product with a medical device component.

- ***A product complaint*** is any written or oral expression of dissatisfaction relative to the physical properties, condition, package insert, and/or packaging of a product. Main activities deal with:
  - Receiving daily reports with complaint information and check if complaint has already been received
  - notifying the company and health authorities
  - reporting out of stocks
  - responding to the external questions

  What can we do differently regarding these topics? To anticipate potential label requests changes or out of stocks and preparing accordingly; make unexpected visits to the warehouse and check for processes and activities; alert colleagues so that they are aware of product quality activities.

- ***Counterfeit*** is the unauthorized production of products represented as an original medicine, by anyone other than an authorized company. Counterfeit is a serious threat to Public Health and Safety and is increasing about 90.0% since 2005, with an estimate associated revenues of about 10.5 billion euros[22] Counterfeit can be of two types: falsified product (the most common) or falsified origin, if original products are stolen to the wholesaler or during any other part of the supply chain process. In any of both situations occur the alert should be immediately given.

2.2.6.7 - Education and Training

Education and training entails providing appropriate available support to enable staff to be competent in their jobs and to develop their own skills, so that they are up to date and knowledgeable about their role. Professional development is a continuous process and should be maintained through lifelong learning. In practice, this involves:

- attending courses and conferences (continuous professional development)

- taking regular assessments to ensure that training is appropriate
- conduct regular appraisals (meant to identify and discuss weaknesses, and opportunities for personal development)
- coaching and mentoring

2.2.6.8 - Promotional and Educational Materials review

Promotional and Educational Materials review aims to ensure:

- the scientific content of the materials
- compliance with internal rules and SOPS
- alignment with local legislation
- compliance with the Portuguese Association of the Pharmaceutical Industry (APIFARMA) Code of Ethics[34]

Challenges of this aspect of clinical governance include Digital materials, Webinar and WebEx's contents, and Disclaimers.

2.2.6.9 - Information & Operational alignment

Information and operational alignment must ensure:

- regular information sharing
- awareness and update on most relevant topics
- operational alignment across functions
- regular review of strategy and goals
- promptly adaption
- follow through
- focus on meaningful goals and metrics

2.2.7- A specific Medical Affairs' budget

To ensure that Medical activities are aligned with business needs, but independent in nature from purely commercial interests, it is relevant that a MA budget is available, for

the investments MA agrees to support. Most of this MA budget will be used to support local studies, registries, publications, posters, medical education activities, etc. These investments should be subject to regular screen from finance, to ensure that investments are aligned with the approved budget.

2.2.8- An effective collaboration and coordination of stakeholders' management

In medium to large organizations, namely those with several BUs, it is essential that alignment and collaboration is ensured. Collaboration is based on common goals, regular information sharing, update communications, adequate organization of processes and team spirit. This applies to both internal and external stakeholders.

2.2.8.1 - Internal alignment

Communication is a common pitfall of pharma both to internal colleagues and to external customers, especially in what concerns the use of the appropriate channels, clarity of the message content and opportunity. Very important occasions for alignment are internal meetings. However, these should be regular and balanced both in their frequency and duration, with a pre-defined agenda. Regular appointments should be made and relevant topics discussed in the team. Managers should request regular updates on ongoing activities. Feedback and suggestions incorporated in the final decision and actions in accordance to appropriate timelines. Minutes about the most important decisions, as well as on actions that need follow-up should be written. For urgent/unexpected topics, the agenda might be avoided. However, minutes and follow-up notes should be taken anyway. Some relevant points to consider are:

- clear purpose setting
- define agenda topics to those involved as core members
- specify personal contributions, order and time allowed for presentation/discussion
- invite non-core members for specific points under discussion where they are experts or potentially impacted
- distribute agenda at least one day before the meeting takes place
- respect time limits
- review minutes from the last meeting
- define actions and who is responsible to follow-up on them

- write minutes and distribute them
- consider virtual contributions through teleconferences, WebEx's or webinars.
- some issues might be discussed directly, not requiring a formal meeting

2.2.8.2 - External alignment

Several functions within the organization might interact with the same customer. A customer relates the MA, or any other function of a certain company, with the company's name, not to the particularities of the reporting lines or its decision making processes. Once the contact is established, an expectation of response is created and should be delivered in a coordinated way. A pharma representative can receive a medical question that he might not be able to respond and which he has to escalate or, an adverse event he has to report. The feedback given to the customer has to be coordinated. Another frequent situation occurs when several functions contact the same customer without alignment among them. It could be the Sales Force representative, the Medical Advisor, the Marketing Manager or the KAM. To be effective, coordination is obviously the key to this process.

Opportunities to consider improvements on this topic include:

- better planning and communication between MKT/sales/KAMs and Medical in order to prioritize these meetings (not only: first come first serve)
- ensure the value of what its delivered to customers
- establish and maintain strong and enduring customer relations
- develop effective scientific communications in a manner that enhances trust
- deploy appropriate resources to support the highest value opportunities
- run advisory boards of KOLs/stakeholders to identify needs and opportunities
- support relevant training and disease awareness programs
- contribute with scientific evidence to guidelines, their development and dissemination
- coordinate these activities in accordance with the operational plan and objectives
- involve other relevant internal experts when appropriate (e.g. R&D, regulatory, pharmacoeconomics, safety, legal, etc)
- save MA availability for special audiences and customer interactions

2.2.9- People's management

2.2.9.1 - Managing the MA workforce

Nine thousand five hundred and eighty people were working for the Pharmaceutical Industry in Portugal during 2010[35], of which around two hundred in MA. Whatever they are at large or small springing up companies, most people have something in common: they want to make a difference[36]. Human resources (HR) and MA share a common goal of facilitating, monitoring and enforcing employee compliance. In order to be able to coordinate and manage these HR activities, the number of dedicated headcount is critical to guarantee a proper support to the organization and to MA. Otherwise, their perceived contribution to the overall wellbeing of the organization has fewer chances to be properly recognized.

For MA these are key colleagues because their collaboration also extends to recruitment, standardization of job descriptions, salary processing, rewards management and equity. People are frequently considered the best asset of an organization. However, companies have to translate this statement into actions that can be perceived and recognized to bring value to their daily lives. These can be done through:

- work conditions: office layouts, updated equipment, canteens, support to their busiest days
- training: which should be aligned with development needs
- incentives: payment levels and rewards on targeted objectives, career opportunities
- interaction: promote interaction among colleagues, especially within medium/big companies where some functions operate greatly apart (discussion forums; team building activities)
- respect working hours, weekends and holidays
- health care: provide medical and medical related services regularly
- healthy life: promote and support activities that could lead to an healthier life
- convenience services: help people's daily life compromises

Commitment takes three forms. It can be "affective" if the individual shares values with the company, "normative" if the individual feels pressured into complying and "continuance" when the employee cannot afford to leave. Only affective commitment leads to proactive behavior that creates value; the others encourage rule following and

over cautiousness[37]. I should be cultivated a culture of excellence, through performance, transparency, compliance and accountability, while leading by example.

2.2.9.2 - People's development

MA development should be discussed according to the individual expectations and company needs. It is important to define learning objectives and prioritize. Suggestions:

- ask MA opinion about important decisions that your group has to take
- ask them to think on alternative solutions
- incentivize direct reports to manage projects themselves, ensuring coaching and surveillance
- look for pragmatic approaches and recognize success promptly
- make sure that important decisions and shared problems are discussed face to face and not by email or telephone
- encourage delegation, send a clear message that Medical staff is just as essential as achieving financial objectives
- expose them to diverse leadership styles through mentoring relationships outside the usual hierarchy, and give those assignments where they have to master negotiating and influencing, rather than pulling.

2.2.9.3 - Recognition

Recognition does not need to be translated in financial benefits; non-financial recognition is also highly appreciated. Consider:

- recognition as part of your usual practice
- communication of impactful stories
- best sharing of ideas and practices
- welcome nominations from colleagues with a small description of the reason behind

2.2.10- Efficient systems and processes

2.2.10.1 - Laws, norms and guidelines

The number of laws, norms, codes and guidelines has been increasing, in particular during the last five years. Guidelines, both at international and national level, define criteria that should be used for the diagnosis, management, and treatment in specific areas. However, their interpretation and practical use has been controversial, namely because quality and innovation are sometimes overruled by direct cost-containment interpretation. Evidence should be collected, particularly local and reliable evidence, to sustain your arguments, present and discuss these both with decision makers and prescribers.

2.2.10.2 - Standard operating procedures

The internal SOPs of most pharma companies also increased dramatically in their number, as well as in their volume, updated versions and acronyms, making the reading and interpretation processes difficult to manage. Collaborators should ask for regular summaries of what is new, discuss about major changes, provide training and share illustrative examples.

2.2.10.3 – Electronic systems

New electronic systems have been created to respond to the record management, logistics and decision processes. Here again, some systems are frequently redundant and not fully compatible across businesses. Despite the currently existence of dozens of these, they are seldom used to respond to a specific request. Why? Because they might not be comprehensive enough, they might not be updated, they might not contain all the information that is requested and they might not cover a specific time frame of interest. Above all it is always better if there is somebody endorsing the report, instead of having a system generated sheet. There must be made an efficient use of the available systems.

2.2.10.4 – Multichannel communications

Medical knowledge is increasingly complex and specialized. The amount of information requested or important to respond to our specific customer needs, involve communication channels and networks that have to be better used.

HCPs but also patients and the general public are now regularly accessing internet chat rooms and web sites looking for health related information. In our days, 73.0% of the European patients search the internet looking for health information before they meet with their physician[38]. Two thirds of the Portuguese physicians search the internet on a daily basis looking for medical information and 96.0% do it at least once a week, while 28.0% of the HCPs use social media to inform, share and debate professional topics[39]. MA should listen and understand what is going on in such platforms, such as: hot topics, recurrent questions, needs/gaps of information, identify opportunities in some more neglected areas, and clarify concerns and misperceptions.

2.2.11- A set of pragmatic metrics

As the role of Medical continues to evolve, measuring Medical Affairs efficiency is of paramount importance. In order to ensure the right level of resources, teams are being pressured to provide greater management with metrics who demonstrate Medical Affairs activity, value and impact. Internal and external stakeholders benefit from the scientific, consistent, credible, proactive communication and the value added propositions made by MA, but it is important to agree on a set of pragmatic metrics that are able to translate the result of this effort. The traditional metrics applied to Sales and Marketing are mostly quantitative in nature and, if they are the only ones available, they will be inadequate to assess Medical Affairs outcomes. These are mainly based on the quality of the interaction, the insights gathered, the support delivered and the established relationship. However, they need to be accurate, adequately described, not too complicated and clear in terms of the impact generated.

2.2.11.1 - Hard vs soft metrics

The most fundamental, difference between a “target” and a “goal” resides in the way these are interpreted. Hard metrics are based on quantity, volume and dates, whereas soft metrics are much refined in nature and try to capture the activities that really have impact, irrespectively of their number. For example, a team might be delivering

consistently a target number of interactions requested by their manager; however, they may have gathered superficial opinions or responses, without gaining the real insight from the customers. This may lead to a biased strategic approach. By contrast, gaining deeper understanding of the environment, finding out the perceived value of our medicines, identifying opportunities to intervene and support the differentiation from competitors, makes all the difference. These value-creating aspects of the MA activity are soft, intangible things like information sharing or building relationships, which cannot be measured easily and only happen in committed, motivated teams. Another very important aspect of success on this regard is full accountability of the relationship which is being established.

In my understanding, every MA should have a list of customers under his/her responsibility. If these are shared, everyone is partly responsible and no one feels fully accountable. As motivation theories predict, individuals put in less effort when they know the blame for failure will be shared[37]. If the study objective is in line with the company strategy, it shows the effectiveness of the MA.[38] When starting a Clinical Trial, if the set of sites that MA has recommended achieved their targets in terms of patient enrolment, it is the quality of the outcome that are being measured too. To assess the Medical Affairs activity as a whole, then the third parties are the most appropriate to be used, in order to ensure a homogeneous approach and proper benchmark among companies[39,40].

2.2.11.2 - A comprehensive approach to metrics

While planning a set of metrics, one should consider them to be comprehensive (quantitative & qualitative), balanced, and relatively easy to understand and to measure. All in all they should be SMART (Specific, Measurable, Attainable, Relevant and Time bounded). The process should then move to a stage where a defined number of customers are attributed to MA person to engage with, develop relationships, identify their needs and interests and exchange scientific information. These interactions will hopefully allow the customer to increase the awareness of a certain therapeutic area, product or device, the upcoming studies and developments and the safety requirements, in order to improve the quality of the care provided to their patients (a series of examples are available for consultation in **Chapter VI)**.

2.2.12- A continuous improvement mindset

2.2.12.1 - Concentrate on core activities

Medical Affairs spend an important part of their time in non-core activities, such as: promotional and educational material reviews, presentation reviews, support to medical information queries, etc. It is more efficient to focus MA contribution in added value activities such as:

- permanent actualization and innovation
- identification of customer needs, proposing/supporting actions
- capture insights and explore opportunities
- incorporate new concepts/science in messages and processes
- incentivize research, publications and posters
- contribute for the adoption of more advanced, agile and less bureaucratic processes

2.2.12.2 - Incentivize pro-activeness and accountability

As in other areas of business, some Medical resources are more pro-active in organizing their work and prioritizing their activities, while others tend to wait until requests come or, orders are given to act. Having agreed on a specific set of objectives, MA should be allowed some freedom to act. Suggestions:

- prepare and commit the Medical team with the company's objectives
- regularly monitor the attainment of these, adapting whenever needed
- develop a greater sense of accountability and autonomy
- ask their own perspective on how to solve issues allowing them to lead some processes. If they succeed, fine! Otherwise analyses what went wrong and provide opportunities for improvement
- show appreciation and recognize positive inputs and results

2.2.12.3 - Gain additional support from global or regional levels

Multinational companies can centralize some common activities like educational and promotional core materials, slide kits, product monographs, translating and adapting them according to the core country requirements. These will then be reviewed locally, easing the burden from the affiliates. Anyway, there will always be opportunity for local material development, namely due to the country specificities such as: trainings, local congresses and symposia, but in general these could be substantially reduced. Some best practices include:

- centralization production of core educational and promotional materials
- producing them from the beginning according to the country specific requirements
- adapting label indications accordingly
- taking in consideration the prominent competitors at the country level
- preparing them on time (consider product launches and cycle meetings)
- monitoring quality and compliance at global and country level

2.2.12.4 - Improve communication

Communication is key, both for internal and/or external interactions namely in what concerns the use of the appropriate channels, clarity of the message content and opportunity. Therefore, MA should:

- convey clear and timely messages
- use the appropriate communication channels to eliminate conflicting perceptions
- avoid replication of emails and similar messages coming from different sources
- disseminate updated information on critical business topics on a regular basis
- monitor acknowledgment, identify gaps and solve them promptly
- share best practices
- use informal communication processes when appropriate

2.2.12.5 - Eliminate redundancies

Most of us experience requests of tables to fill in with data, or information that could be directly obtained from the actual systems in place. Therefore:

- make good use of the available systems
- make them more user friendly
- keep these regularly updated
- for questions, allow a reasonable time for response
- do not ask the same data from different channels – coordinate

2.2.12.6 - Regularly assess workload distribution

Due to an increase demand on Medical one should assess the workload and work/life balance, by:

- adopting internal metrics
- plan a reasonable workload and a balanced distribution
- benchmark workload among other colleagues
- discuss on regular meetings
- make pro-active suggestions for improvement
- manage time properly
- try to achieve a better workload/life balance for the team

2.2.12.7 - Make pragmatic evaluations of activity and impact

There should be a review of the focus of the activities (Fig. 6). Which ones are really impactful? Seize the opportunity: if developed in a considered and holistic way, Key Performance Indicators (KPIs) in Medical Affairs can provide a valuable platform for continuous improvement and capability development, as well as organizational alignment. One should consider how measuring, tracking and reporting any KPI will influence events in the organization. If the KPI does not influence decisions or behaviors then, we should not bother measuring it[41].

Traditional Focus	Proposed Focus
Efficiency and Costs	Broader MA value proposition
Operational/internal focus	Impact/extended focus
Short-term only	Short and long-term
Functional measures within MA	Functional measures & interface with partner functions
Evaluation	Alignment, involvement and evaluation

Figure 6: Evolution of performance management in Medical Affairs organizations (adapted from Kinapse Consulting, 2011)

An external survey performed across Europe by Pfizer in 2012, with a participation rate of 92.0% of the 595 customers interviewed, showed that Medical interaction is being appreciated and valued, with 88.0% of the responses attaining 5 or 6 in a scale of six points[16,42].

2.2.12.8 - Nourish a continuous improvement mindset

"*There's always room for improvement, for doing things better, more effectively and more efficiently. Continuous improvement is part of our ordinary course of business*,"[43] This is mainly based on seven main features:

- *systematic and sustained*: characteristics performed on a consistent basis, understanding that if not closely managed, processes tend to degrade over time
- *rigorous & data driven:* teach colleagues to measure efficiency, effectiveness, customer needs and return of investment. Explore examples. Be pragmatic
- *focused on the customer:* ask colleagues to think from the customers' point of view what they believe are the most valuable and critical needs
- *improve processes:* seek to improve overall process performance. Try to minimize errors, steps and time wasted, maximizing speed

- *consistent:* avoid customer experience variability
- *empowerment and collaboration:* involve and empower people closest to the problem and solve it. Share examples and promote a problem solving attitude
- *track outcomes:* emphasize continually tracking outcomes to ensure that the results achieved are consolidated and excelled.

2.2.12.9 - Fight for Reputation

It is hard to gain trust, because it takes time, requires consistent performance, compliance with standards, scientific rigor, transparency and quality of the services provided. However, the level of trust from the general public to the Pharma Industry is not high. To change this perception, one should:

- increase scrutiny in everything MA does by promoting responsibility and accountability at all levels
- avoid inadequate promotional messages or attitudes
- approve only materials of flawless quality
- respond in time and fully to specific questions
- despite all this cautions, if an error occurs, admit it and correct it promptly
- use new communications channels, be creative, anticipate tendencies
- focus on key messages
- invest in an open door policy, invite customers in. If allowed, make your premises available for scientific and patient associations or societies to run their own meetings.
- talk proudly about what you do

" Even when they are doing good, we always suspect that they have hidden interests"

Alexandre Borges, in *Introdução ao Pessimismo*

CHAPTER III - The Pharmaceutical Industry perspective

3.1- Introduction

This report analyses the results of the questionnaire presented to Pharmaceutical Industry professionals at all levels and functions, aiming to capture their perception of the Medical Affairs contribution to the business operations, both at national and multinational companies.

3.2- Methods

A structured questionnaire (Appendix I) covering the most relevant activities performed by the Medical Affairs personnel on a daily basis was created, tested and made available through email, to a sample of professionals people working in the Pharmaceutical Industry in Portugal, covering all areas of responsibility. These emails contained a link directly to Google[44] where the anonymous answers could be inserted. All the collected data were entirely confidential, governed under the observation of the law on Data Protection[45], and was automatically transposed to an Excel sheet, with the only purpose to produce this report. The data analysis was performed using the software: SAS Enterprise V4[46], Statistics V9[47] and JASP 0.8.6.0[48].

Our sample included Pharmaceutical Industry professionals at all levels and functions, both from national and multinational companies. Consulting the literature on this subject we found out that similar surveys performed through e-mail got a response rate of 17.3% while survey monkeys 27.7%[49]. A recent survey conducted in Portugal by Banco de Portugal for the International Monetary Fund with a similar method, got a response rate of 17.4%[50]. Taking in consideration that, according to APIFARMA[51], there were 6231 people working for pharma in 2013, we estimated the minimal requested sample size:

- Population: 6231
- Expected response rate: 27.7 %
- Worst acceptable result: 17.3 %
- Requested n for 95% confidence limits: 70
- Requested n for a confidence level of 99%: 120

Assuming a more demanding 99% confidence level and that 20.0% (24) of the responses could be incomplete, the minimum sample requested would be 144 (120 + 24). We have

not defined quotas per type of company because we did not have such level of detail. The author sent 400 emails, 61 of which were rejected (wrong email address), therefore considered invalid. The remaining 339 inviting emails generated a total of 169 questionnaires which were duly completed and considered for analysis. The response rate to this e-mail/web questionnaire was of 49.9% (169/339) and the incompleteness of some variables 10.0%, much better than expected.

3.3- Results: Descriptive Analysis

The range of specific roles of the 169 responders is illustrated below (Fig. 7). Medical Affairs, Commercial, Marketing and Medical Information acounts for 56.2% of the total respondents.

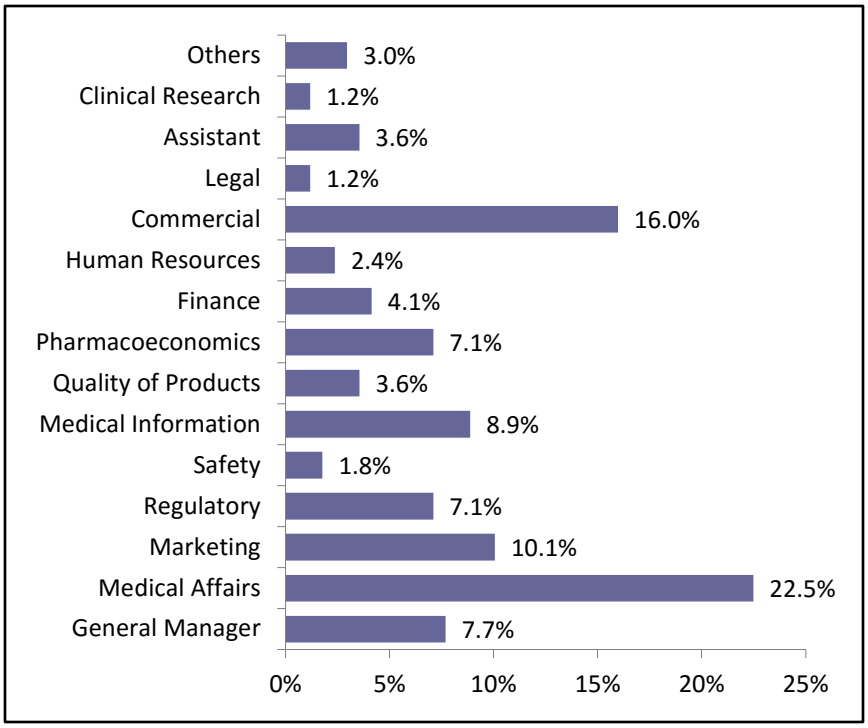

Figure 7 – Responders activity in pharma

In terms of gender the distribution was quite balanced with a small percentage in favor of the females (Fig. 8).

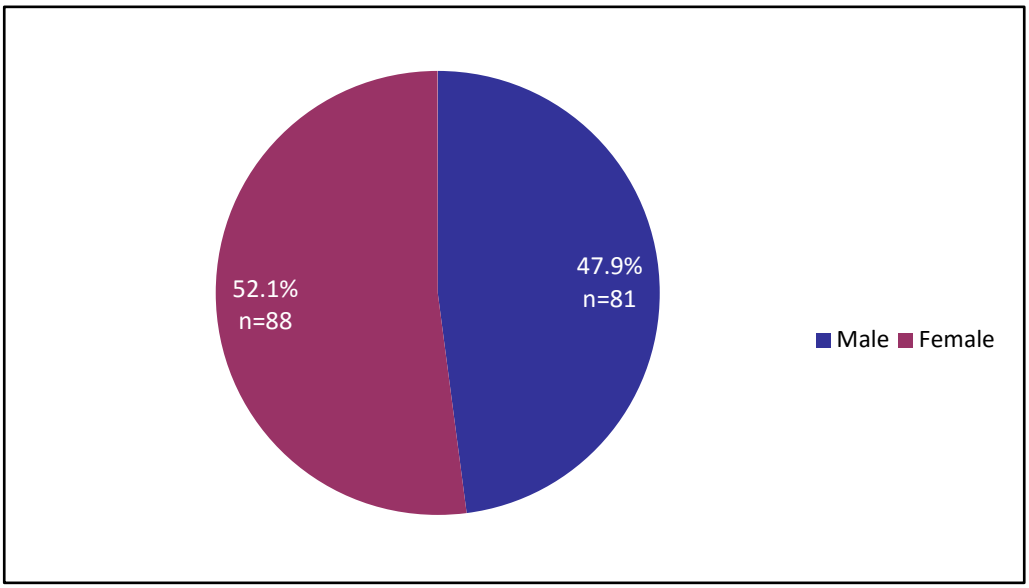

Figure 8 – Responders distribuition according to gender

The overall mean age was 42.4 years old (minimum=23; median=42; maximum=71; standard deviation (std)=9.04). The great majority of pharma professionals belong to age group of 35 to 44 years old (Fig. 9).

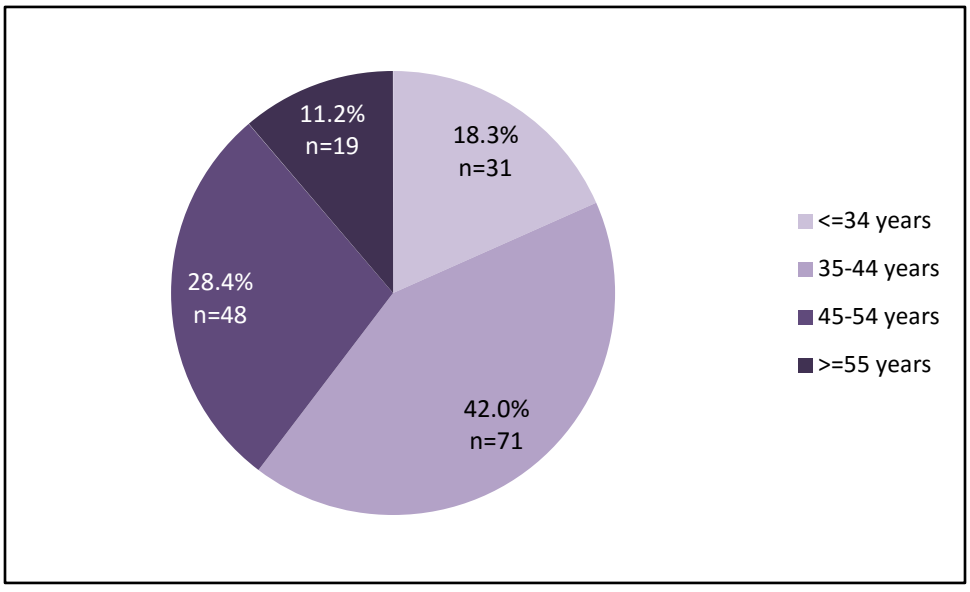

Figure 9 – Age distribuition

The average age of the male responders was 44.4 years old (median=45.0 years old) while 40.6 years old for females (median= 40years old). This difference was statistically significant (t=2.81; p=0.0055) and there was homogeneity of the variances of both groups (F=1.08; p=0.7263). There were no age differences between respondents per type of Company (t=0.43; p=0.6766 for unequal variances -F=2.25; p=0.0237), although National companies keep some colleagues at higher ages (Fig. 10).

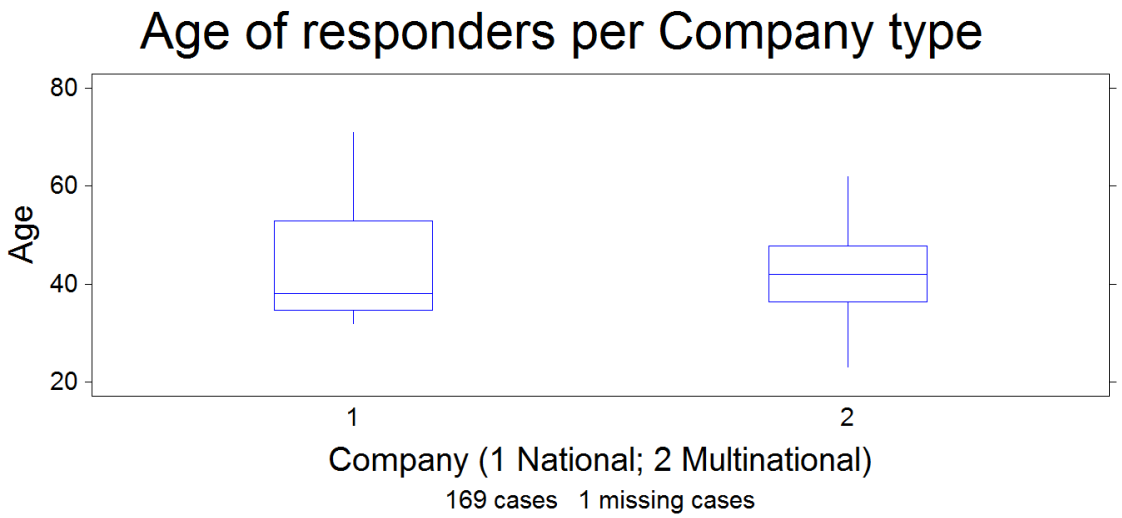

Figure 10 – Age distribution per type of pharmaceutical company

The majority of responders to this survey (92.3%) work for Multinational companies (Fig. 11).

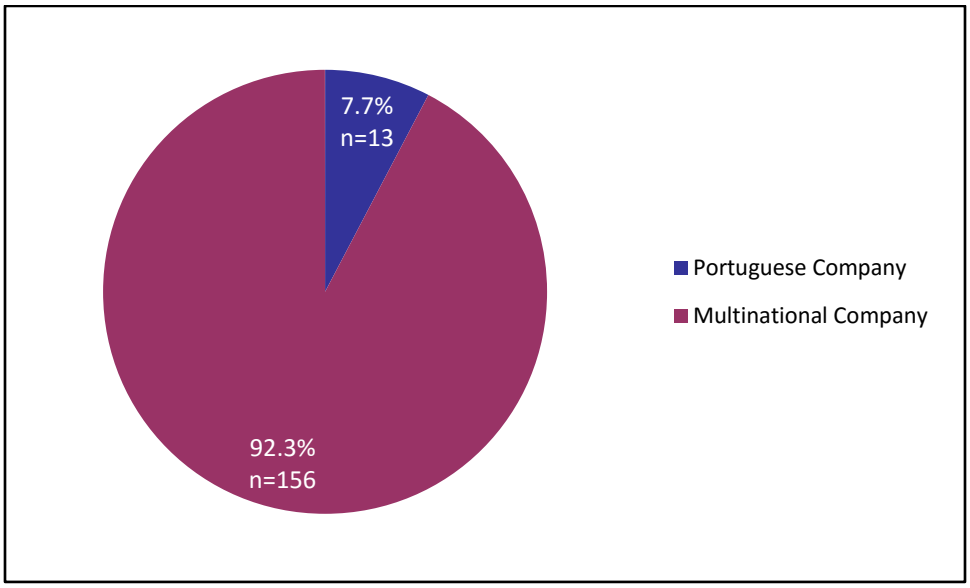

Figure 11 – Responders per type of pharma company they work to

In National companies, strategic decisions are taken by default at Local level. In Multinational companies, strategic decisions are thought to be taken at All levels (37.9 %) followed by Regional (22.5 %), Local (21.9 %) and Global level (10.1 %) - (Fig. 12). This distribution does not differ significantly by responders business area/ condition (Medical Affairs vs other; p=0.5754).

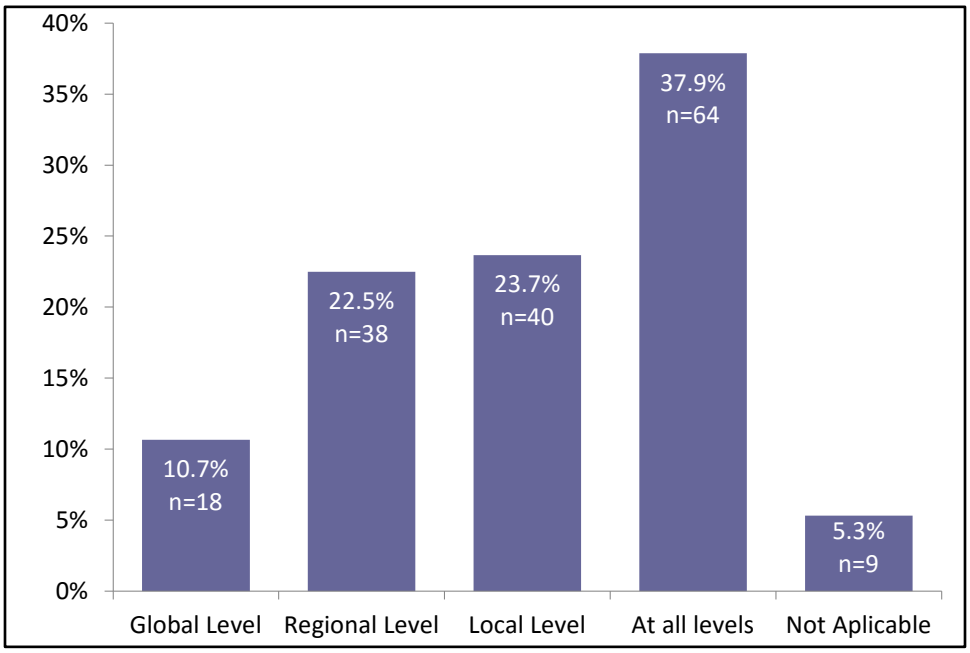

Figure 12 – Level of Strategic Medical Affairs Decisions in Multinational Companies

In Multinational companies, Medical Affairs should preferably report at “Both Central and Local levels” (50.3 %), “Locally to the General Manager” (27.2%), or “Centrally/Regionally” (16.6%) – (Fig. 13).

This distribution does not differ significantly by condition (Medical Affairs *vs* other; p=0.18654), meaning that the observed pattern is used not only for Medical Affairs, but across other functions.

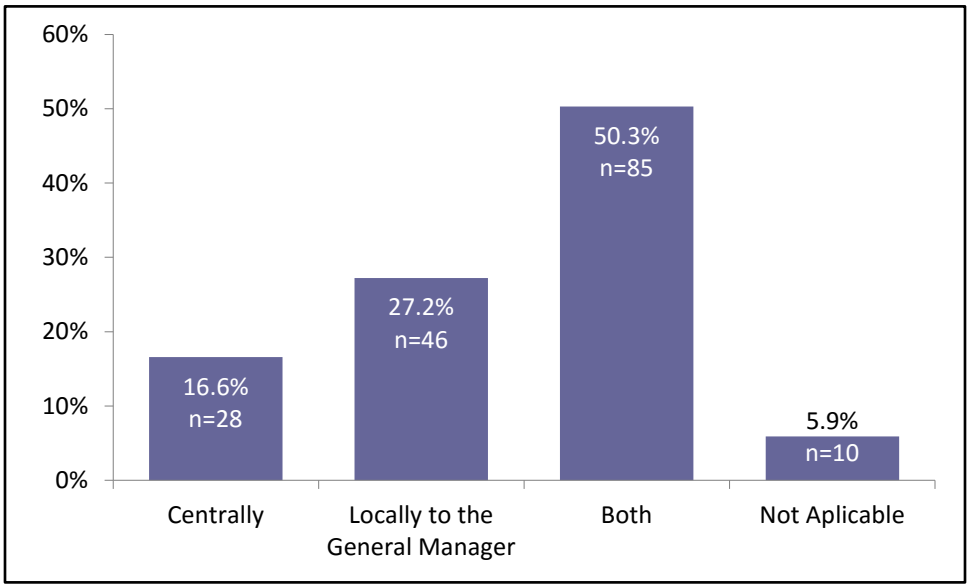

Figure 13 – In multinational companies, Medical Affairs should preferably report

In this sample 11.8% of the responders exercise their activity in companies with less than 100 employees, 9.5% up to 199 employees and 78.7% equal or over 200 people, with a minimum of 5 and a median of 220 (Fig. 14).

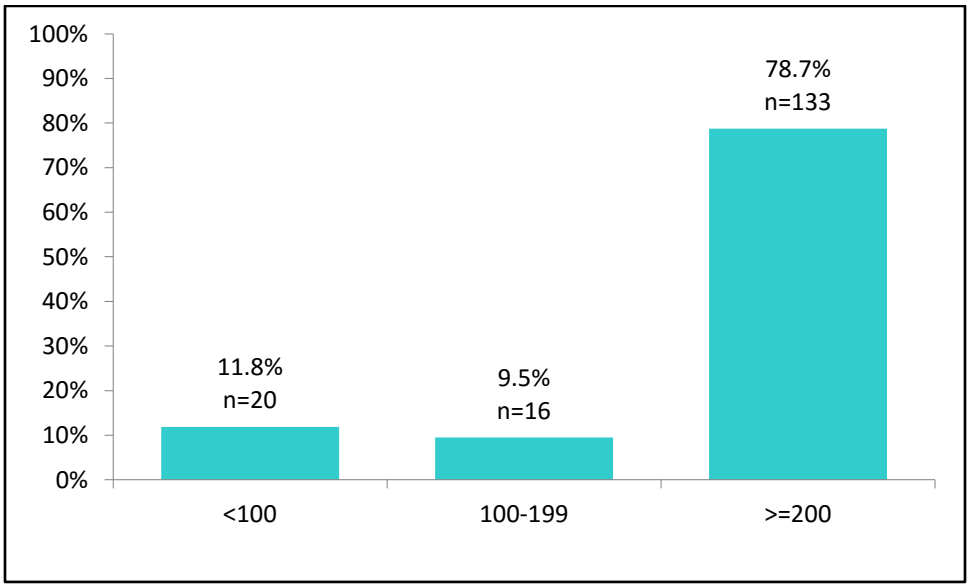

Figure 14 – Number of employees per pharma company of the responders

At National level, two persons worked for companies with "<100"employees, while 10 developed their activity in companies with ">=200"workers (there was one missing value). The sample distribution in Multinational companies was: 18 (11.5%) for the "<100" class, 16 (10.3%) for the "100-199" class and 122 (78.2%) for the ">=200" class.

The minimum number of Medical Affairs reported employees was one, with a median of 13 both in National and Multinational companies, whereas the maximum in Multinational was 52 while 13 at National ones (Fig. 15).

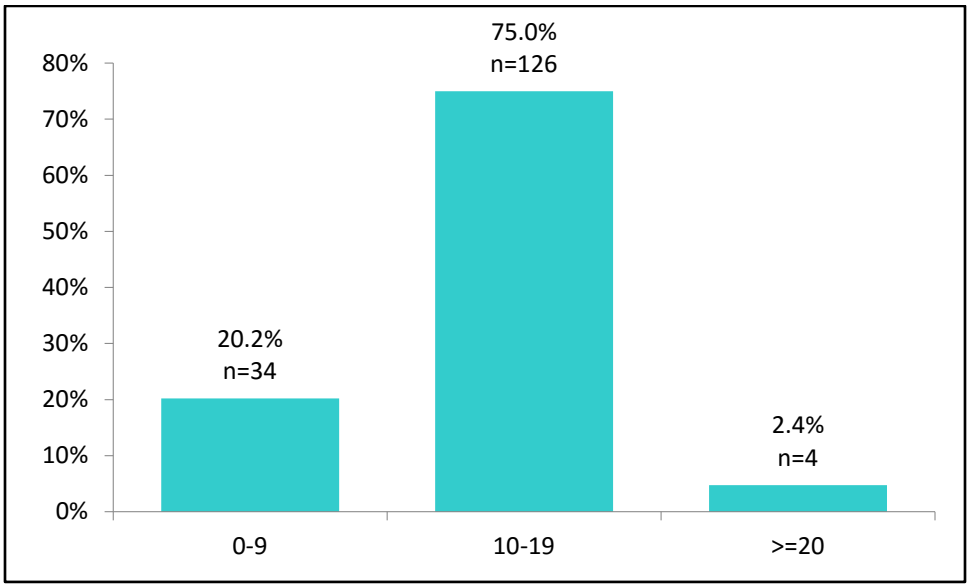

Figure 15 – Number of Medical Affairs resources in the Company

The importance of the Medical Affairs to the overall results of the company was very high rated; in fact, more than 90.0% ranked it as level 4 or 5 (mean=4.35; median=4.0; Fig. 16).

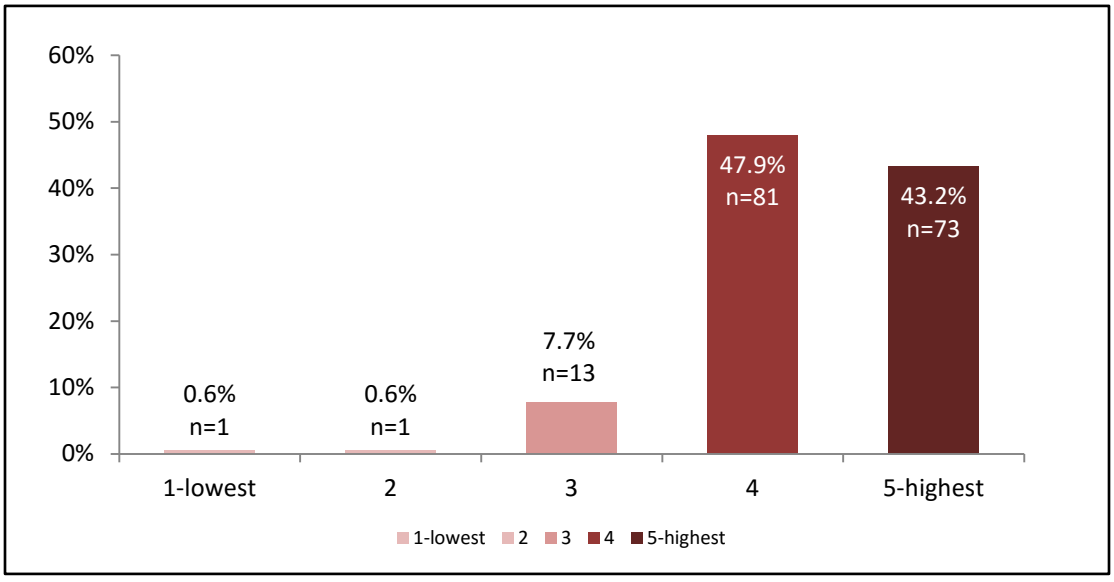

Figure 16 – Importance of the MA contribution to the overall results of the company

In terms of the contribution of Medical Affairs to "Strategic Activities", higher scores were given to: "Product Launch support" (median=5) and KOL mapping (median=5). Engagement, Business Development, Training, Medical Education and Medical Information were among the activities reported as "other" (Fig. 17, Table 1).

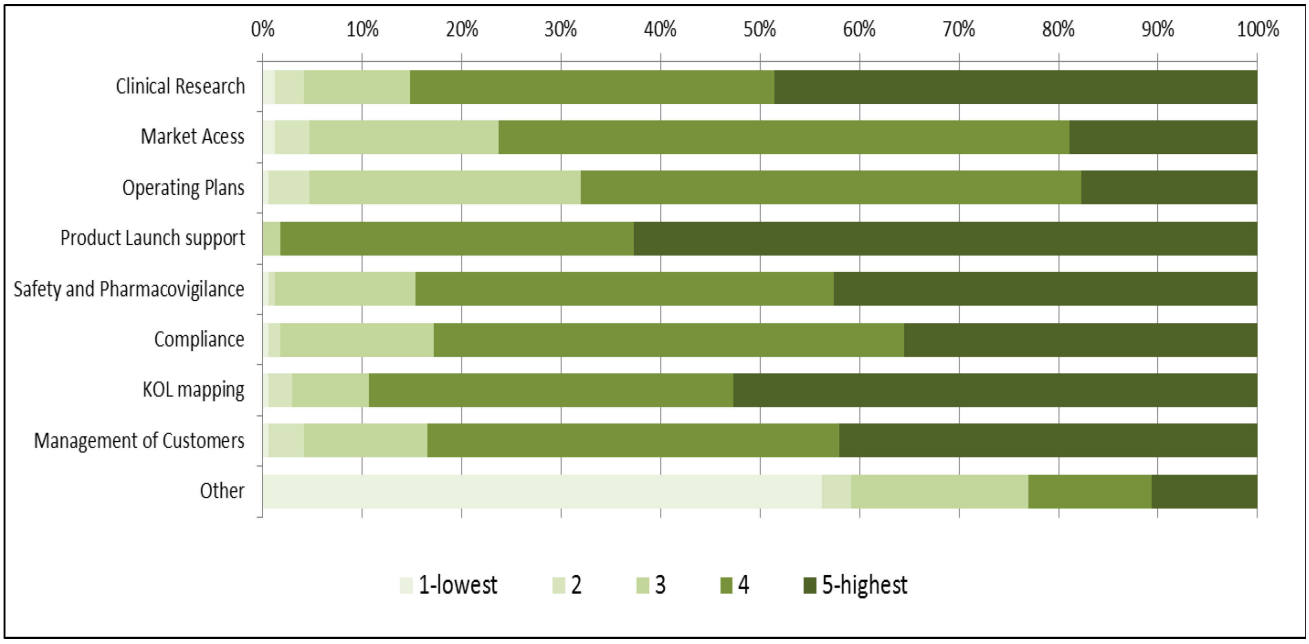

Figure 17 – Medical Affairs contribution to Strategic Activities

Table 1. Medical Affairs contribution to Strategic Activities

Parameter	Average	Median	Levels 4 and 5
Clinical Research	4.3	4	85.2%
Market Access	3.9	4	76.3%
Operating Plans	3.8	4	68.0%
Product Launch support	4.6	5	98.2%
Safety and Pharmacovigilance	4.3	4	84.6%
Compliance	4.2	4	82.8%
KOL mapping	4.4	5	89.3%
Management of Customers	4.2	4	83.4%
Other	2.2	1	23.1%

Higher scores were given to the following operational activities: “Education Materials preparation and review”, “Symposium preparation”, “Internal Training” and “Advisory Board preparation and management” (above 90% gave it 4 or 5 scores). Activities such as: Support to Clinical Research, Disease Awareness, Virtual Training and Virtual Forum, as well as Compliance, were mentioned as “other” (Fig. 18, Table 2).

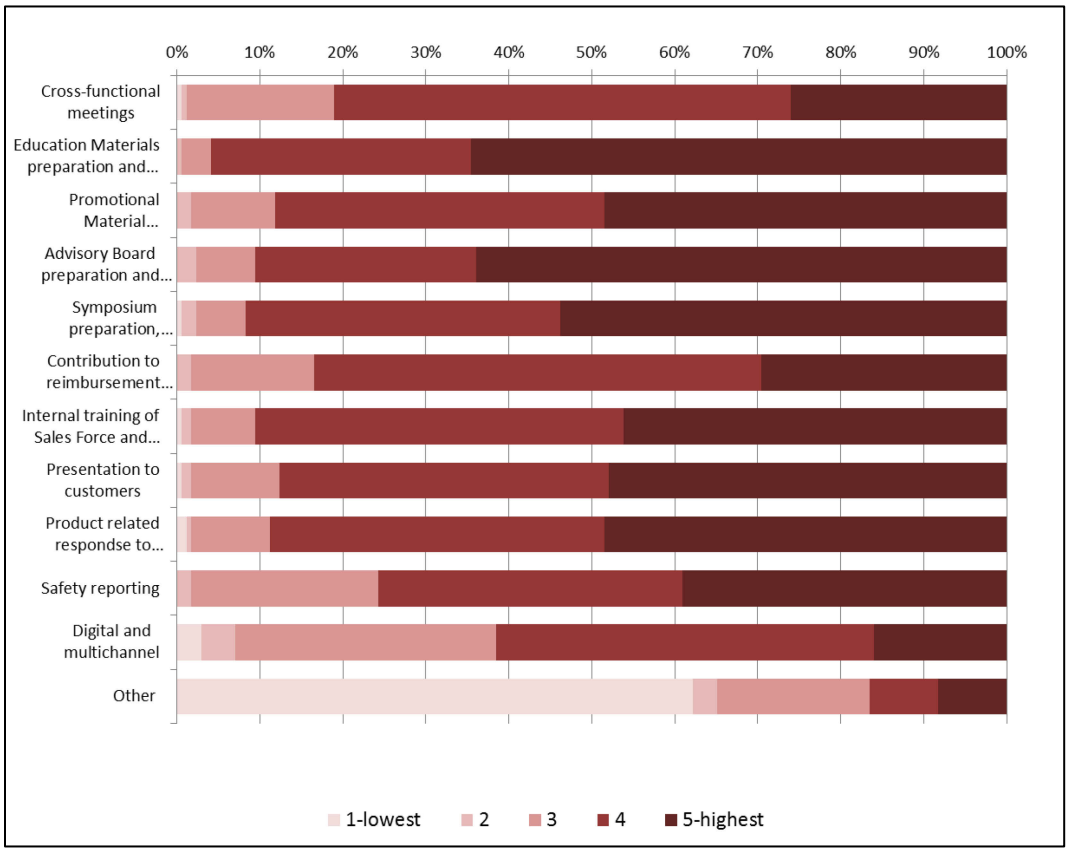

Figure 18 – Medical Affairs contribution to Operational Activities

Table 2. Medical Affairs contribution to Operational Activities

Parameter	Average	Median	Levels 4 and 5
Cross-functional meetings	4.05	4	81.1%
Education Materials preparation and review	4.60	5	95.9%
Promotional Material Preparation and review	4.35	4	88.2%
Advisory Board preparation and management	4.52	5	90.5%
Symposium preparation, invitation and content review	4.43	5	91.7%
Contribution to reimbursement dossiers	4.11	4	83.4%
Internal training of Sales Force and other colleagues	4.34	4	90.5%
Presentation to customers	4.33	4	87.6%
Product related response to questions	4.34	4	88.8%
Safety reporting	4.13	4	75.7%
Digital and multichannel	3.67	4	61.5%
Other	1.98	1	16.6%

The contribution of Medical Affairs to the "Digital & Multichannel Development and Implementation" did not score as high as the "Contribution to Strategic and Operational Activities", previously analyzed. However, there were some items that were rated by more than 80.0% as 4 our 5 , such as: "Preparing/reviewing Materials for Self-detailing" and "Training Materials for Health Care Professionals" (self-education); Market Research, Educational Quizzes, Linking Scientific interests were mentioned as "other" (Fig. 19, Table 3).

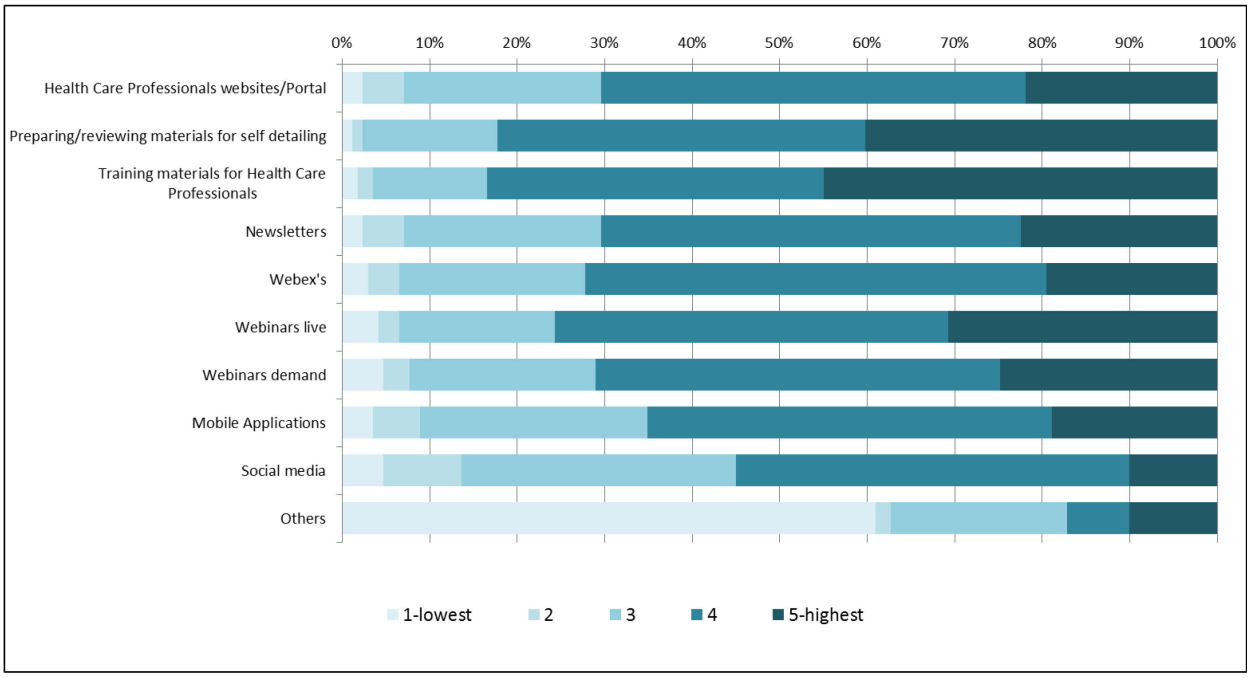

Figure 19 – Medical Affairs contribution to Digital & Multichannel implementation

Table 3. Medical Affairs contribution to Digital & Multichannel implementation

Parameter	Average	Median	Levels 4 and 5
Health Care Professionals websites/Portal	3.82	4	70.4%
Preparing/reviewing materials for self-detailing	4.18	4	82.2%
Training materials for Health Care Professionals	4.23	4	83.4%
Newsletters	3.83	4	70.4%
Webex's	3.82	4	72.2%
Webinars live	3.96	4	75.7%
Webinars on demand	3.83	4	71.0%
Mobile Applications	3.72	4	65.1%
Social media	3.47	4	55.0%
Other	2.03	1	17.1%

Considering the three main domains under evaluation:

- ***Strategic activities***
- ***Operational activities and***
- ***Digital and Multichannel development***

a similar number of scores were created for these major areas, related to the Medical Affairs contribution. The score is 0% if a respondent rated all items with "1" and 100% if a respondent rated all items with "5". From Table 4 one can conclude that respondents give higher importance to "Operational activities", followed by "Strategic activities", and finally "Digital/ Multichannel Development activities".

Table 4. Scores given to MA main domain activities

Score	Minimum	Q1	Median	Q3	Maximum	Average	STDev
Strategic activities	40.6%	75.0%	81.2%	87.5%	100.0%	79.9%	11.5%
Operational activities	40.9%	72.7%	84.0%	90.9%	100.0%	81.5%	12.1%
Digital and Multichannel	0.0%	63.9%	75.0%	83.3%	100.0%	71.8%	18.7%

Note: The score did not include rates for the question "Other"

Analyzing these scores by condition (Medical Affairs vs Others), statistical significant differences were only found for "Operational activities" (Median Test; p=0.0274) with higher scores for Medical Affairs respondents.

When recruiting a Medical Affairs person, the perceived most important Medical Affairs Characteristics to take in consideration by the responders were a "Problem Solving Attitude", "Pro-activeness" and "Flexibility" (median=5, above 90.0% rated 4 or 5) closely followed by "Competency". Academic Skills, Strategic Thinking, Leadership Skills, Communication Skills, Willingness to Learn, Creativity, Networking, Emotional Intelligence, Ethics and Compliance were also mentioned as "other" (Fig.20, Table 5).

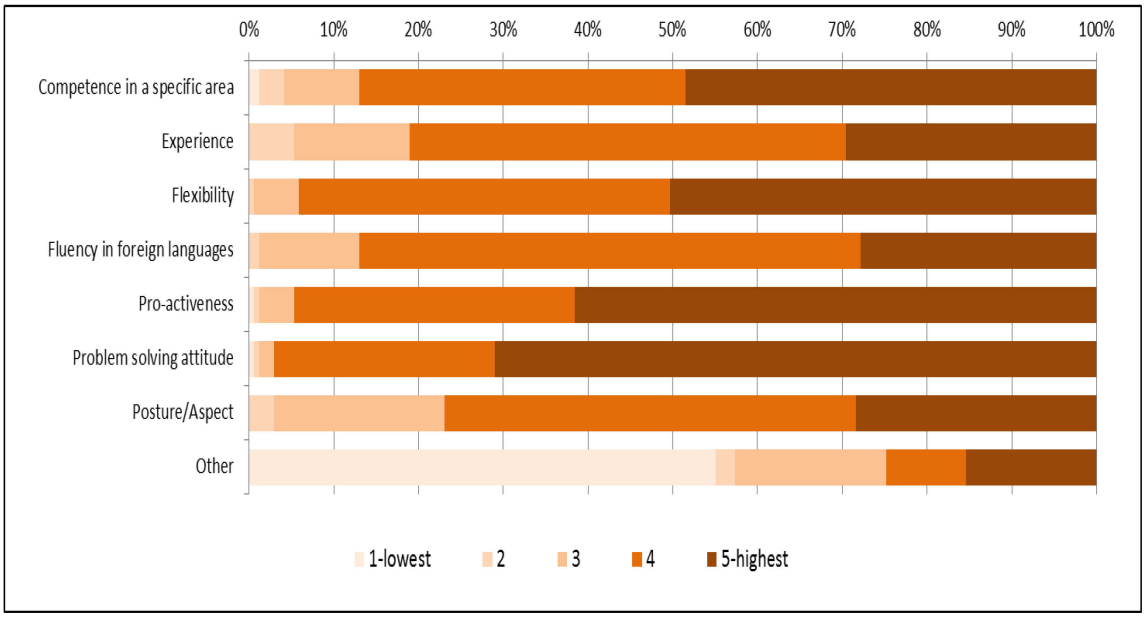

Figure 20 – Medical Affairs most valued characteristics upon recruitment

Table 5. Medical Affairs most valued characteristics upon recruitment

Parameter	Average	Median	Levels 4 and 5
Competence in a specific area	4.30	4	87.0%
Experience	4.05	4	81.1%
Flexibility	4.44	5	94.1%
Fluency in foreign Languages	4.13	4	87.0%
Pro-activeness	4.54	5	94.7%
Problem solving attitude	4.66	5	97.0%
Posture/Aspect	4.02	4	76.9%
Other	2.27	1	24.9%

The number of products considered reasonable for a Medical Affairs FTE to handle was considered by 35.1% of the responders to be “2”, while 23.2% mentioned “3” (average= 3.58 and median= 3). Nevertheless, 11.3% of the responders considered that “6 or more medicines” could be acceptable (Fig. 21).

Interestingly, in National companies the reasonable acceptable number of products has a median of “5” (38.5% of the answers) while in Multinational Companies it is only “3”

(24.4% of the answers). In these companies the preference goes to "2" (37.8% of the answers).

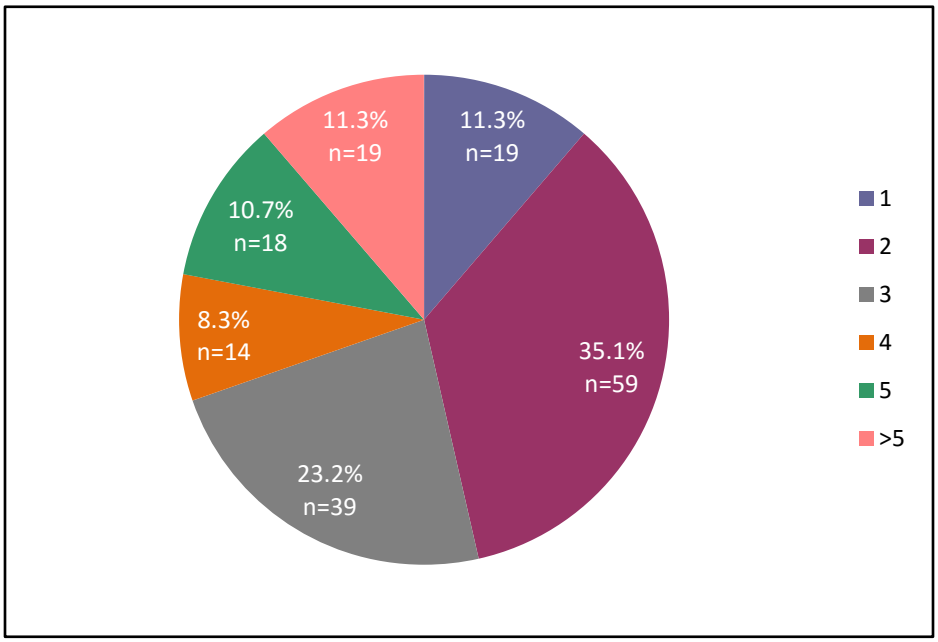

Figure 21 – Number of products a Medical Affairs FTE should have under her/his responsibility

During a product life cycle, the expected Medical Affairs FTEs considered to be needed was mainly reported to be 1 or 2. Some differences, however, can be acceptable along the way. "One year before launch" 36.7% of the responders believe that 1 FTE will be enough and that remains valid "Six months before launch" (36.1%). "At Launch" 2 Medical Affairs FTEs are stated as required, and this number of resources remains valid up to "Two years after launch". Thirty seven percent of the responders think that this allocation can be eventually reduced to 1 FTE three through five years after launch, or even "0.5" (40.2%) "After 5 years".

This is, of course, very much dependent on the prevalence of the disease, approved indications, product characteristics and competitors but, gives an insight on what level of resources are thought to be required (Fig. 22, Table 6).

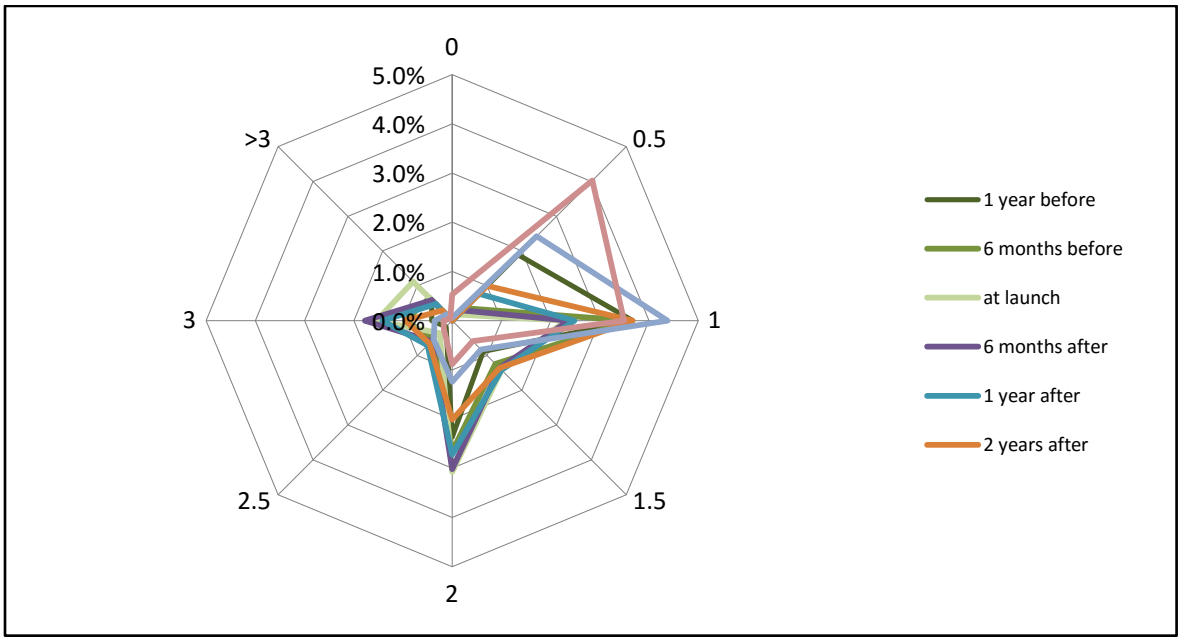

Figure 22 – Medical Affairs FTEs thought to be needed to support a medicine along its life cycle

Table 6. Medical Affairs FTEs thought to be needed to support a medicine along its life cycle

Time \ Nº of FTEs	0	0.5	1.0	1.5	2.0	2.5	3.0	>3	Total %
1 year before	0.0	18.9	**36.7**	8.9	23.7	1.8	4.1	5.9	100.0
6 Months before	0.0	3.6	**36.1**	12.4	26.6	5.3	9.5	6.5	100.0
At Launch	0.0	1.8	23.1	14.2	**30.2**	3.6	16.0	11.2	100.0
6 Months after	0.0	3.0	23.7	13.6	**30.2**	5.9	17.8	5.9	100.0
1 year after	0.0	7.7	24.9	14.2	**27.2**	7.1	14.2	4.7	100.0
2 years after	0.0	10.1	**36.7**	14.2	20.1	6.5	9.5	3.0	100.0
3 to 5 years after	0.6	24.3	**43.8**	8.3	12.4	5.3	3.6	1.8	100.0
> than 5 years after	5.3	**40.2**	34.9	5.9	8.9	2.4	1.8	0.6	100.0

Customer facing activity is highly regarded both by pharmaceutical companies and customers. In fact, 17.8% of the responders suggest that a Medical Affairs person should regularly interact with less than 5 customers, 18.9% considered that "5-10" would be reasonable and 63.3% accepted even a higher number (Fig. 23).

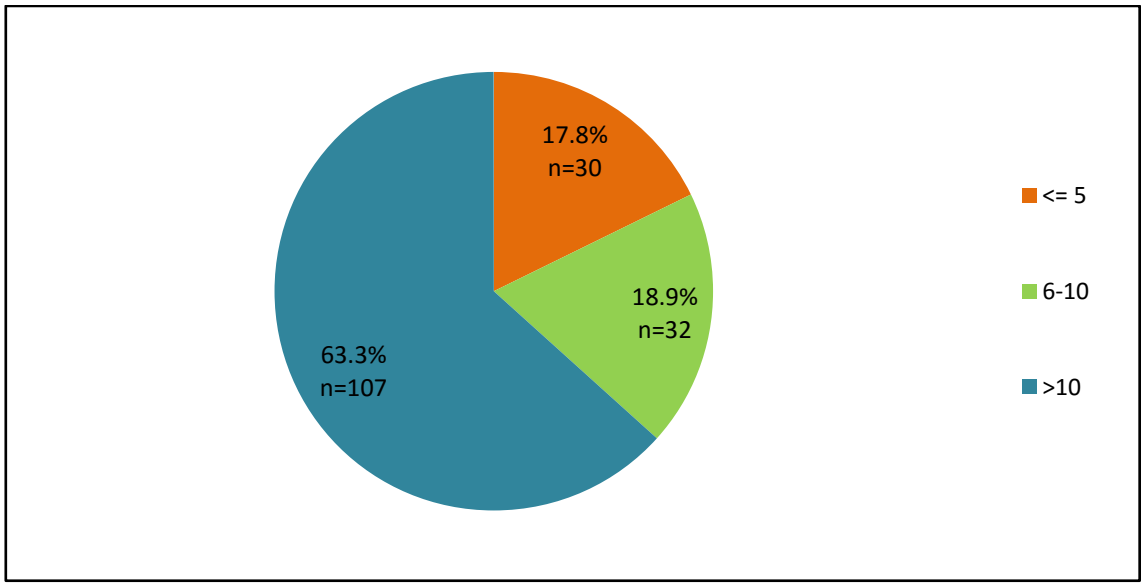

Figure 23 – Number. of customers a MA person should manage on his/her customer facing activity.

In general, all of the listed Medical Affairs activities were considered highly valuable (Fig. 24, Table 7), with average rating scores above 4. All activities mentioned below got high scores, being "Scientific Arguments" and "Scientific Updates" the most highly rated. Contribution for Brand Plans, Support to Clinical Research, Compliance, Contribution to Adequate Preparation and Review of Educational and Promotional Materials, Respond to Queries (Medical Information) and Coaching to Colleagues were among the activities regarded as "other".

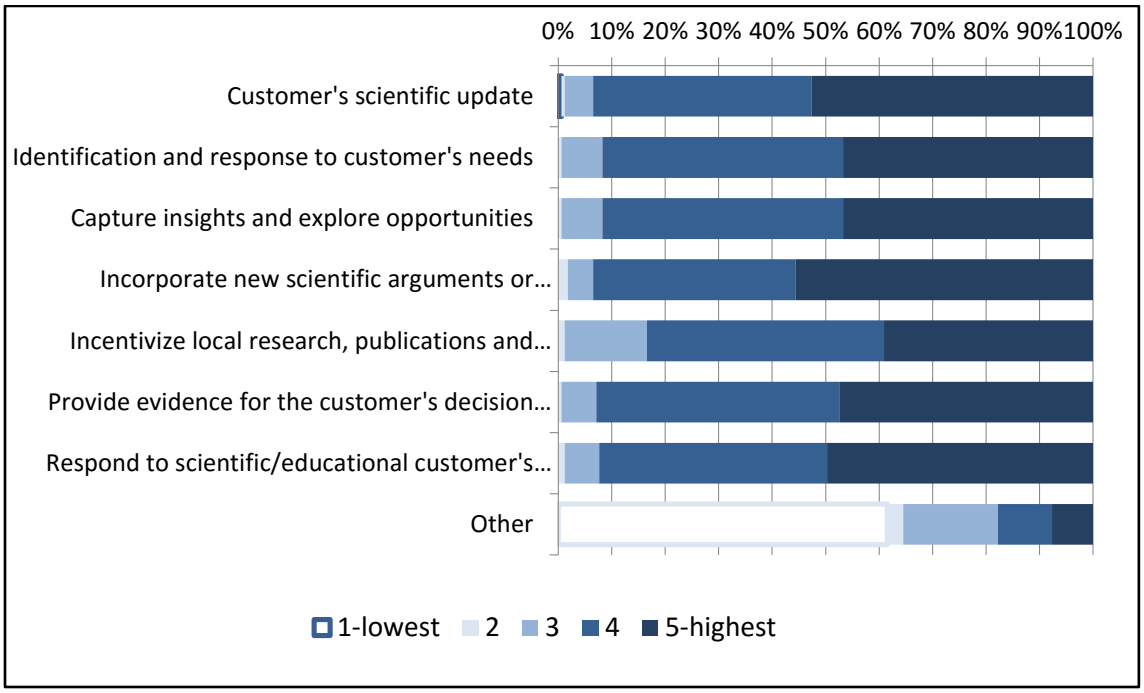

Figure 24 – Value of some Medical Affairs activities

Table 7. Value of some Medical Affairs activities

Parameter	Average	Median	Levels 4 and 5
Customer's scientific update	4.44	5	93.5%
Identification and response to customer's needs	4.38	4	91.7%
Capture insights and explore opportunities	4.27	4	91.7%
Incorporate new scientific arguments or differentiation messages	4.47	5	93.5%
Incentivize local research, publications and posters	4.21	4	83.4%
Provide evidence for the customer's decision making process	4.40	4	92.9%
Respond to scientific/educational customer's requests	4.41	4	92.3%
Other	1.99	1	17.8%

When asked about the level of efficiency of Medical Affairs if “Office based”, “Home based” or “Virtual”, about 74.0% respond that Medical Affairs resources are more efficient

when Office based (Fig. 25). The option "Other" was mentioned by 13.0% of the responders and basically referred to a hybrid or combined model.

No statistically significant differences were found regarding the responder's condition (χ^2=40.4; df 42; p= 0.5436), gender (t=-1.1; p=0.2811), or type of company (χ^2= 0.47; df 3; p=0.9251).

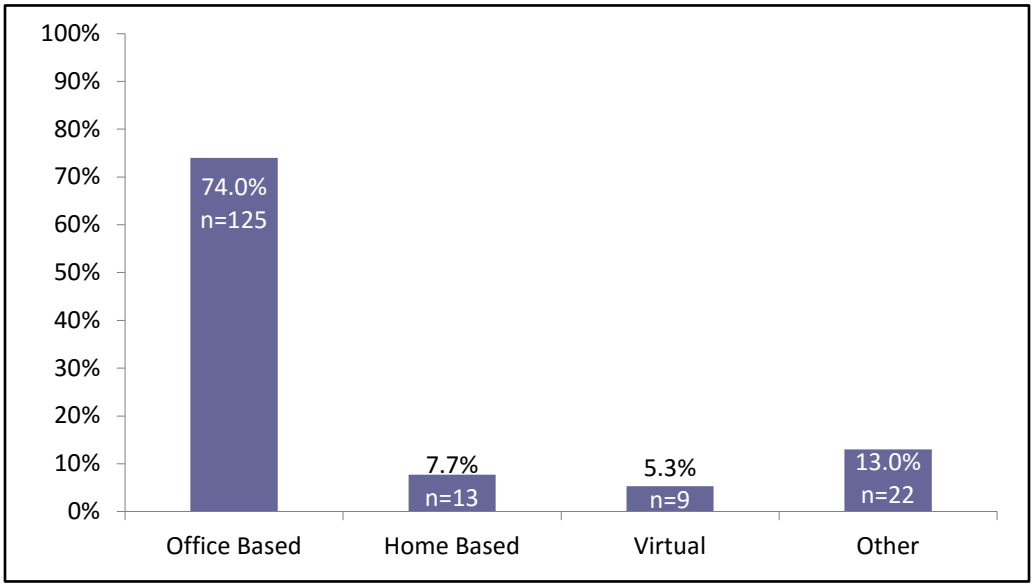

Figure 25 – How do see Medical Affairs resources being more efficient for the business.

In what concerns the Clinical Research Management "Internally with Company Resources" or by "Outsourced resources - CROs", about half of the responders think that Clinical Research is more efficient if performed by Company resources, whereas about 40.0% are in favor of a combination of both Company and Outsourced resources (Fig. 26).

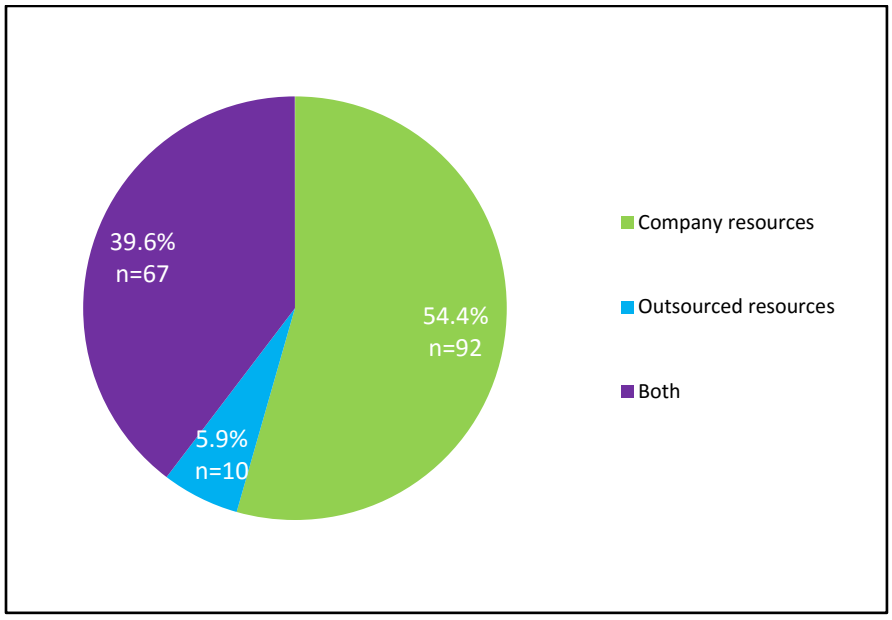

Figure 26 – Efficiency of Clinical Research per Internal or Contracted-out Resources

The most relevant factors impacting Medical Affairs Retention were: “Opportunities for Personal Development”, “Recognition” and “Work conditions”, which were rated by more than 89% as “4” or “5“(Fig. 27, Table 8).

Other aspects to take in consideration were: Culture & Values, Motivation and Commitment, Team Spirit, Brand Awareness, Professional Development and Credibility.

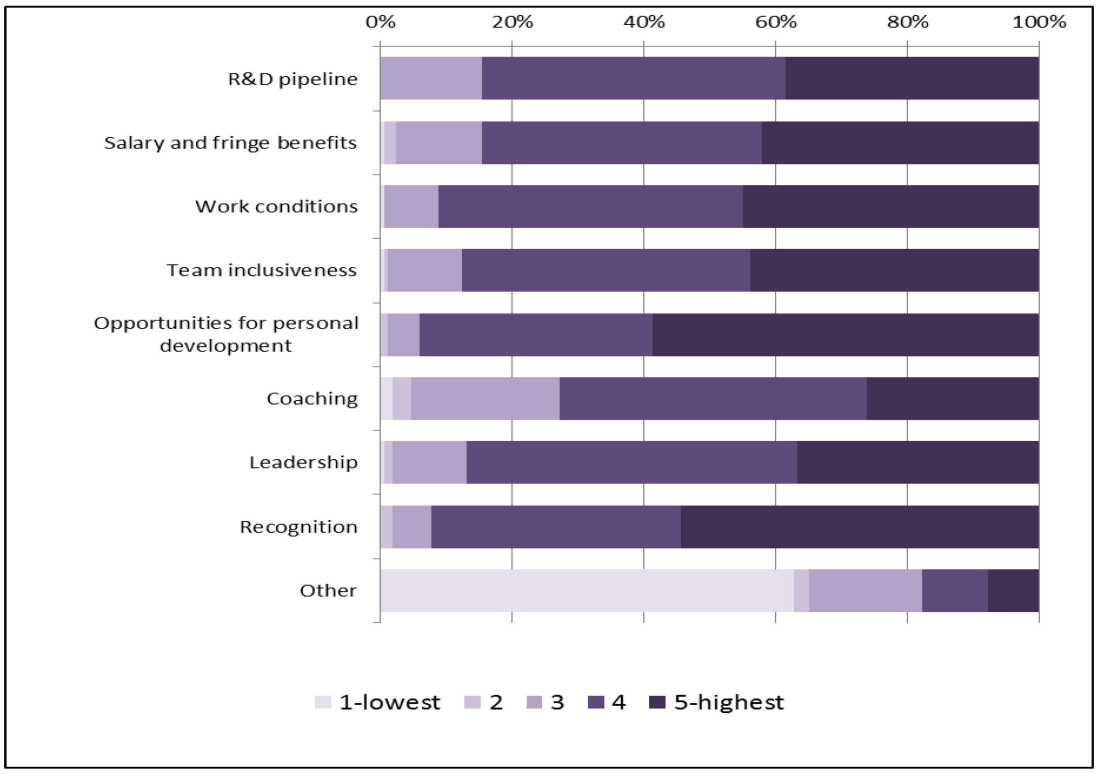

Figure 27 – Factors impacting Madecal Affairs retention

Table 8. Factors impacting Madecal Affairs retention

Parameter	Average	Median	Levels 4 and 5
R&D pipeline	4.23	4	84.6%
Salary and fringe benefits	4.24	4	84.6%
Work conditions	4.35	4	91.1%
Team inclusiveness	4.30	4	87.6%
Opportunities for personal development	4.51	5	94.1%
Coaching	3.92	4	72.8%
Leadership	4.21	4	87.0%
Recognition	4.45	5	92.3%
Other	1.98	1	17.8%

The contribution of the Medical Affairs to the “Company Reputation and “Credibility” was rated as “5” by 70.4% of the responders, and as “4” by 27.8% (Fig.28). There were no rates below “3” for this dimension.

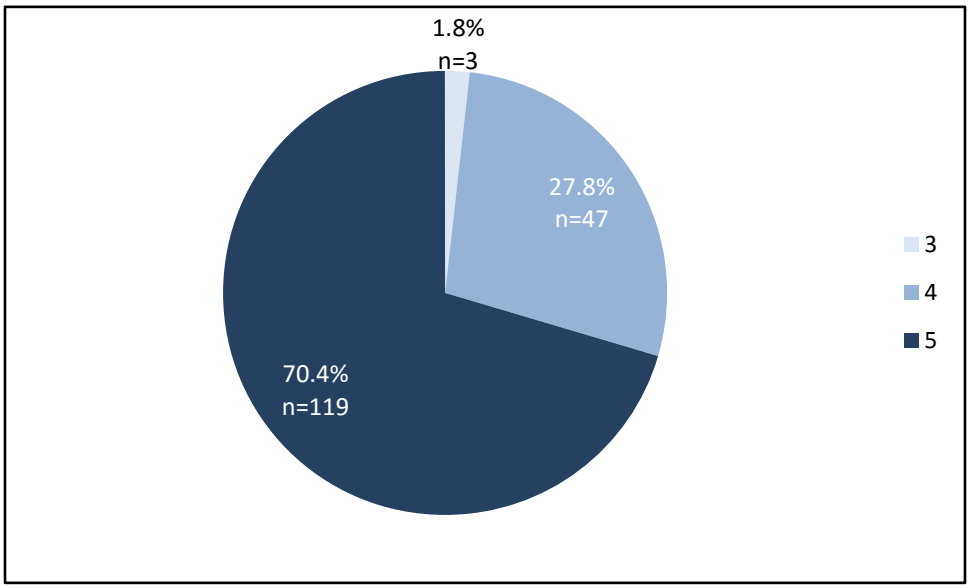

Figure 28 – Medical Affairs contribution to the Company Reputation and Credibility.

As for the future, 68.0% of all respondents forsee "More" operations involving Medical Affairs, while 29.0% believe that it will be "About the same". Only a minority of 3.0% admit that these could be reduced (Fig.29).

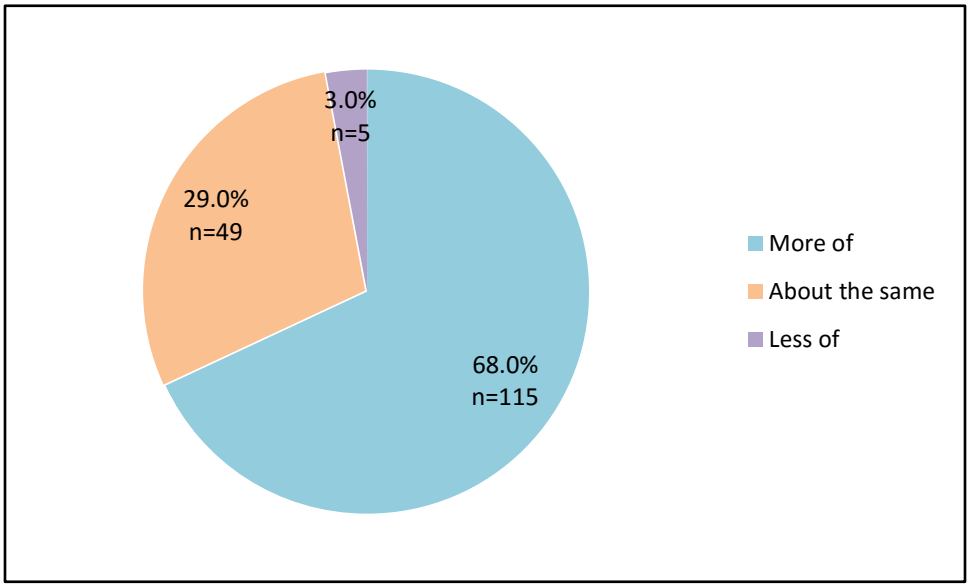

Figure 29 – Expected Medical Affairs contribution for the business operations in the future

3.4- Bivariate analysis

In addition to the descriptive analysis previously described, we have also explored through bivariate analysis (Appendix II) the results of the variables:

- **V9** - Medical Affairs contribution to the overall results of the company
- **V10**- How do you rate the Medical Affairs contribution to Strategic activities
- **V12** - How do you rate the Medical Affairs contribution to Operational activities
- **V14** – Assessment of the Medical Affairs contribution to Digital & Multichannel

and their relation with some responders characteristics such as: ***Participant Condition*** (V1), ***Gender*** (V2), ***Age Class*** (V3) and ***Company Type*** (V4), using the Man-Whitney test and One-Way ANOVA (with Bonferroni and Turkey Post-Hoc comparison test), and considering a significance level of 0.05.

The bivariate analysis of V9 **Medical Affairs** vs V1 **Participant Condition**, where (V1) was stratified as "Medical Affairs" vs "Other"; **Gender** (V2) "Male" vs "Female"; **Age Classes** (V3) "≤34" "35-44" "45-54" "≥55"; and **Company Type** (V4) "National" vs "Multinational", showed no significant differences between groups (Table 9).

Table 9. "Medical Affairs contribution to the overall results of the company" by Condition, Gender, Age Class and Company Type

	Condition (V1)		Gender (V2)		Age classes (V3)		Company type (V4)	
	W*	p	W*	p	F[&]	p	W*	p
V9	2873.000	0.108	3094.000	1.000	1.207	0.309	826.000	0.219

* Mann-Whitney test; [&] One-way ANOVA

However, it is worthwhile mentioning that the association V9:V1 estimated by the Odds Ratio was 1.65 (0.8016; 3.4219) $\chi 2$= 1.87 (p=0.1708). Meaning that, although not statistically significant, there was a probability 65.0% higher of Medical Affairs contributing to the overall results of the Company.

The bivariate analysis of **Strategic Activities** (V10) vs **Condition** (V1), **Gender** (V2), **Age Classes (V3)** and **Company type** (V4) are presented in Table 10.

Table 10. "How do you rate the Medical Affairs contribution to Strategic Activities" by Condition, Gender, Age Class and Company Type

	Condition (V1)		Gender (V2)		Age classes (V3)		Company type (V4)	
V10	W*	p	W*	p	F[&]	p	W*	p
V10.01	2471.000	0.943	3666.500	0.725	1.609	0.189	813.500	0.197
V10.02	2428.500	0.800	3170.500	0.166	2.557	0.057	914.000	0.511
V10.03	3058.000	**0.020**	2835.500	**0.013**	0.761	0.517	892.000	0.436
V10.04	2939.000	**0.044**	3262.000	0.260	2.618	0.053	1008.500	0.972
V10.05	2437.000	0.833	3631.500	0.819	3.874	**0.010**	1144.000	0.406
V10.06	2896.500	0.096	3283.500	0.338	3.050	**0.030**	885.500	0.412
V10.07	3028.000	**0.024**	2760.500	**0.005**	1.903	0.131	620.000	**0.010**
V10.08	2886.500	0.105	2590.500	**<0.001**	0.736	0.532	891.500	0.436
Average (V10.01:V10.08)	2959.000	0.076	2845.500	**0.023**	2.352	0.074	739.500	0.104

* Mann-Whitney test; [&] One-way ANOVA

Medical Affairs contribution was rated by MA responders with higher values to Strategic Activities such as **Operating Plans** V10.03 (p=0.020), **Product Launch & Support** V10.04 (p=0.044) and **KOL Mapping** V10.07 (p=0.024), when compared with other pharmaceutical industry professionals.

Females valued more than males the contribution of MA to **Operating Plans** V10.03 (p=0.013), **KOL Mapping** V10.07 (p=0.005) and the **Management of Customer Relations** V10.08 (p<0.001), as well as, the overall average of **Strategic Activities** (p=0.023).

Responders aged between 45 and 54 valued more the MA contribution to **Safety and Pharmacovigilance** V10.5, when compared to responders from lower age classes (p=0.010). Also, the 45 to 54 year old responders gave more value to MA contribution to **Compliance** V.10.6 than the ones with 34 years or less (p=0.030).

Responders from multinational companies recognize greater value to MA contribution to **KOL Mapping** V10.07 (p=0.010), when compared with responders from Portuguese companies.

The bivariate analysis of Operational Activities (V12:V1) by Condition, Gender, Age classes and Company type are presented in Table 11.

Table 11. "How do you rate the Medical Affairs contribution to Operational Activities" by Condition, Gender, Age Class and Company Type

	Condition (V1)		Gender (V2)		Age classes (V3)		Company type (V4)	
V12	W*	p	W*	p	F[&]	p	W*	p
V12.01	2789.500	0.209	2921.500	**0.025**	2.620	0.053	628.500	**0.012**
V12.02	2819.000	0.138	3556.500	0.979	1.162	0.326	807.500	0.147
V12.03	2292.500	0.416	3286.000	0.336	0.037	0.990	996.500	0.912
V12.04	3160.500	**0.003**	2801.500	**0.005**	0.578	0.630	810.000	0.157
V12.05	2815.500	0.167	2874.500	**0.015**	1.453	0.229	1019.000	0.976
V12.06	2555.000	0.785	3594.000	0.918	1.810	0.147	991.500	0.886
V12.07	2764.500	0.251	3121.000	0.123	3.143	**0.027**	1102.500	0.565
V12.08	3293.500	**<0.001**	3224.000	0.240	1.919	0.128	718.500	0.056
V12.09	2731.000	0.315	3572.500	0.978	3.930	**0.010**	1204.500	0.216
V12.10	2766.000	0.267	3371.500	0.519	1.745	0.160	1030.500	0.920
V12.11	2520.000	0.902	3175.000	0.190	2.880	**0.038**	1092.000	0.624
Average (V12.01:V12.11)	2995.500	0.056	2971.500	0.062	2.529	0.059	883.000	0.440

* Mann-Whitney test; [&] One-way ANOVA

Medical Affairs contribution for Operational Activities such as **Product Launch & Support** V12.04 (p=0.003) and **Management of Customer Relations** V12.08 (p<0.001), were better valued by responder MA colleagues, in comparison with other pharmaceutical industry professionals.

The support of MA for Operational Activities such as **Clinical Research** V12.01 (p=0.025), **Product Launch & Support** V12.04 (p=0.005) and **Safety & Pharmacovigilance** V12.05 (p=0.015), was evaluated with higher values by females than by male responders.

The younger responders (≤ 34 years) valued less the MA contribution to the Operational Activities of - **Social media** V12.09 when compared to responders with 35-54 years old and 45-54 years old (p=0.010), as well as, to **Digital and Multichannel activities** V12.11 (p=0.038). The contribution of MA to **Webinars** V12.07 was also evaluated with lower values by the responders with ≤ 34 years old or less, when compared with the older ones (p=0.027).

Responders from multinational companies recognized more value to the contribution of the MA to **Clinical Research** V12.01 (p=0.012) when compared with responders from Portuguese companies.

The bivariate analysis of Digital & Multichannel Activities (V14:V1) by Condition, Gender, Age classes and Company type are presented in Table 12.

Table 12. "Assessment of the Medical Affairs contribution to Digital & Multichannel" by Condition, Gender, Age Class and Company Type

	Condition (V1)		Gender (V2)		Age classes (V3)		Company type (V4)	
V14	W*	p	W*	p	F[&]	p	W*	p
V14.01	2239.000	0.312	894.500	0.450	1.552	0.203	894.500	0.450
V14.02	2549.500	0.807	830.000	0.242	1.495	0.218	830.000	0.242
V14.03	2609.000	0.625	811.000	0.195	0.939	0.423	811.000	0.195
V14.04	2590.000	0.684	1151.500	0.385	1.622	0.186	1151.500	0.385
V14.05	2314.500	0.474	1074.000	0.701	0.679	0.566	1074.000	0.701
V14.06	2268.500	0.376	953.000	0.703	0.721	0.541	953.000	0.703
V14.07	2131.000	0.150	988.000	0.872	0.599	0.617	988.000	0.872
V14.08	2480.000	0.973	852.500	0.310	0.718	0.542	852.500	0.310
V14.09	2256.000	0.350	973.000	0.799	2.298	0.079	973.000	0.799
Average (V14.01:V14.09)	2320.500	0.526	912.000	0.548	1.069	0.364	912.000	0.548

* Mann-Whitney test; [&] One-way ANOVA

No statistically significant differences were found to the assessment of Medical Affairs contribution to Digital & Multichannel Activities, across: Condition, Gender, Age classes and Company type.

3.5- Modeling

In addition to the descriptive and bivariate analysis already presented, we have also explored through regression analysis, to which extent the independent variables V10, V12 and V14 best explain (best fit) the results expressed by the dependent variable V9.

- V9 – Medical Affairs contribution to the overall results of the company
- V10 - How do you rate the Medical Affairs contribution to strategic activities
- V12 - How do you rate the Medical Affairs contribution to operational activities
- V14 – Assessment of the Medical Affairs contribution to Digital & Multichannel

3.6- Logistic regression

As, in general, most of the responses to these variables got very high ratings, the frequency distribution was skewed to the right (many 4s and 5s), we have decided to make a Logistic Regression approach (Appendix III), by considering two alternatives:

a) plotting the highest ranks (4-5) against the other ratings (1-3), so that the rating (4-5) would be "1" while all the others (1-3) would be "0"

b) plotting the highest rank (5) against the other ratings (1-4), so that the rating (5) would be "1", while all the others (1-4) would be "0".

For the plotting the (4-5) against (1-3) the area under the curve (AUC) of 0.9832 indicates a good discriminant power regarding the evaluation of the **Medical Affairs contribution to the overall results of the company**. It also means that 98.2% of the cases in the current model correctly predict this contribution, with a 100% sensitivity, 93.3% specificity and 99.4% precision.

The explicative variables are: **Product Related Response to Questions** V12.09 (p=0.018), **HCP Websites/Portals** V14.01 (p=0.015), **Preparing/reviewing Materials for Self-detailing** V14.02 (p=0.020), **Mobile Applications** V14.08 (p=0.005) and **Social Media** V14.09 (p=0.018).

This option (a) turned out to be one with highest concordance and the one we ended-up choosing (Table 13). Option (b) showed a lower AUC (0.848), sensitivity (76.7%), specificity (82.3%) and precision (76.7%) and therefore was left out.

Table 13. Logistic regression analysis by "*Enter*" method - response variable V9 (independent variables: V10, V12 and V14); (4-5) vs. (1-3)

	Estimate	Robust Standard Error	z	p
(Intercept)	-76.125	40.020	-1.902	0.057
V10.01	5.536	3.316	1.669	0.095
V10.02	-0.149	1.183	-0.126	0.900
V10.03	5.292	3.579	1.478	0.139
V10.04	9.432	5.652	1.669	0.095
V10.05	-6.539	4.149	-1.576	0.115
V10.06	-1.021	0.922	-1.108	0.268
V10.07	0.759	0.894	0.849	0.396
V10.08	4.354	3.263	1.335	0.182
V12.01	2.721	2.452	1.110	0.267
V12.02	-3.992	2.263	-1.764	0.078
V12.03	1.323	0.772	1.715	0.086
V12.04	2.848	1.683	1.692	0.091
V12.05	-3.501	2.639	-1.327	0.185
V12.06	-0.362	0.844	-0.428	0.668
V12.07	-1.098	1.682	-0.653	0.514
V12.08	3.615	4.162	0.869	0.385
V12.09	1.786	0.755	2.366	**0.018**
V12.10	6.854	3.857	1.777	0.076
V12.11	3.438	2.267	1.516	0.129
V14.01	7.156	2.933	2.440	**0.015**
V14.02	-3.546	1.520	-2.333	**0.020**
V14.03	-3.024	1.962	-1.542	0.123
V14.04	-7.195	4.498	-1.600	0.110
V14.05	-3.428	1.758	-1.950	0.051
V14.06	-1.817	3.649	-0.498	0.618
V14.07	4.324	3.335	1.297	0.195
V14.08	3.392	1.197	2.834	**0.005**
V14.09	-5.432	2.287	-2.375	**0.018**

3.7- Discussion

The results of this questionnaire were based on a sample of 169 responders with a wide range of roles. According to APIFARMA, there was a consistent decrease of professionals working for the Pharmaceutical Industry in Portugal of at least -18.0% since 2010 (-21.0% in Multinational Companies), being the estimated number of resources in 2013 of about 6231[51]. Therefore, although not representative in nature, the results of this survey should have been able to capture the feedback of about 2.7% of the Pharma Industry professionals at all levels.

In fact, in addition to Medical Affairs, the opinion of General Managers, Business Units Directors, Regulatory, Pharmacovigilance, Medical Information, Marketing, Sales, Legal,

Quality, Access, Business Technology, Distribution and Communication, contributed to a comprehensive evaluation of the relevance of the Medical function in a broad range of perspectives.

Most of the responders (92.3%) work for Multinational Companies, in line with the results published by APIFARMA where 82% of the Companies operating in Portugal are of such nature[51]. In terms of gender, the survey shows a greater percentage of female professionals working for Pharmaceutical Industry (52.1% vs 47.9% males). This percentage is even higher within Medical Affairs (63.2%). In another survey led by AMPIF[52,53] the percentage of female collaborators working in Medical Affairs Departments reached 78.0%.

The overall average age of the responders was of 42.4 years old, males being five years older than females. The great majority these pharma professionals belonged to the age group of 35 to 44 years old. A predominance of this age group has also been reported by AMPIF[52,53] (51.3%). National companies tend to have older professionals.

In National companies, strategic decisions are taken, by default, at local level, while in Multinational companies, these are thought to be taken at all levels, followed by Regional, Local and Global. This distribution is similar between Medical Affairs and other functions, meaning that this is a consensual evaluation across all areas of activity. Considering that the main strategy should come from the headquarters, it is relevant that about 22.0% of these strategic decisions are thought to be taken at Local level.

According to respondents, the reporting of the Medical Affairs in Multinational companies should be split both at Central and Local levels (50.3 %). However, locally is the preferred option to the General Manager, leaving centrally/regionally reporting in second place. This pattern is observed across all functions and reinforces the importance of the Local decision making power.

Out of the 169 responders to this survey, less than 10% worked for National, whereas 92.3% for Multinational companies. In this sample, nearly 80% exercise their activity in companies with less 200 employees, and the other were equally distributes among companies with 100 or 101 to 199 workers. Compared with the distribution made available by APIFARMA[51] on this regard, despite the different class intervals provided, it is likely that there was an over representation of responders from larger multinational companies in this survey, which was purely accidental.

There was no correlation between the number of total employees and MA resources per company, the ratio “Medical Affairs/total employees” varying from 3 to 120, with a

median value of 20. In addition, according with the AMPIF report, there are pharmaceutical companies operating in Portugal without a formal Medical Department in place[52,53].

The importance of the Medical Affairs on the overall results of the company was rated very high, with more than 90% of responses scoring level “4” or “5”. This is in line with the majority of papers and reports on the Medical Affairs role in Pharmaceutical Industry[19,52,53,54].

The association of the Medical Affairs contribution to strategic activities is higher for “Product Launch Support” and “KOL Mapping”, however, all the remaining listed dimensions such as “Clinical Research”, “Safety and Pharmacovigilance”, “Customer Management” and “Compliance” ranked very high.

Higher scores were also given to Operational Activities such as “Education Materials”, “Symposium Preparation”, “Internal Training” and “Advisory Board preparation and management”. A great deal of Medical effort is spent in “Content creation, Preparation and Review”, as well as in “Product Related Responses”, “Presentations”, “Contribution to Reimbursement Dossiers”, “Safety Management and Reporting” and internal “Cross Functional Meetings”, although some of these actions are not so visible, especially to general public. Therefore, it is interesting to acknowledge the recognition provided to it by these Pharma Industry professionals.

The “Digital and Multichannel Medical” labor is a relatively new component and as such, a little bit below the average rank. When specifically analyzed, there were some items that were rated by more than 80.0% as“4” and “5”, such as: “Preparing/reviewing Materials for Self-detailing” and “Training Materials for Health Care Professionals” (self-education). Other components of customer interaction like “Webexes and Webinars”, or “Newsletters” were also important and “Mobile Applications” in a crescendo of interest.

Despite its importance, “Social Media” was regarded at a lower level but it plays a major role in ensuring the adequate level of communication internally and externally, also in crisis management.

When analyzing the highest scores for the overall contribution of Medical Affairs to Strategic, Operational and Digital activities, stratified by condition (Medical Affairs vs Others), statistical significant differences were only found for “Operational activities” probably because colleagues pay more attention to the operational component of MA.

The recruitment of Medical Affairs positions requested to head hunters in our market, increased from 19.0% (2005-2010) to 47.0% (2010-2015), while Commercial positions decreased during the same time period, from 42.0% to 29.0%, and Marketing positions from 39.0% to 24.0%[12].

When recruiting a Medical Affairs person, the characteristics perceived as most relevant to take into consideration by the responders were: a "Problem Solving Attitude", "Pro-activeness and Flexibility" closely followed by "Competency".

The "Aspect" and "Posture" were seen as much less important". Other important attributes pointed out were: "Academic Skills", "Strategic Thinking", "Leadership Skills", "Communication Skills", "Willingness to Learn", "Creativity", "Networking", "Emotional Intelligence", "Ethics" and "Compliance".

The number of medicines considered reasonable for a Medical Affairs FTE to handle was found to be between "2 and 3". Nevertheless, 11.3% of the responders considered that "6 or > medicines" could be acceptable. This is certainly difficult to achieve in particular if one is dealing with several therapeutic areas but, unfortunately, it is not so uncommon.

During a product life cycle the expected number of Medical Affairs requested to ensure an adequate level of support was mainly reported to be "1 or 2" FTEs, even "3" during a certain period . This is of course very much dependent of the disease prevalence, disease awareness, target population, product characteristics, therapeutic gap supposed to be filled, type of market (Hospital vs Health Center driven), available budget and potential return of investment. Even so, it provides an insight on which level of resources is thought to be required and when to have them in place.

Customer facing activity is highly regarded both by pharmaceutical companies and customers. In fact, 17.8% of the responders suggest that a Medical Affairs person "should regularly interact with less than 5 customers", 18.9% considered that "5-10 would be reasonable" and 63.3% accepted even a higher number. In current practice the number of customers a Medical Affairs person interacts with is higher, frequently reaching "15 to 25". Again, the dedicated approach to these customers is similarly related with most of the parameters mentioned above. One thing is clear; the number of customers under the reach of a Medical Affairs person is much higher than what was expected, even by colleagues with other functions.

All listed Medical Affairs activities m got high scores, being "Scientific Arguments" and "Scientific Updates" the most highly rated. "Contribution for Brand Plans", "Support to Clinical Research", "Compliance", "Contribution to Adequate Preparation and Review of

Educational and Promotional Materials", "Responses to Inquiries" (Medical Information) and "Coaching to Colleagues" were among the activities regarded as "other".

When asked about the efficiency of Medical Affairs being "Office based" vs "Home based" or "Virtual", about three thirds responded that Medical Affairs resources are "More efficient Office based" and some mentioned a hybrid or combined model. The responders' condition, gender, or type of company did not impact this evaluation.

In what concerns the management of Clinical Research "Internally with Company Resources" vs "Conducted by Clinical Research Organizations", about half of the responders think that Clinical research is more efficient if performed by company resources, while about 40% defended a combination of both company and outsourced resources. The delegation of R&D activities on contracted resources (CROs) is of major relevance and concern, not only because they assume the face of the company while interacting with the investigators and investigational teams, but also because they frequently operate from outside the country, sometimes they are not native Portuguese speakers, they do not make the follow-ups so closely, nor they are so easily at reach. In addition, they tend to use the usual list of sites, limiting new entries; they do rotate quite frequently, making it difficult to establish a medium long-term relationship with the investigational teams and, they are frequently more costly[12].

The most relevant factors impacting Medical Affairs Retention were: "Opportunities for Personal Development", "Recognition" and "Work Conditions", which were rated the highest punctuations for more than 90.0% of respondents. Other aspects to take in consideration were: "Culture & Values", "Motivation and Commitment", "Team Spirit", "Brand Awareness", "Professional Development" and "Credibility". "Being proud of working for pharma", "Demonstrating the value of M. Affairs for patients, HCP and the population as a whole[55], is something that worthwhile mentioning too. The contribution of the Medical Affairs to the Company Reputation and Credibility was very highly rated.

This is the reflex of seriousness, rigor and compliance directly associated with the Medical Affairs contribution for the business and the differentiation from Marketing and Commercial activities. This is also recognized by other external surveys[54].

Looking at the future, the majority of the respondents forsee a "Greater Involvement of Medical Affairs"; nevertheless nearly one third believe that it will be "similar" or even "reduced".

The exercise of multivariate analysis and modeling reinforced the recognition of the Medical Affairs contribution to the overall results of the company, both from the Strategic

and Operational point of view. Clinical Research, Product Launch and Safety & Pharmacovigilance, were better rated by females. Younger responders (≤34 years) valued less the MA contribution to Social Media, Digital and Multichannel activities, while multinational industry professionals recognize greater value in the MA contribution to Clinical Research.

Product Related Response to Questions, support to HCP Websites/Portals, the Preparation and Review of Materials for Self-detailing, Mobile Applications and Social Media were the variables that better explain the higher response rates on this dimension.

3.8- Conclusions derived from the questionnaire to Pharma

In National companies Medical Affairs usually report to the General Manager, while in multinational companies MA should report to both central and local levels.

The strategic contribution of MA is considered particularly important to:

- Support product launch
- KOL mapping and management
- Clinical Research
- Safety and Pharmacovigilance
- Customer management
- Compliance
- Support to Market Access but, Business Development, Training and Medical Education were also mentioned.

The Operational contribution of MA is particularly rated in terms of:

- Education materials preparation and review
- Symposia preparation
- Internal Training
- Advisory Boards preparation and management
- Clinical Research

The contribution of MA to Digital and Multichannel development and implementation is particularly valued in:

- Preparation & review of materials for self-detailing
- Training materials for HCP
- Webinars

- Newsletters
- WebEx's
- Mobile applications

When recruiting a MA person, the most important attributes were said to be:

- A problem solving attitude
- Proactiveness
- Flexibility
- Competency
- Experience
- Posture/aspect
- Academic skills
- Strategic thinking
- Leadership skills
- Communication skills
- Willingness to learn
- Creativity
- Networking
- Emotional intelligence
- Ethics and compliance

MA are said to be more efficient if they are office-based, although a combined model (office/home) could be also considered, depending on size and reach.

Clinical Research should be managed preferably internally with company resources; outsourcing is a second choice.

The most important factors to influence MA retention are:

- Opportunities for personal development
- Recognition
- Work conditions (salary & fringe benefits)

Other relevant aspects to consider are: team inclusiveness, R&D pipeline and leadership.

The MA contribution to both company reputation and credibility was considered paramount.

In the future, MA resources will tend to increase.

The exercise of multivariate analysis and modeling reinforced the recognition of the Medical Affairs contribution to the overall results of the company both from the Strategic and Operational point of view.

"The real voyage of discovery consists not in seeking new lands but, in seeing with new eyes".

Marcel Proust

CHAPTER IV - The Customer's perspective on the value of Medical Affairs

4.1- Introduction

The following section presents the results of the questionnaire addressed to customers with whom Medical Affairs interact on a daily basis, such as Physicians, Pharmacists, Nurses, Health Administrators, Regulatory Authorities, Investigators, Faculty Professors and Administrative staff. It aimed to capture their perception of the Medical Affairs contribution to service provided by pharmaceutical companies.

4.2- Methods

A structured questionnaire was sent out by email to an unselected sample of customers on April 2015 (Appendix I). These emails contained a link directly to Google[56] where the anonymous answers could be inserted. All the data collected was entirely confidential, observing the law on Data Protection[45] and were automatically transposed to an Excel database with the only purpose to produce this report. The data analysis was performed using the software SAS Enterprise V4[46], Statistics V9[47] and EpiInfo V6[48].

For this questionnaire no sample size was previously determined. All customers we had an e-mail address were targeted. Due to the limited number of customers for which we had an e-mail address, we have not defined quotas per type of institution. A total of 197 emails were sent, 13 of them were rejected (wrong e-mail address), and 40 answers were received (40/184). This translates in a response rate of 21.7%. From these 40, the data was only available for all the variables in 36 (90.0%).

4.3- Results

The participation per type of responding customer shows that 58.3% of the valid contributions came from Physicians, 22.2% from Universities, 5.6% from Regulatory Authorities or Pharmacists, and 8.3% from other sources such as: Legal, Health Administration Board Members and Administrative Support staff (Fig.30).

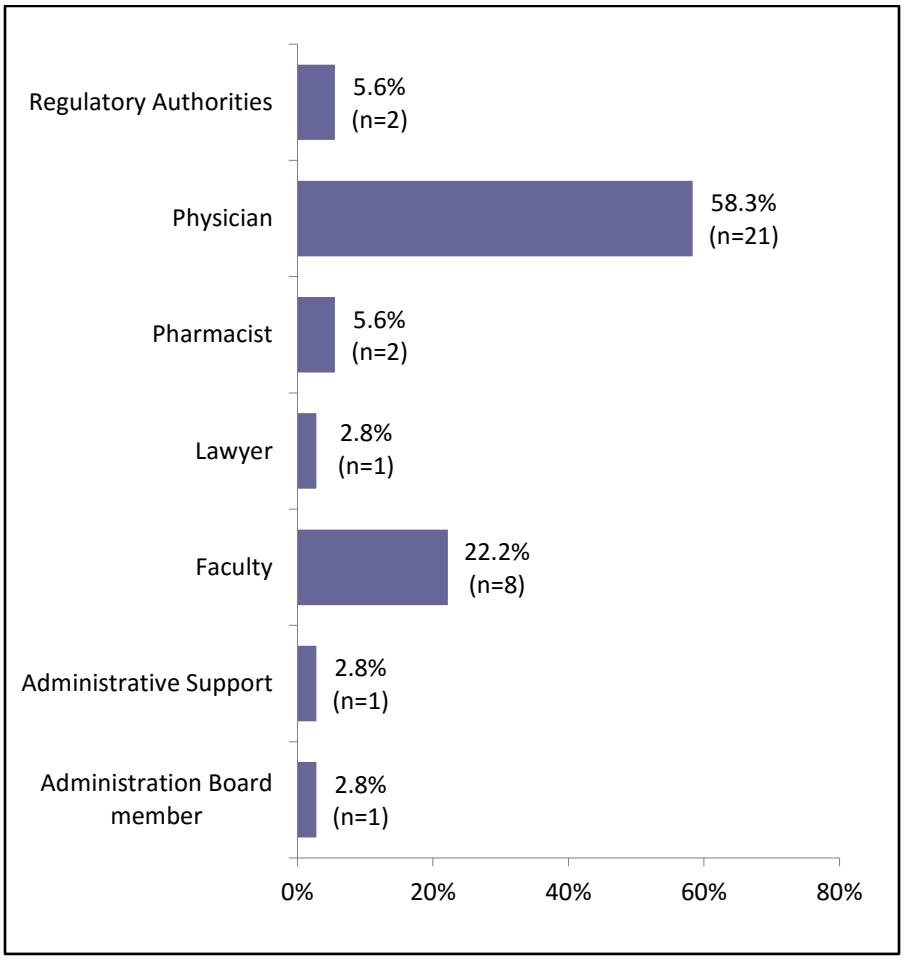

Figure 30- Type of responding customer

In terms of gender (Fig. 31), most of the responders were males (72.2%), the majority having 45 years old or more (Fig. 32), with a mean age of 56.1 years old and a median of 58.0 years old (Fig.33).

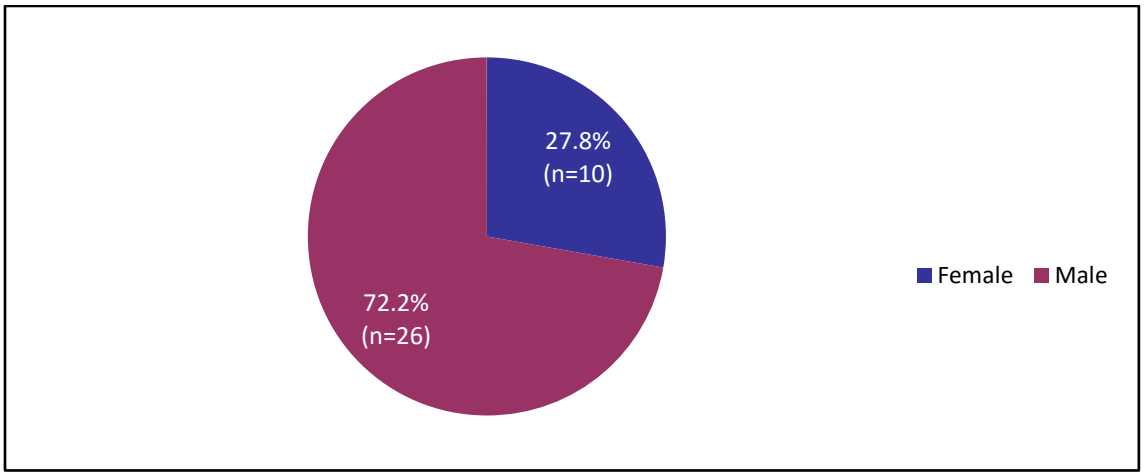

Figure 31- Customer distribution according to Gender

The females account for 27.8% of the responders (Fig. 31) with a mean age of 48.8 years old and a median of 48.0 years old (Fig. 33) .

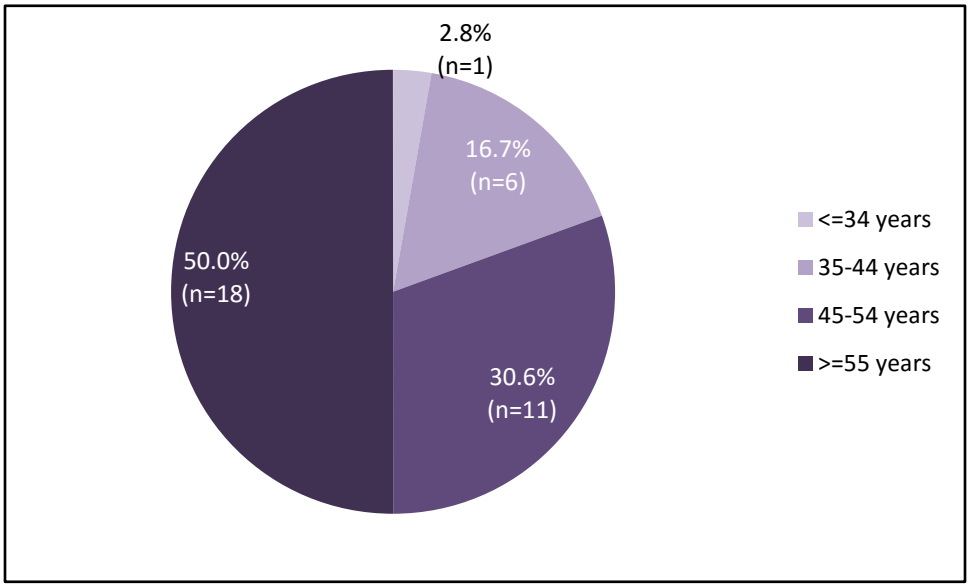

Figure 32- Customers distribution according to the Age group

There was homogeneity of the variances of the age distribution in both groups (F=2.65; p=0.0651), therefore the T Test for these independent groups was applied (T=1.91; p=0.0641) showing no statistical significant difference of the means.

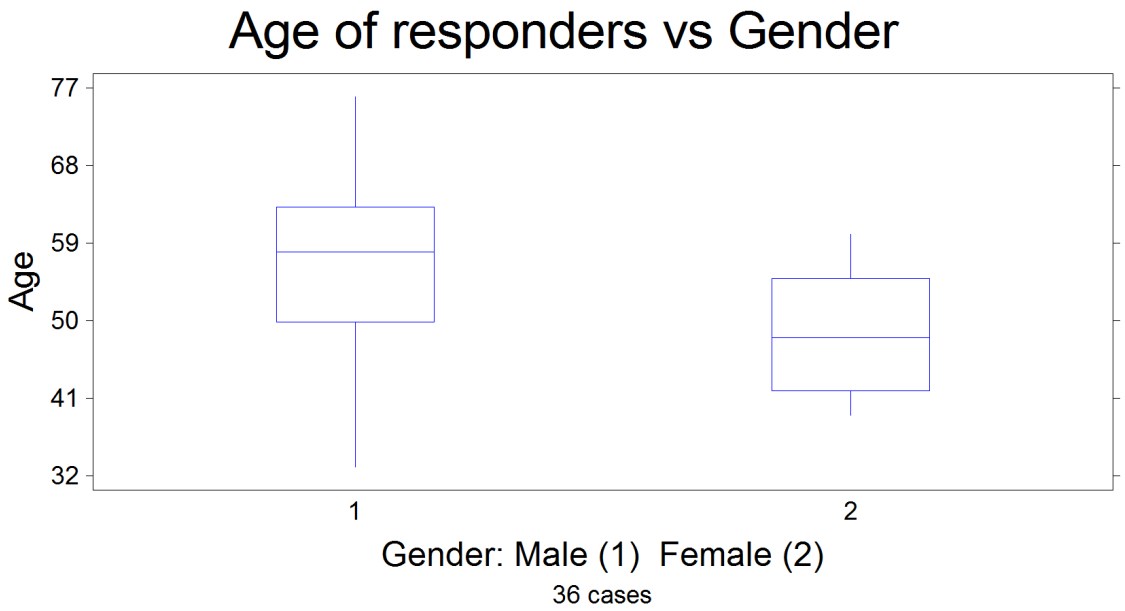

Figure 33 – Age distribution by gender

In what concerns the type of institution they work for (Fig. 34), 36.1% of respondents develop their activity for the "National Health Service", while a similar percentage (33.3%) work in "Private settings". Seventeen percent have "State related activities other than SNS" (most Universities or Research Centers) and 13.9% work in "Other areas".

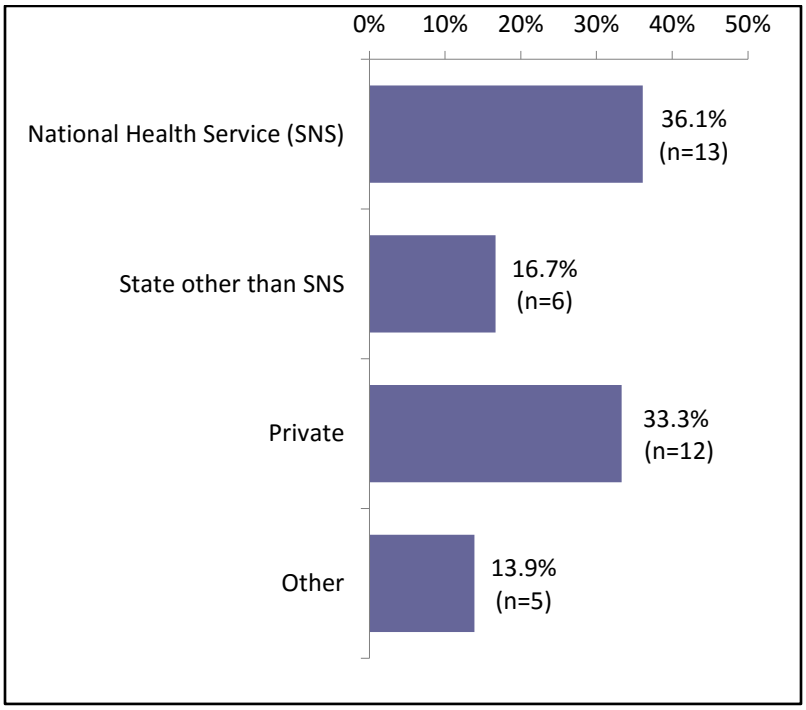

Figure 34 - Type of Institution Customers' work for

Regarding the number of employees per institution, most responders work for institutions with "200 or more employees" (55.6%), while 36.1% work at institutions with "Less than 100 people", only a minority of 8.3% work for entities with resources "Between 110 and 199 employees" (Fig. 35). The third stratum encompasses the vast majority of responders who work for the "NHS" or "State other than NHS". Half of the respondents from the first group, and all from the second, work for private institutions, including Social Solidarity ones.

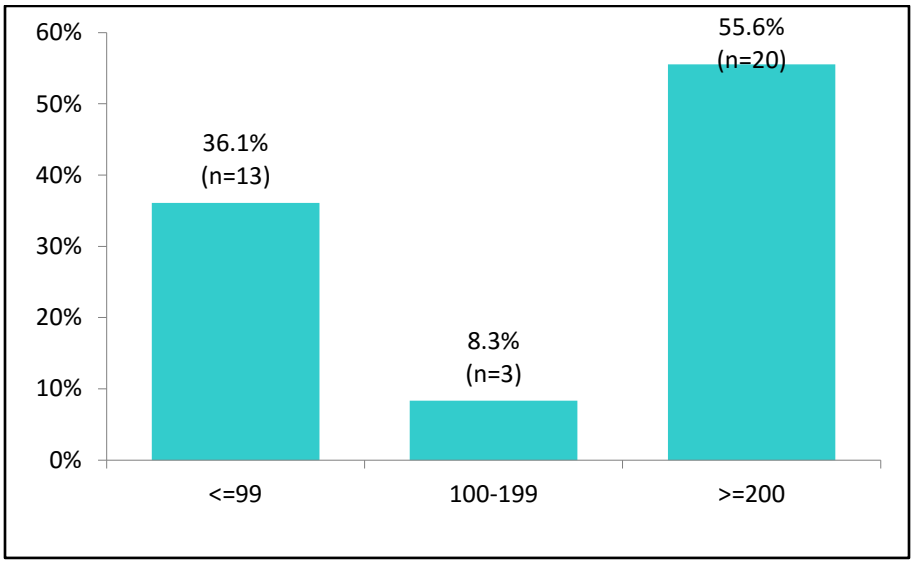

Figure 35- Number of employees per institution

In terms of the number of Direct Reports, all responders had at least one direct report, 47.2% "Up to 5 reports", while 52.8% had "More than 5 reports", and 13.9% of these with "More than 10 reports" (Fig. 36).

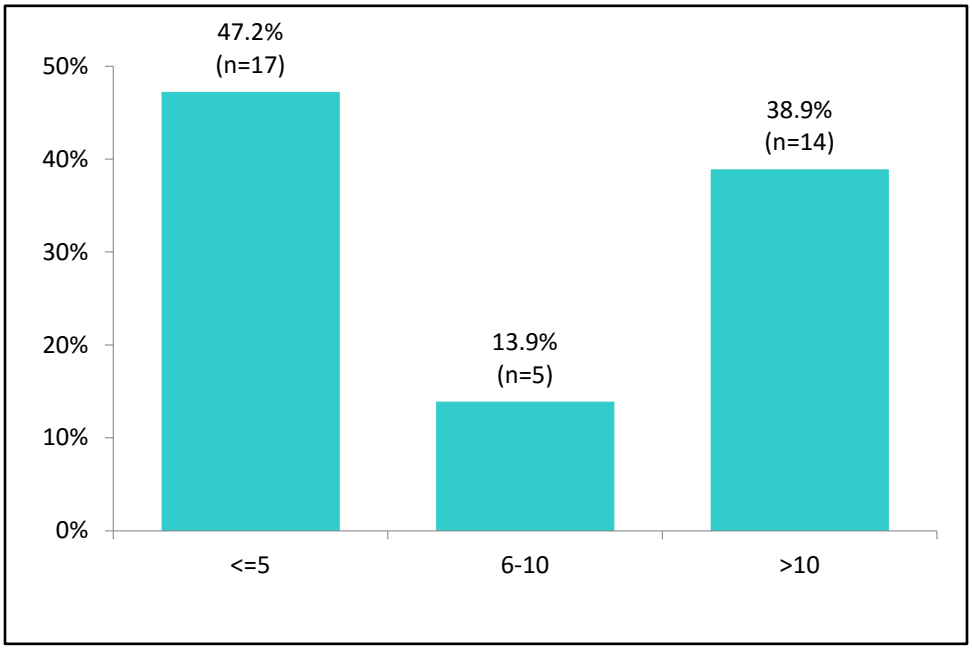

Figure 36- Number of customers' direct reports

When comparing the rates attributed to the value of the interactions with different Pharmaceutical Industry Representatives (Fig. 37), 60.0% rank the Medical Affairs interaction very high ("4"). Interestingly, a small percentage of customers attributed the highest score to other functions such as Key Account Managers showing that they have clear managerial responsibilities in their organizations.

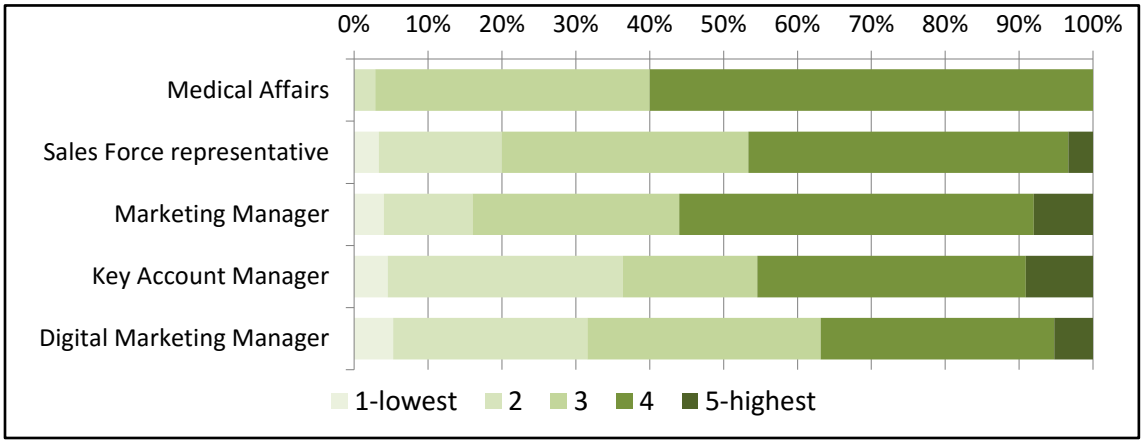

Figure 37- Value of interactions with different Pharmaceutical Industry representatives

Based on their experience, the scientific knowledge of Medical Affairs was very much recognized by the majority of the responders (97.2%, Fig. 38).

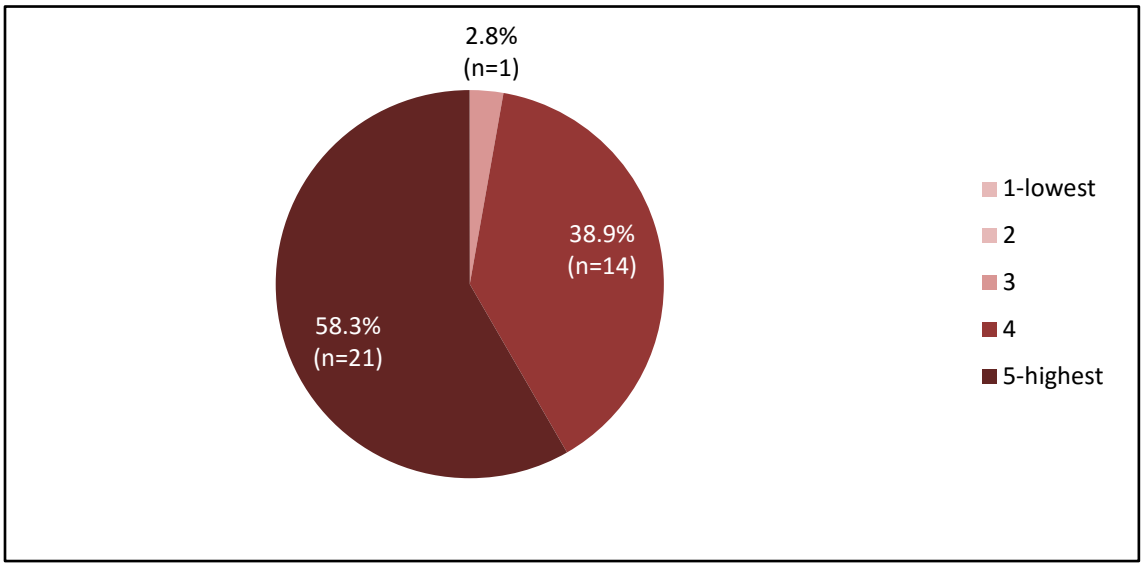

Figure 38 - Scientific knowledge of Medical Affairs

The Medical Affairs contribution to the different activities usually performed by pharma was also very much appreciated. Not surprisingly the "Response to Product Related Questions", as well as "Safety Reporting", "Pharmacovigilance" and "Advisory Boards Management", were among the ones capturing higher attention. The rating of "Management of Customer Relations" is certainly lower than expected, while "Digital & Multichannel Development and Support" achieved a very interesting result (Fig. 39).

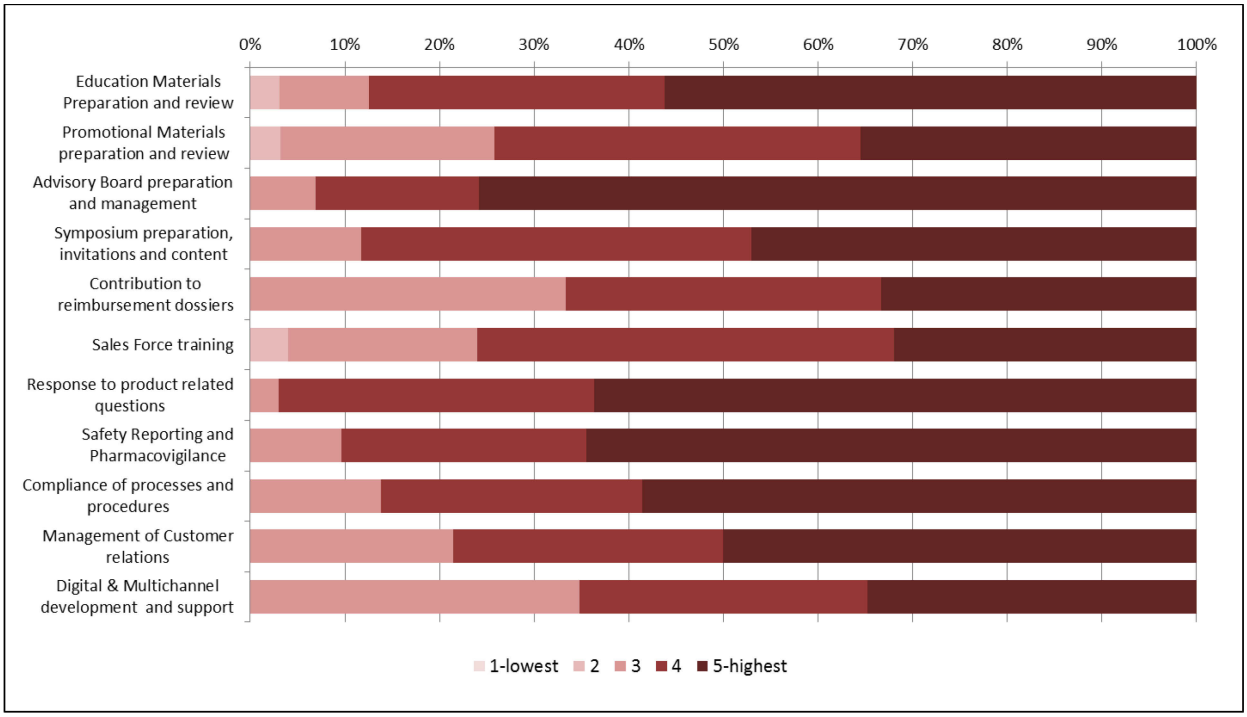

Figure 39 – Customers' rating of Medical Affairs contribution to selected activities

The use of Digital Communication Channels ranks very high in some categories such as "e-mails" and the average assessment of the remaining ones like "Webinars" and "Webexes" were also good. Not surprisingly, there was already some experience with Virtual Advisory Boards in Portugal, which is not so common across Europe (Fig. 40).

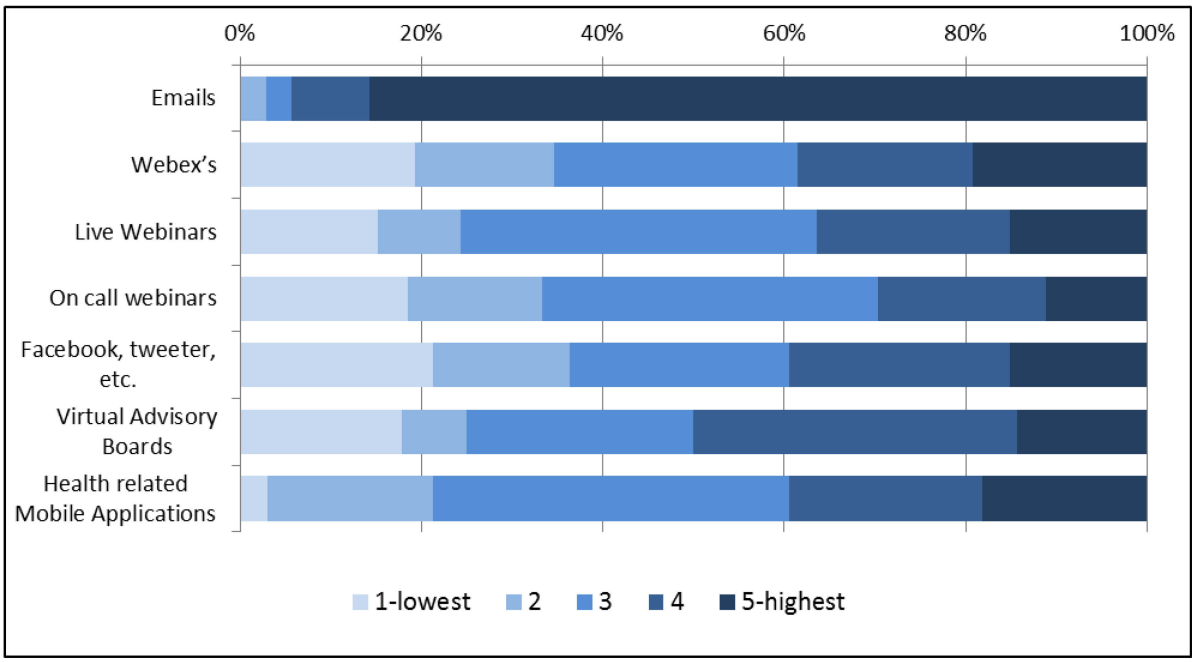

Figure 40 - Comfortable usage of digital communication channels

The current contribution of Medical Affairs to the Digital & Multichannel Development and Implementation is particularly relevant to the use of "Websites/Portals", "Self-Detailing", "Training materials" but also to "Newsletters", "Webinars" (live and on demand) and for the adoption of some "Mobile Applications". Although less notorious, "Social Media" ranked high by more than 30.0% of the responding customers (Fig. 41).

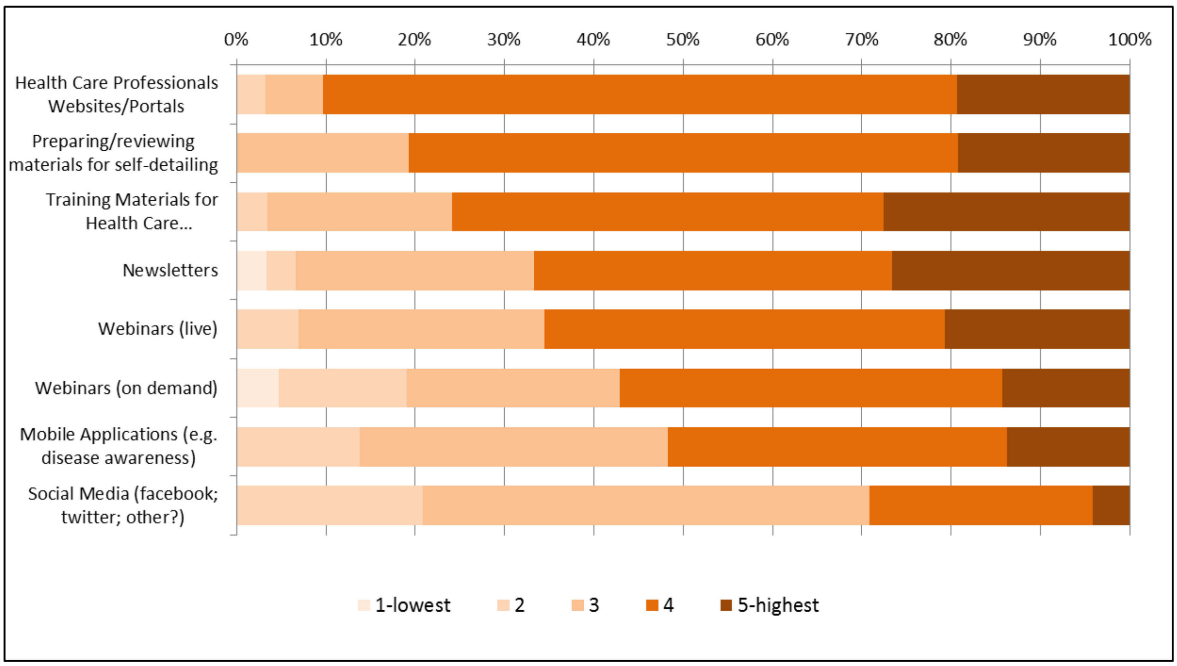

Figure 41 – Current Medical Affairs contribution to Digital & Multichannel development

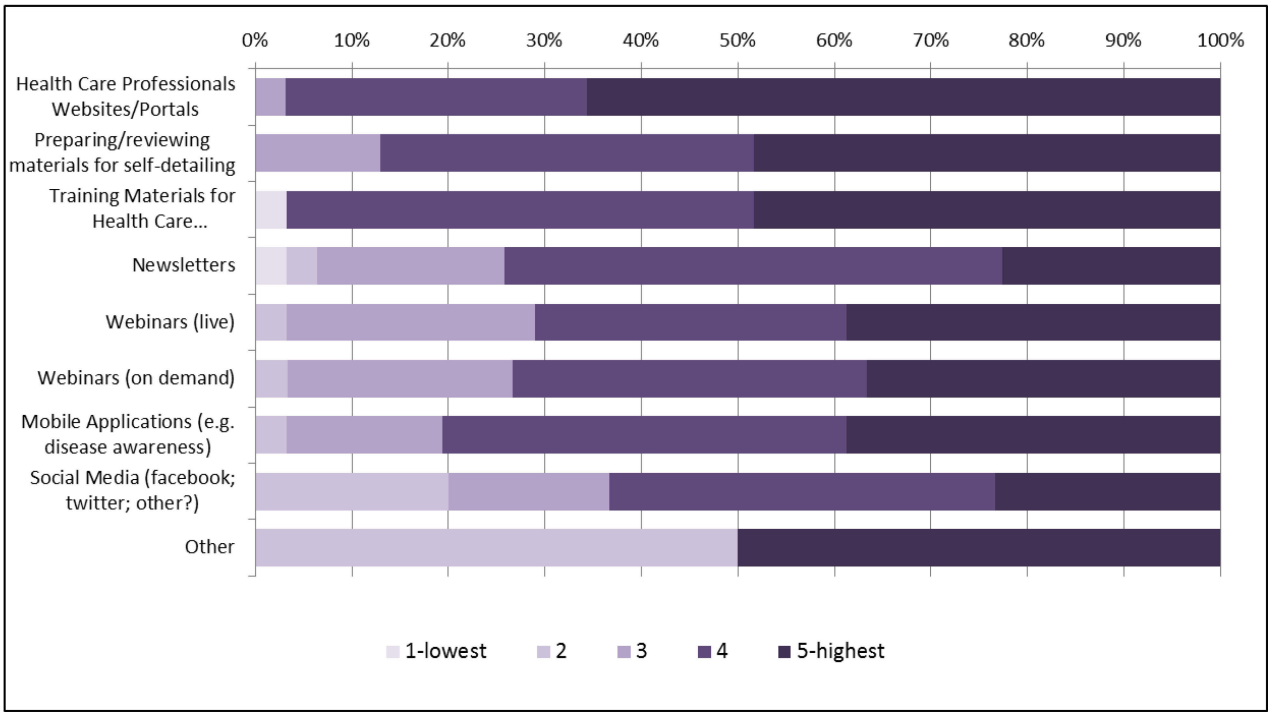

Figure 42 – Future contribution of MA for the Digital & Multichannel Processes

In order to ensure an adequate level of support to all these activities, companies need to grant an adequate level of Medical Affairs' resources, namely by considering a reasonable number of medicines a Medical Affairs person should be responsible for. In our survey 38.9% of the customers considered that "3 medicines" per Medical Affairs would be reasonable, whereas 16.7% consider "5" and 11.1% agree on only "2 products" (Fig. 43).

Being the Product Launch one of the most important milestone of a medicine, the customer expectations are that these Full Time Equivalent (FTEs) resources should be in place sometime before, during and after the product is on the market.

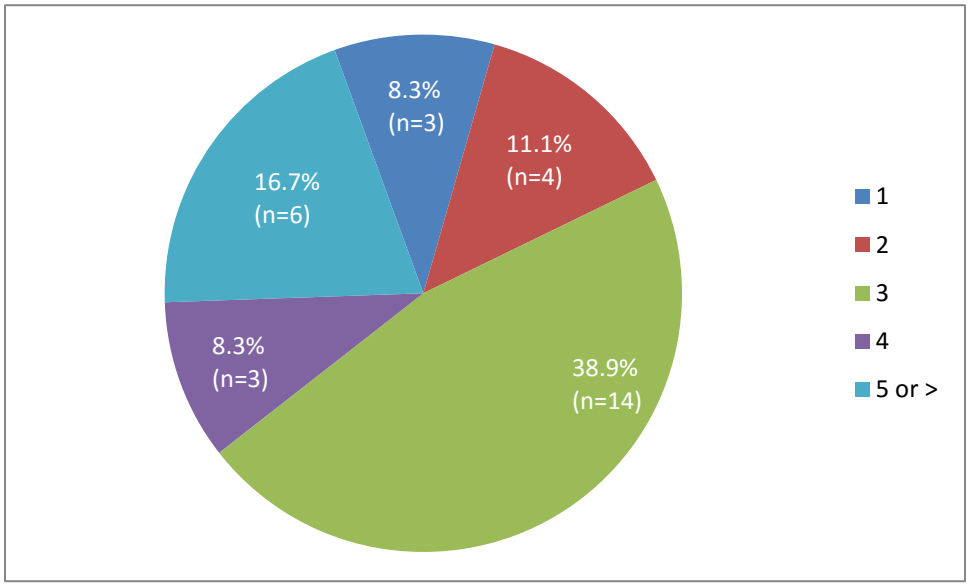

Figure 43 - Reasonable number of medicines a Medical Affairs should be responsible for

This is, of course, very much dependent on the prevalence of the disease, target indications and competitors, but gives an insight on what level of resources are thought to be required.

Consistency is clearly shown around one and two FTEs across the different launch phases, with some greater resource variance across the remaining options (Fig. 44; Table 14).

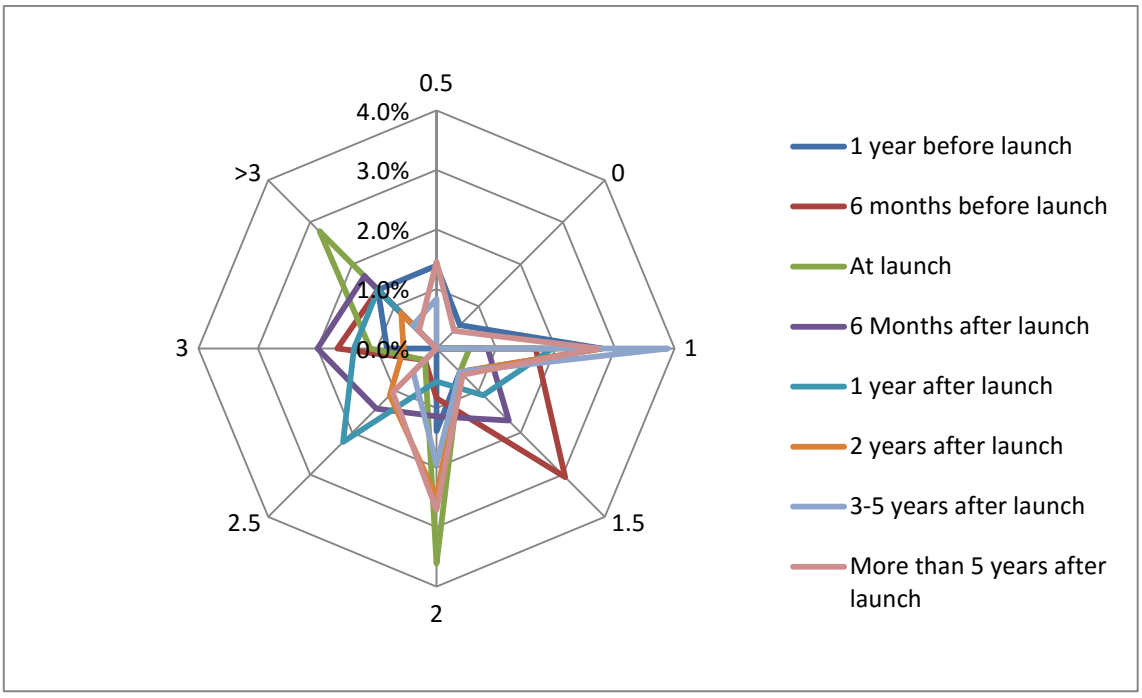

Figure 44 – Medical Affairs resources though to be needed to support a medicine launch

Table 14. Expected number of Medical Affairs FTEs around product launch

Time \ Nº of FTEs	0	0.5	1.0	1.5	2.0	2.5	3.0	>3.0	Total %
1 Year before	6.3	15.6	**31.3**	6.3	15.6	0.0	9.4	15.6	100.0
6 Months before	0.0	0.0	18.8	**34.4**	9.4	3.1	18.8	15.6	100.0
At Launch	0.0	0.0	6.3	6.3	**40.6**	3.1	12.5	31.3	100.0
6 Months after	0.0	0.0	9.4	21.9	12.5	15.6	**21.9**	18.8	100.0
1 Year after	0.0	0.0	22.6	12.9	6.5	**25.8**	16.1	16.1	100.0
2 Years after	0.0	0.0	**33.3**	6.7	30.0	13.3	6.7	10.0	100.0
3 to 5 Years after	0.0	10.0	**46.7**	6.7	23.3	6.7	0.0	6.7	100.0
> than 5 Years after	10.7	21.4	**50.0**	7.1	36	0.0	0.0	7.1	100.0

On the other hand, the perception regarding the number of customers a Medical Affairs person should manage shows a wide variability (Fig. 45). About 53.0% of customers mentioned "> 10", while 32.4 % think that "5-10" would be an appropriate number and, 14.7% believe that "< 5" would be reasonable number for Medical to manage during her/his customer facing activity.

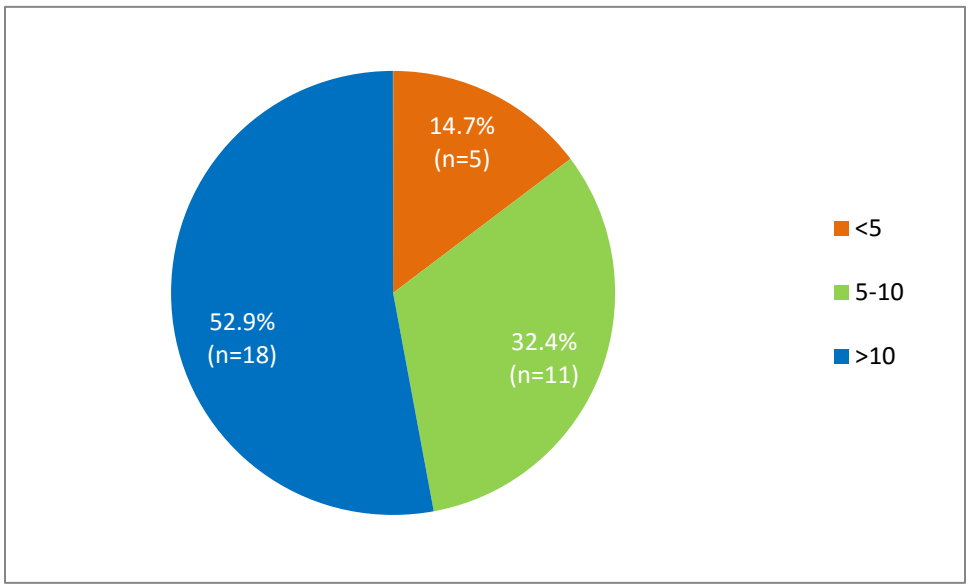

Figure 45 – Number of customers a Medical Affairs person is thought to manage

The value attributed by customers to some of the major Medical Affairs activities is translated in the following graph (Fig. 46). “Clinical Research“ stands out and, as in Fig. 37. “Product Support”, “Safety and Pharmacovigilance”, as well as “Management of Customer Relations”, are among the highest rated.

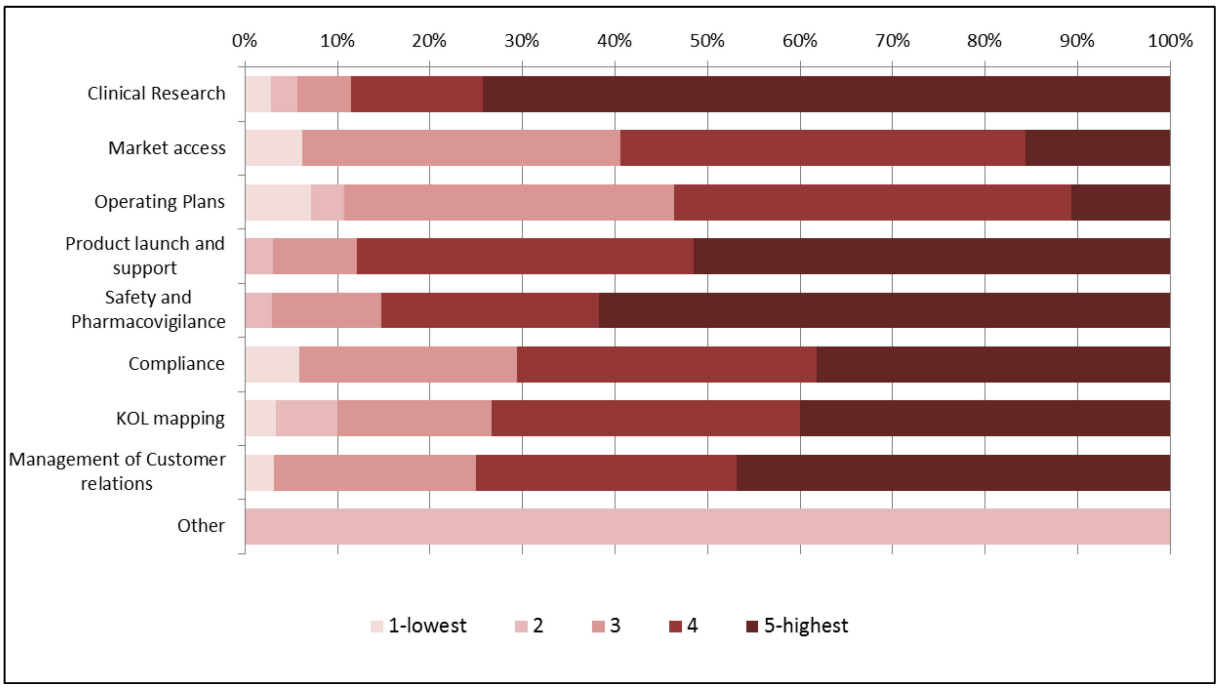

Figure 46 - How much do you value the Medical Affairs activities?

Customers involvement according to study type show that they seem to have more experience with the Clinical Trials, than with Investigator Initiated Research (IIRs); however, the different type of studies have been experienced by most of the respondents (Fig. 47). There were no statistically significant differences between the rates attributed to the three groups ($\chi 2=0.034$; 2df; $p=0.983$).

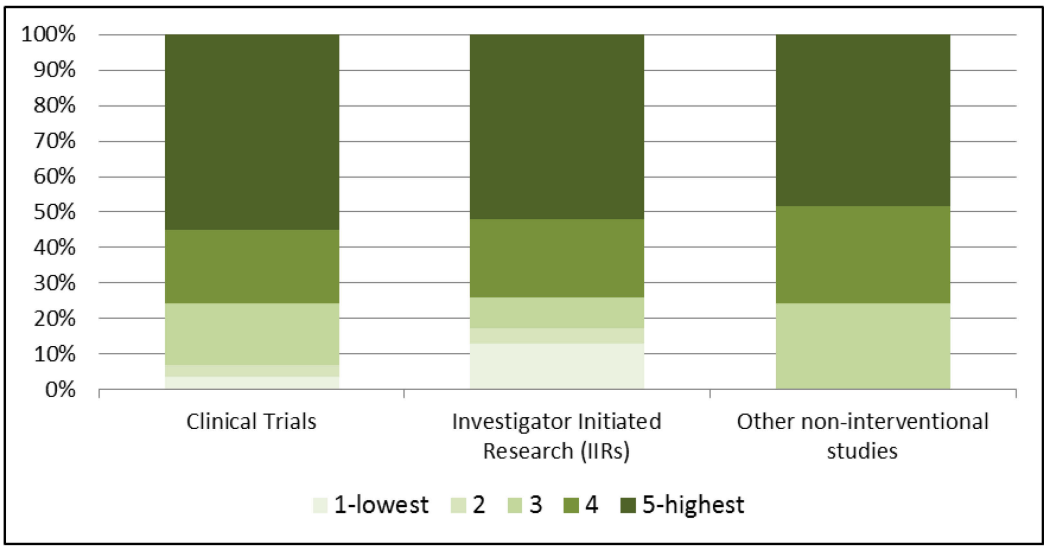

Figure 47 – Customers' involvement according to study type

In terms of value attributed to the different Clinical Research type of projects, more credit is granted to Clinical Trials when compared with other types of information gathering, namely Institutional Real World Data, IIRs or other non-interventional studies (Fig. 48).

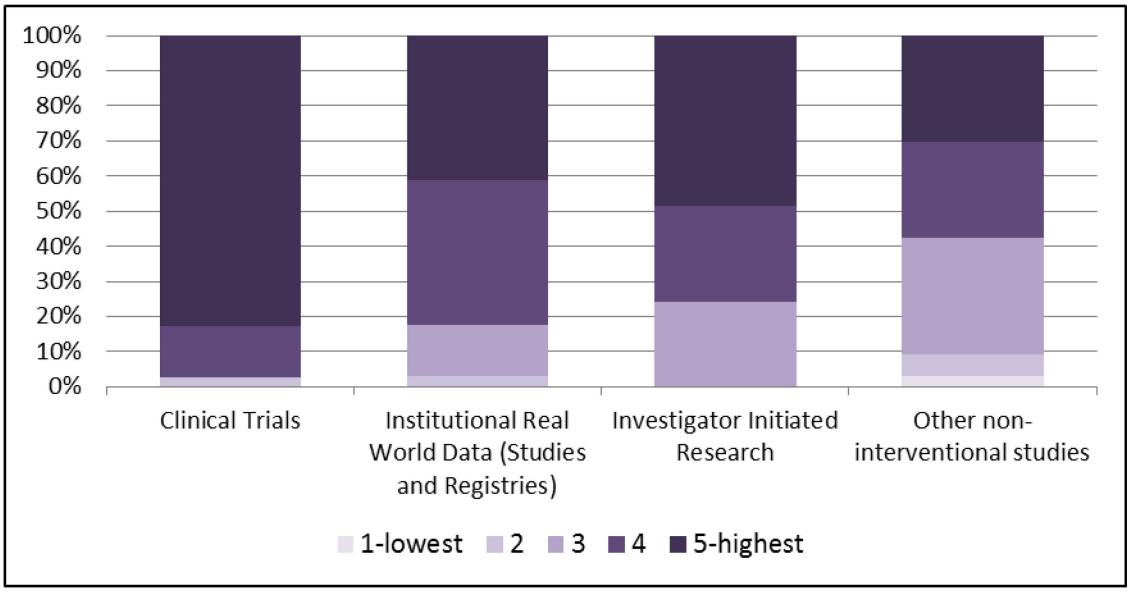

Figure 48 – Value attributed to the different Clinical Research type of projects

There are statistical significant differences between the value given to the four groups ($\chi 2=16.3$; 3df; p=0.001). This differences are particularly evident between "Clinical Trials" and "Other Non-interventional studies" ($\chi 2=15.5$; 1df; p=0.0001), the former presenting higher scores.

The "Interest and perceived value" is pointed out as the most important driver to improve the efficiency of Clinical Research in Portugal having been selected by 55.6% of the customers, and followed by "Proper conditions" (25.0%) and "Available budget" (16.7%). Only one customer responded that time could be a limiting factor (Fig. 49).

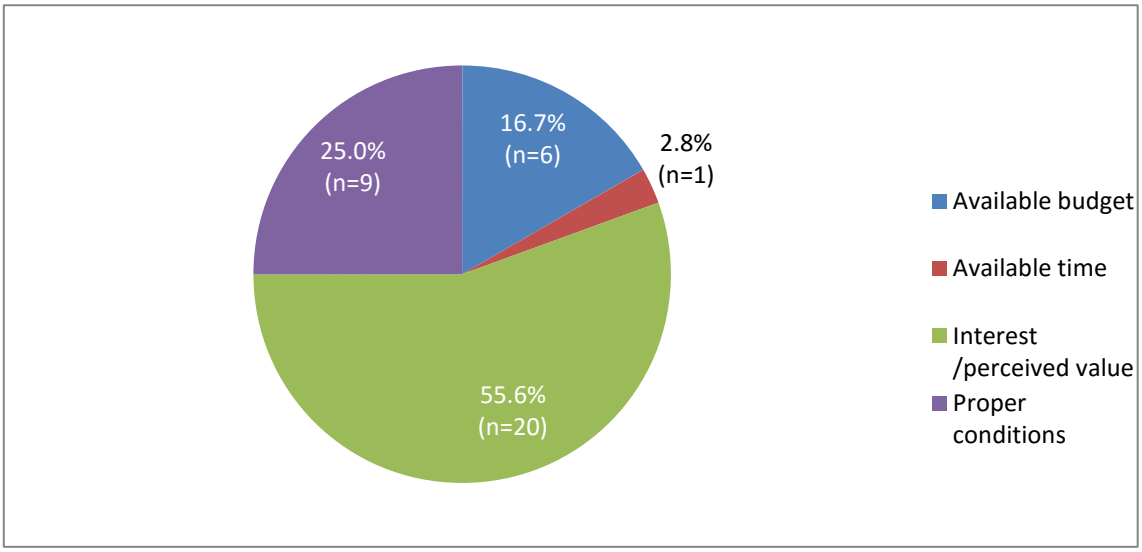

Figure 49 – Most important drivers to improve efficiency in Clinical Research in Portugal

The major roadblocks for Clinical Trials implementation were identified as "Long approval timelines", "Lack of resources" and "Low Curriculum Vitae impact". Factors of other nature such as: lack of appropriate coordination and support, were also pointed out (Fig. 50).

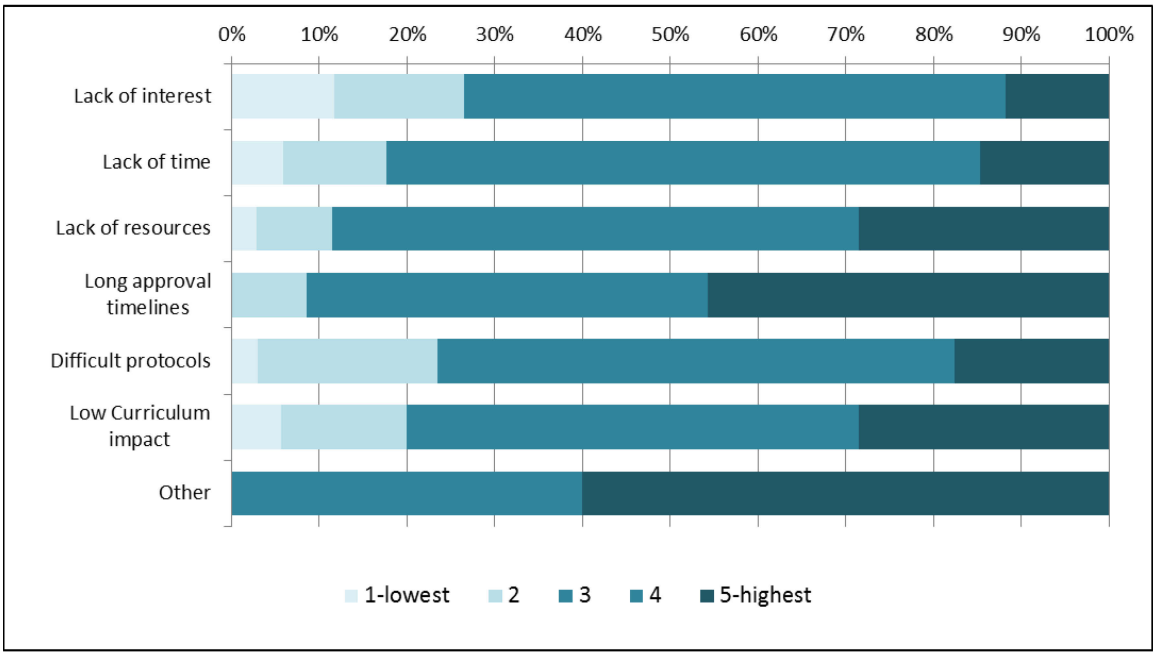

Figure 50 - Major roadblocks for Clinical Trials implementation in Portugal

To check the specific contribution of Medical Affairs around a topic that is relevant for both the Pharma Industry and health care professionals, customers were asked about the relevance of the work done by the Medical Affairs informing them about the the European Federation of Pharma Industry Association (EFPIA) Code of Ethics and Transparency implementation. The results are remarkable, with 61.1% responses ranking as “High” and 36.1% as “Medium”. Only one customer (2.8%) considered this impact to be low (Fig. 51).

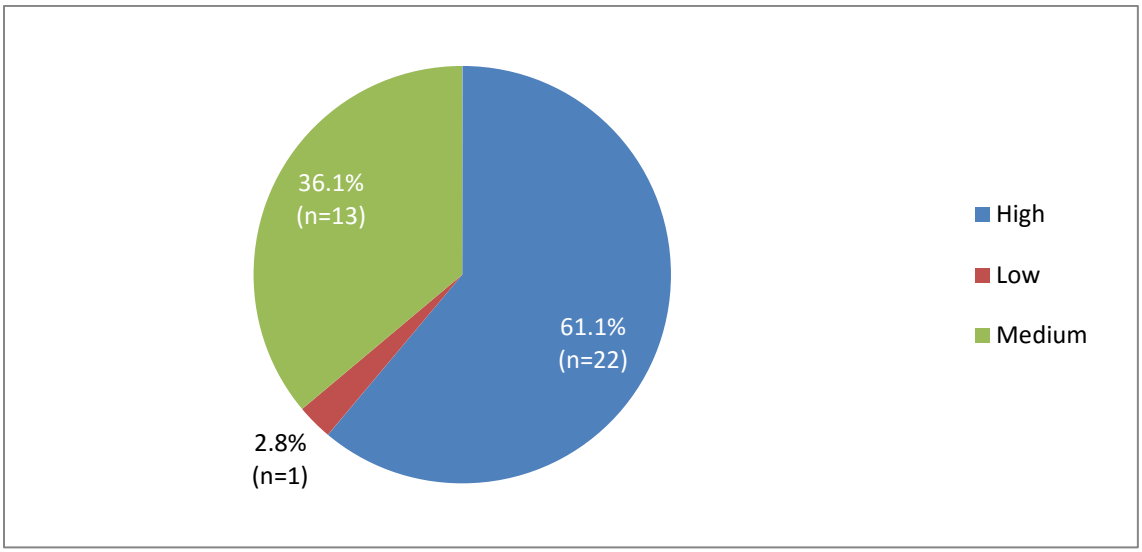

Figure 51 – Impact of MA in the implementation of the EFPIA disclosure code of Ethics and Transparency, between the Pharma Industry and HCPs

The Pharmaceutical Industry in Portugal cannot communicate directly with patients. In order to indirectly address the impact of the Medical Affairs on this matter, customers were asked: How can patients benefit from the Medical Affairs activity?

According to customers, patients can benefit most from the Medical Affairs activity by ”Providing HCPs with updated Information on Available Medicines”, by “Helping to bring these Medicines Into the Market”, by “Raising Disease Awareness” and “Contributing to develop more efficient treatment options” (Fig. 52). “Treatment adherence” and the “Support to Patients’ Associations” were also mentioned.

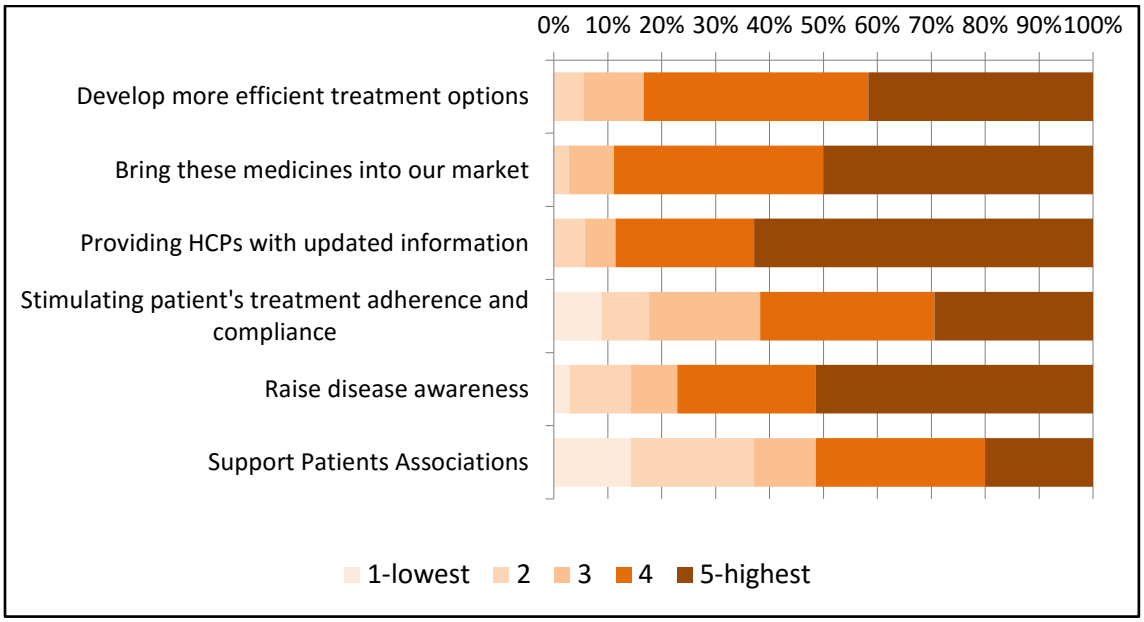

Figure 52 - How can patients benefit from the Medical Affairs activity?

In terms of Health Gains achieved so far (Fig. 53), 80.6% of customers considered the Pharmaceutical Industry contribution as "High", while 16.7% ranked it as "Medium" and one responder assessed it as "Low" (2.8%).

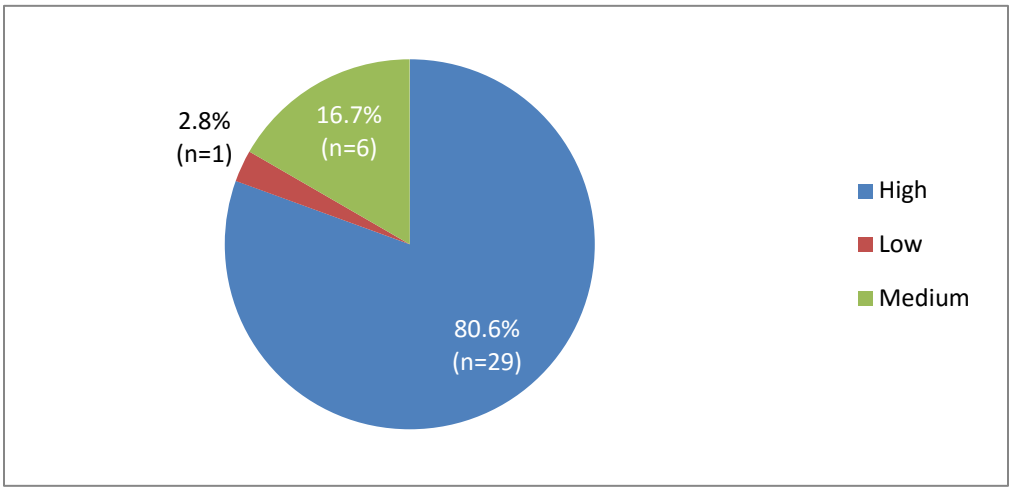

Figure 53 - Pharmaceutical Industry contribution to the health gains achieved so far

The majority of the customers (52.8%), considered the Image of the Pharmaceutical Industry as “Good”, 25.0% assessed it as “Satisfactory”, while 11.1% found it “Fair” and a similar percentage labeled it as “Poor” (Fig. 54).

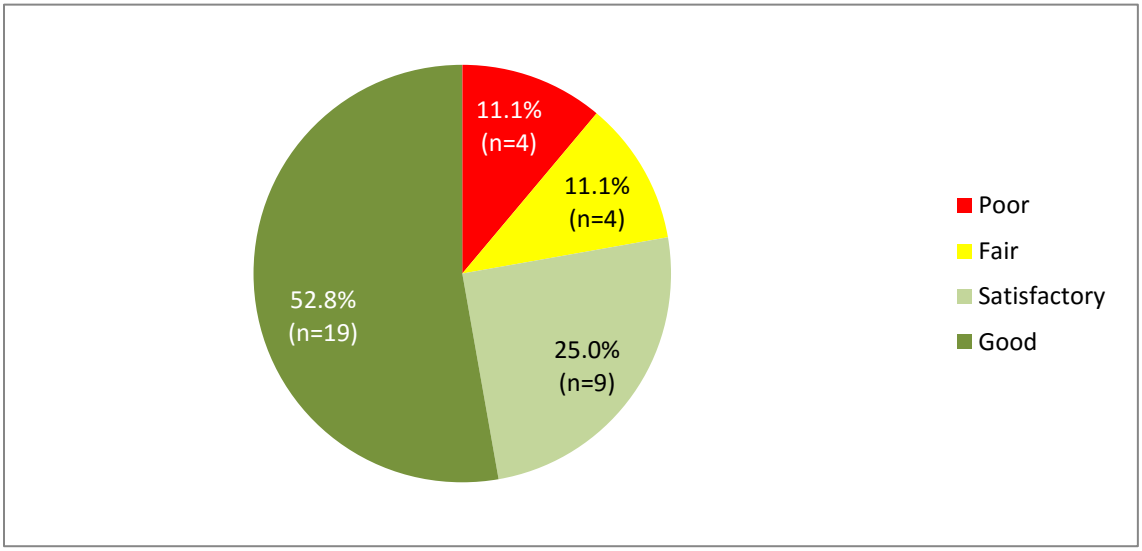

Figure 54 – Customer perception of the Pharmaceutical Industry image

Research, New drug development, Health care and Scientific information sharing, are among the additional arguments mentioned supporting a good image, whereas, Prices, Profit and some cases of Lack of transparency and fraud justified less positive assessments.

Almost 2/3 of customers find the scientific Medical Affairs support to be unbiased (69.4%), while 30.6% have a different opinion (Fig. 55).

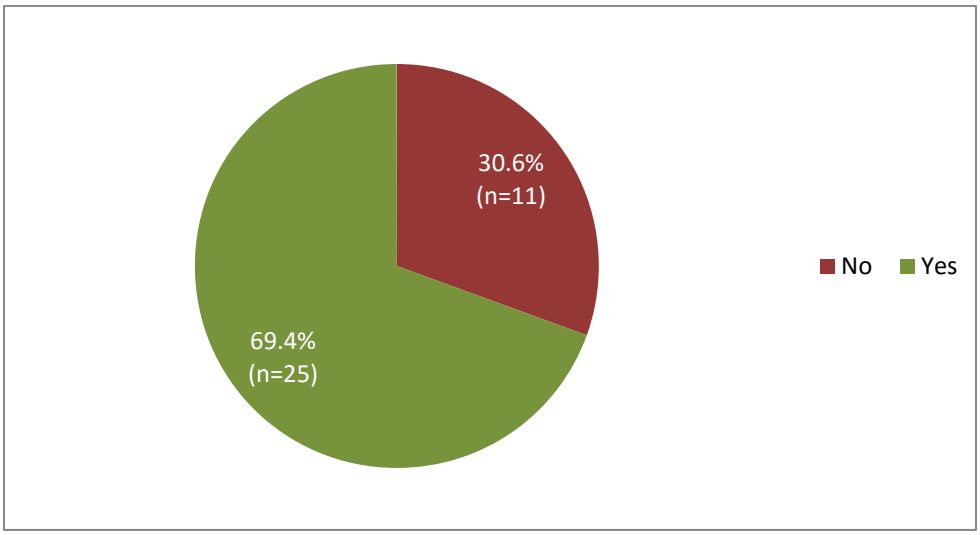

Figure 55 – Does Medical Affairs provide unbiased scientific support?

Among the most relevant outcomes resulting from a Medical Affairs/customer interaction, the "Scientific update" ranks first, followed by the "Safety" and "Efficacy profile" of medicines and "Differentiation vs competitors" and "Scientific Update on publications". Webinars are not yet very much recognized by these customers (Fig. 56).

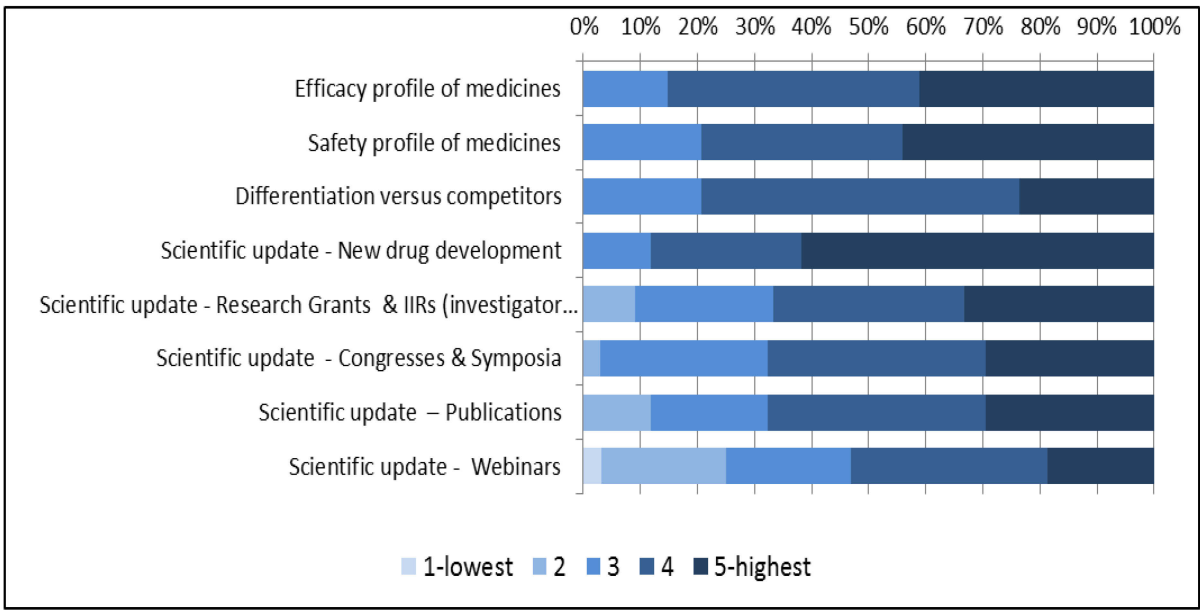

Figure 56 - Valued outcomes resulting from a Medical Affairs/customer interaction

A majority of customers foresee greater Medical Affairs involvement in the future (72.2%), whereas 22.2% believe that this contribution will be similar, and 5.6% expect it to be "less of" (Fig. 57).

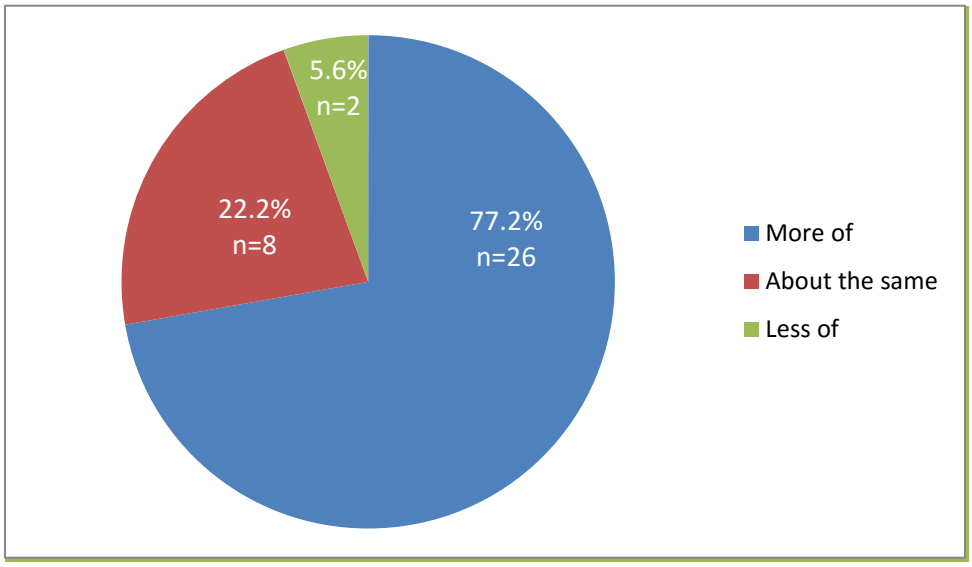

Figure 57 – Involvement of Medical Affairs in the future

4.4- Discussion

Receiving customer feedback on the Medical Affairs activity is very important. The response rate to this e-mail/web questionnaire was not very high (21.7%), but in line with what has been reported by other authors, namely by surveys performed through e-mail (17.3%) or Survey Monkey (27.7%)[49]. A recent survey conducted in Portugal by Banco de Portugal for the International Monetary Fund with a similar design, got a response rate of 17.4%[50]. Therefore, despite not being a large group of customers, the response rate was within what was initially expected. To be able to respond to this questionnaire, customers should have access to a computer and internet. We know that internet users are not representative of the general population. However, that was not considered to be a problem since, as Medical Affairs, we do not interact with the general population. These customers are the ones with whom we regularly meet and from whom we wanted feedback.

Among the advantages we have considered by using this survey method, one could underline: speed, the virtual elimination of data entry costs, convenience to both sides, the likelihood of getting more accurate answers to sensitive questions and the elimination of interviewer bias. We understand also that there was limited control of people

potentially responding multiple times, which we did try to validate by comparing the responder's age, gender and type of institution.

The image of the Pharmaceutical Industry has been affected in recent years by several unfortunate events that could, in a way, reduce the customer's willingness to respond to such questionnaires. In addition, customers could easily quit in the middle of the questionnaire. However, since it was not long, this only happened in 10.0% of the cases. Those who contributed to this survey came from quite a broad variety of institutions, state owned or private. These customers were experienced people with several direct reports, working for national and international companies.

The value attributed to interactions with Medical Affairs show a high combined score. Interestingly, Key Account Managers work was also very much appreciated, showing that some of these responders share clear managerial responsibilities in their organizations. The scientific knowledge of Medical Affairs was duly recognized by the majority of the responders (97.2%), and their contribution to the different activities was also noted. Not surprisingly, the response to Product Related Questions, as well as Safety Reporting and Pharmacovigilance, Advisory Boards Preparation and Management, were among the ones capturing higher customer's attention.

The Management of customer relations being rated as "reasonable" was lower than expected. This was probably influenced by the limited number of Medical Affairs resources available and the number of products they have to support. In fact, not only the reality shows that the number of FTEs available is less than expected[52], but also that the number of customers they need to cover is much higher.

Customers' usage of digital and multichannel communications, namely with e-mails, WebEx's, Webinars, virtual Advisory Boards and Mobile applications is relatively common, less so with Facebook, Tweeter, or on-call webinars. The current contribution of Medical to Digital & Multichannel Development and Support achieved a very interesting result, particularly in what concerns Websites and Portals, Training materials, Self-detailing, Newsletters, Webinars and mobile applications. Social Media was considered less important, but still got some attention. Future expectations on this field are even higher. The Medical Affairs contribution to Digital and Multichannel tend to grow in all areas. In order to ensure an adequate level of support to all the activities attributed to Medical Affairs, companies need to recruit and develop a reasonable number of resources to adequately manage the different therapeutic areas and product portfolio. Three medicines per Medical Affairs FTE was the most voted opinion (nearly 40%), varying from 2 to a maximum of 5 products.

The Product launch is one of the most important milestones of the life cycle of a medicine. Resources should be in place several months before the launch, during, and sometime after the product is on the market. The perception regarding the number of customers a MA person should manage shows a wide variability, although the majority of customers suggest ten or more. According to our best knowledge, this really varies very much across companies, and it is mainly determined by the prevalence of the disease, number of KOLs/prescribers and payers involved, product characteristics, competitors in the market and product life cycle. In some companies the number of customers a MA has to manage may easily reach 20 or 30.

The value attributed by customers to some of the major Medical Affairs activities, highlights Clinical Research, Product Support, Safety and Pharmacovigilance, as well as Management of Customer relations and Compliance. These are indeed activities predominantly performed by Medical. It is very good to see them recognized and differentiated from Commercial. Customers are more experienced with the Clinical Trials, than with IIRs or other types of studies. In fact, much more credit is granted to Clinical Trials when compared with the other options.

The most important driver to improve the efficiency of Clinical Research in Portugal is Interest and Perceived value. Other determinants are: Proper Conditions to develop research and an Available Budget. Time was rarely mentioned as limiting factor. The major roadblocks for Clinical Trials implementation were said to be: “Long approval timelines”, Lack of Resources” and “Low Curriculum Vitae impact” whereas “Lack of appropriate coordination and support”, was pointed out as a contributing factor.

In terms of Ethics namely in what regards the implementation of the EFPIA disclosure Code of Ethics and Transparency, which governs the relationship between pharma and HCPs, the awareness of the impact of MA in the implementation of such measures was very high. Medical Affairs were key elements in informing and explaining to HCPs the additional procedures reinforcing the APIFARMA code of Ethics, as well as the ones derived from the need of reporting into the INFARMED platform any potential support given or received.

The Pharmaceutical Industry is one of the few, if not the only business, where prescription medicine producers cannot directly interact with their consumers. In order to indirectly address the impact of the Medical Affairs on this matter, customers were asked the question: *How can patients benefit from the Medical Affairs activity?* ”Providing HCPs with updated Information”, “Helping to bring Medicines Into the Market”, “Raising Disease Awareness” and “Contributing to develop more efficient treatment options” were the

most voted statements. “Treatment adherence” and the “Support to Patients’ Associations” were also mentioned. All pre-identified dimensions were considered valid.

In terms of Health Gains the contribution of pharma was outstanding, with 81% classifying it with high punctuations, and the majority of the customers considered the image of the Pharmaceutical Industry as “Good”, while a quarter assessed it as “Satisfactory”. Therefore, there is clear room for improvement. The Scientific support given by Medical was considered unbiased by almost 2/3 of the customers, being the “Scientific update on new drug development”, “Safety”, “Efficacy” and “Differentiation vs competitors” among the most recognized. In the future, a majority of customers foresee greater Medical Affairs involvement.

4.5- Conclusions derived from the questionnaire to Customers

The value attributed by customers to the interactions with MA show a high level of appreciation, supported on the recognition of scientific expertise and contribution to the different activities, such as:

- Response to Product Related Questions
- Safety Reporting and Pharmacovigilance
- Advisory Boards Preparation and Management

Customers’ usage of digital and multichannel communications, namely with e-mails, WebEx’s, Webinars, virtual Advisory Boards and Mobile applications is relatively common, less so with Facebook, Tweeter, or on-call webinars.

The current contribution of MA to digital & multichannel development and support was very positively mentioned, particularly in what concerns Websites and Portals, Training materials, Self-detailing, Newsletters, Webinars and mobile applications. The Medical Affairs contribution to Digital and Multichannel tend to increase in all areas.

In order to ensure an adequate level of support to all the activities attributed to MA, companies should consider having a maximum of 3 to 5 medicines per FTE. The product launch is one of the most important milestones of the life cycle of a medicine. Resources should be in place several months before the launch, during, and sometime after the product is on the market.

The perception regarding the number of customers a MA person should manage shows a wide variability, the majority of customers suggesting ten or more.

Customers are more experienced with the Clinical Trials, than with Investigator Initiated Research (IIRs) or other types of studies. The most important driver to improve the efficiency of Clinical Research in Portugal is Interest and Perceived value. Other determinants are: Proper Conditions to develop research and an Available Budget. Time was rarely mentioned as limiting factor. The major roadblocks for Clinical Trials implementation were said to be:

- Long approval timelines
- Lack of Resources
- Low Curriculum Vitae impact d
- Lack of appropriate coordination and support, was pointed out as a contributing factor.

In terms of ethics and transparency, Medical Affairs were key in informing and explaining to HCPs the additional procedures reinforcing the APIFARMA code of Ethics, as well as the ones derived from the need of reporting into the INFARMED platform any potential support given or received.

According to customers, the indirect impact of MA in patient's lives can be translated by:

- Providing HCPs with updated information
- Helping to bring Medicines Into the Market
- Raising Disease Awareness
- Contributing to develop more efficient treatment options

Treatment adherence and the support to Patient's Associations were also mentioned and this is quite important, because it shows the awareness of MA progressive involvement, also at this level.

The perceived contribution of Pharma to health related gains was outstanding. Although more than half of the customers considered the image of the Pharmaceutical Industry as "Good", one quarter assessed it as "Satisfactory"; therefore, there is clear room for improvement.

The scientific support given by Medical was considered unbiased by almost 2/3 of the customers, underlying on this respect:

- Scientific update on new drug development
- Safety
- Efficacy
- Differentiation vs competitors

In the future, the majority of customers foresee greater Medical Affairs involvement.

"Good common sense is something that everybody talks about but it's lacking the most"

José Manuel Fernandes

CHAPTER V - Conclusions and suggestions

In our current environment, resource allocation within Pharma is key. We have shifted from a structure based on sales reps who repeatedly convey a set of structured messages, to a level where discussion takes place on the roots of scientific arguments, and investments are balanced according to the expected value and impact. Customers such as health care professionals, patients, regulators, payers and the general population, expect Pharmaceutical companies to deliver not only medicines but a continuum of care, ranging from disease awareness, prevention, diagnosis and efficient treatment options. These customers request increasing attention, patients and Patients' Associations are more vocal and intervenient, payers and regulatory authorities look much closer no only to the efficacy and safety of the medicines, but also to its economic value and differentiating factors. Medical Affairs are the best prepared and the most credible to communicate service value messages, discuss health topics, pave the way for new medicines launch and hopefully improve the quality of care.

5.1- Questionnaires results' comparison

When results from both questionnaires (Pharma vs customers) were compared, regarding the variables that were similarly collected, one can see that:

a) In terms of gender, customer responders were predominantly males (72.2%), while in pharma they only account for 47.9 % (χ^2= 7.02; p=0.008) of the participants. As most customers have one or more direct reports and are leaders in their settings, this unbalanced distribution of gender with only 27,8% of females responding to customers' survey, is probably influenced by the general pattern of the European companies administration boards members/directors, where women are still only occupying 23.0% of the places[57].

b) the age class distribution was also statistically different (χ^2=34.4; 3df; p=0.000) with a predominantly younger population at pharma vs customers;

c) the number of employees per institution show a statistically different class distribution (χ^2=13.0; 2df; p=0.0015) mainly due to the higher percentage of "<100" employees per institution responding to the customer's survey;

Looking at the different markers of evolution (from 1 year before through 5 years and more) we found that there is a good fit between the results of questionnaires from Pharma Industry professionals and customers (Fig. 58). The total absolute numbers of

suggested FTEs from these two samples are different due to sample sizes considered (industry professionals (1352) vs customers (247); χ^2=59.7; 7df (p=0.0000).

However, the distribution pattern is quite similar up to 3 years after launch (Pearson correlation coefficient= 0.8275), diverging from then on.

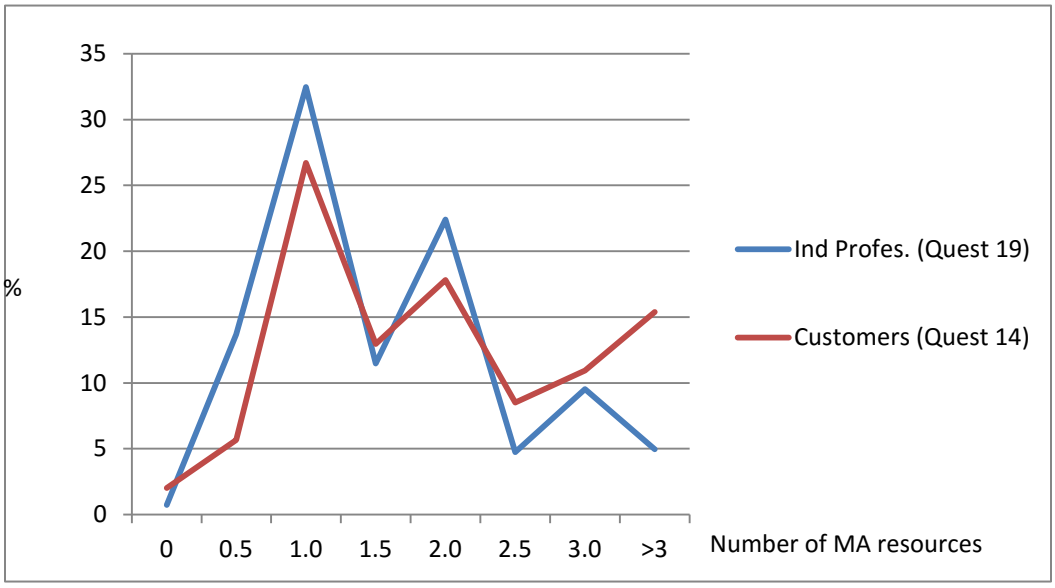

Figure 58 – Medical Affairs resources estimates on Pharma Industry (Table 6) and customers' (Table 14) surveys

Comparing the evaluation from customers with the one provide by colleagues from the Pharmaceutical Industry one can see that Clinical Research is even more valued, being the difference marginally not statistically significant (χ^2=9.3; 4df; p=0.0531). For Market Access (χ^2=4.2; 3df; p=0.2417), Operating Plans (χ^2= 8.4; 4df; p=0.0787), Safety & Pharmacovigilance (χ^2=5.5; 3df; p=0.1406), Compliance (χ^2= 4.5; 3df; p=0.2091) KOL mapping (χ^2=6.6; 4df; p=0.1574) and Customers' Management (χ^2=3.2; 3df; p=0.3686) no statistically significance differences were found between pharma and customers assessments. In Product Launch and Support pharma colleagues valued more the involvement of Medical, being the difference statistically significant (χ^2=9.1; 2DF; p=0.0105) versus customers.

5.2- Major conclusions

The Pharmaceutical Industry is a strategic sector for health and the country economy, translated in innovation, qualified work and health gains. Medical Affairs should contribute to strategic decisions namely at local level. The MA view and scientific advice are independent from commercial, and this should be clearly stated and shown in the field. Clinical Research is paramount to understand in depth the disease characteristics and treatment options. Complementary investigations such as real world data and pharmacoeconomic studies are important to demonstrate the value of medicines and devices in the usual settings. Access to innovative medicines is critical for the continuous improvement of the quality of care. Customers expect Pharmaceutical companies to deliver not only medicines but a continuum of care – Medical Affairs must drive this effort!

Pharma needs to be closer to the customer, understanding its needs, capturing insights, communicating and responding timely and appropriately. Medical Affairs are the best resources to manage expectations and respond to this challenge. Communication is a common pitfall, in Pharma, especially in what concerns the use of the appropriate channels, clarity of the message content and opportunity to intervene. Medical Affairs are trained to make timely assessments and identify gaps, use the appropriate communication channels to eliminate conflicting perceptions, share best practices and convey clear and pragmatic messages. Health managers at all levels need to understand and better explore digital and multichannel tools that are already available, to provide a better service to the populations.

The exercise of multivariate analysis and modeling reinforced the recognition of the Medical Affairs contribution to the overall results of the company both from the Strategic and Operational point of view.

5.3- Key suggestions to ensure a Medical Affairs winning strategy in Pharma

- *Search for the best structure to operate in a rapid changing environment*
- *Focus the pipeline and portfolio on areas of unmet medical need*
- *Prove the value of innovative medicines and communicate adequately*
- *Overcome market access challenges by providing robust clinical and real world evidence*
- *Invest in win/win partnerships*

- *Ensure access to new customers and decision makers (stakeholder scope)*
- *Find new ways of supporting heath care providers and patients, namely through digital and multichannel capabilities*
- *Strive for continuous improvement*
- *Develop and apply performance metrics and measure impact*
- *Gain reputation and trust through transparency, compliance and ethical behavior*
- *Invest in open door policy, invite customers in, share experiences*
- *Talk proudly about what you do*

"Not counting all the interactions but, counting the interactions that count!..."

Rory O'Connor

CHAPTER VI - Metrics

Metrics are valuable to guide the decision making process and to evaluate progress regarding specific objectives. This is not about reporting everything we do, or about an aimless progress but, towards objectives we are trying to accomplish. Since Medical Affairs resources are always scarce, one needs to make a pragmatic evaluation of those metrics that worthwhile using, in order to track the achievement of our business goals. If one does not know where to go, metrics will be helpless. A good metric should be meaningful, comparable, reproducible, understandable, preferably based on rates or ratios than on absolute numbers (e.g. "number of products/Medical Affairs"; "number of publications/year", etc.)[58].

6.1- Quantitative metrics

These are the most commonly used. They are easy to understand, they are valuable to record the variety and volume of the MA most relevant activities, namely requests responded, trainings performed, number of studies, support provided, and advisory boards organized.

6.2- Qualitative metrics

Qualitative metrics are more difficult to gather. They are more subjective in nature and imprecise[59]. Qualitative data makes you go out and talk, interview, identify opportunities (gaps or areas in need), provide solutions, capture insights, create a relationship and build confidence. These metrics can be generated:

- Internally, by colleagues from other areas such as: Business Unit Leaders, Key Account Managers, Sales Reps, Medical and Nursing personnel), or/and
- Externally, by customers

6.3- Combined Metrics

Mix both quantity (volume, rates or ratios) with quality, aiming to assess impact (low, medium or high). In addition to internal quantitative metrics (what do we do? how much we do? how many resources/time/investments are we allocating to? etc.), external

metrics such as interviews and surveys, focus groups or case studies, are extremely important to collect our customers' opinion (how we do it? why we do it? how efficient were we in supporting their needs? what can we do better? which things we are not doing? which things are the others doing better than us?). The traditional metrics applied are mostly quantitative in nature, and not discriminative enough to fully assess Medical Affairs outcomes. These last ones are mainly based on the quality of the interaction, the insights gathered, the support delivered and the relationship established. However, they need to be accurate, adequately described, not too complicated and clear in terms of the impact generated. For these types of metrics, the difficulty resides in clearly defining not only the outcome, but also the major influencing factors. Some of these are just "contributing factors" (ex: lack of time, stress, inappropriate moment of interaction, wrong perception, etc…); while others can critically influence the MA/customer interaction, either negatively (a complaint) or positively (a research grant; a very successful treatment; an opportunity for personal development). Customer and stakeholder metrics are important to communicate the value of Medical, and a powerful indicator of the way MA and the Company is performing. If these sound negative, they most probably require a reassessment and, eventually, a change in customer's management. Action needs to be quick! If these assume the form of complaints, implement correction measures immediately, in order to secure current relationship and minimize future impacts.

Strategically, one needs to understand to which extent there is a causal association between the topic highlighted by the customer as a "threat" or "opportunity" and the perceived outcome. Sometimes these could be biased by the area of expertise, product portfolio, etc., or even confounded by other variables. MA should not make quick assessments without taking in consideration all potential intervenient factors listing those that might contribute and the ones which could be "potentially causal". For these, not only the association with the underlying factor is needed, but they must also be directly linked with the outcome. For example: the number of meaningful MA interactions with a site might directly correlate with the number of sales of that particular unit, just by chance. The association might exist but it is not causal, because there is no commercial activity directly developed by Medical. A different situation would be, if the number of Investigator Initiated Research grants has a similar correlation pattern, once in addition to the association of both activities, the probability of MA to support directly these kinds of initiatives is much stronger.

A complaint not properly and timely addressed might undermine a MA/customer relationship, irrespectively of the moment when it occurred, stressed experienced, availability to meet/discuss and other aspects that could be cumulative but not necessary causal. One needs to look at the metrics, analyze them and understand. To me, the highest level of confidence is reached when the customer himself proactively alerts you for threats, identifies areas where you should focus, suggests approaches, make recommendations and is willing to be take part on the solution. Some of these insights are just information that could be worth pursuing. They don't need to change your business model completely, but could make a difference regarding differentiation or highlighting opportunities that could be further explored. For instance, just focus on a group of customers that are truly engaged and could make a difference, instead of interacting with the all group (ex: Cardiologists vs general practitioners).

A set of potential quantitative, qualitative and combined metrics is listed as examples. Some of them can be used separately or in a combined manner (e.g. the "number of educational materials" is a quantitative metric, which can be refined if we add a denominator: "number of educational materials/month", or "per MA""). They can be also combined with a qualitative assessment measuring the level of impact as presented next.

Examples of Medical Affairs Metrics

Internal Stakeholder Management		Measurement	Frequency of collection	Impact
	Administration Board meetings	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours		
	Country Medical meetings	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours		
	Talent Management meetings	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours		
	People's Development meetings	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours		
	Other Internal activities	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours		
	Internal Customer feedback survey	Number of hours	yearly	High; Med; Low

Strategic Product Support		Measurement (quantitative)	Frequency of collection	Impact (qualitative)
	Internal meetings	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours	tbd	
	Internal Training delivered	Number of meetings	tbd	High; Med; Low
	Time spent	Number of hours	tbd	
	Educational materials reviewed	Number of materials	tbd	High; Med; Low
	Pages	Number of pages	tbd	
	Slides	Number of slides	tbd	
	Videos	Number of videos	tbd	
	Time spent	Number of hours	tbd	
	Promotional materials reviewed	Number of materials	tbd	High; Med; Low
	Pages	Number of pages	tbd	
	Slides	Number slides	tbd	
	Videos	Number of videos	tbd	
	Time spent	Number of hours	tbd	
	Clinical Research	Number of studies	tbd	High; Med; Low
	Protocol & Country feasibilities	Number of feasibilities	tbd	
	Site feasibilities	Number of feasibilities	tbd	
	Oversight	Number of hours	tbd	
	Value Dossiers prepared	Number of dossiers	tbd	High; Med; Low
	Pages	Number of pages	tbd	
	Time spent	Number of hours	tbd	

External Customer Stakeholder Management	Measurement	Frequency of collection	Impact
Customer interactions	Number of interactions	tbd	High; Med; Low
Face to face	Number of interactions	tbd	High; Med; Low
WebEx; webinars	Number of interactions	tbd	High; Med; Low
Other Significant Interactions (Phone, e-mail with a meaningful content)	Number of interactions	tbd	High; Med; Low
Time spent	Number of hours	tbd	High; Med; Low
Congress and Symposia	Number of events	tbd	High; Med; Low
Content development (concept; invitations; materials)	Number of hours	tbd	High; Med; Low
Customer attendance	Number of attendees	tbd	High; Med; Low
Customer presentations	Number of presentations	tbd	High; Med; Low
Time spent	Number of hours	tbd	High; Med; Low
Institutional Management			
Reg Bodies	Number of meetings	tbd	High; Med; Low
Time spent	Number of hours	tbd	
Med Societies; Med Associations	Number of meetings	tbd	High; Med; Low
Time spent	Number of hours	tbd	
Universities; Research Sites	Number of meetings	tbd	High; Med; Low
Time spent	Number of hours	tbd	
Requests			
Unsolicited requests	Number of requests	tbd	High; Med; Low
Support to scientific events / activities	Number of activities	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Support to partnerships & other business opportunities	Number of activities	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	High; Med; Low
Advisory Boards	Number of sessions	tbd	High; Med; Low
Customer attendance	Number of participants	tbd	
Time spent	Number of hours	tbd	
Group Presentations	Number of sessions	tbd	High; Med; Low
Customer attendance	Number of participants	tbd	
Time spent	Number of hours	tbd	
Non-interventional studies	Number of studies	tbd	High; Med; Low
Initiated	Number of studies	tbd	
Ongoing	Number of studies	tbd	
Completed	Number of studies	tbd	
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Investigator Initiated Research	Number of studies	tbd	High; Med; Low
Initiated	Number of studies	tbd	
Ongoing	Number of studies	tbd	
Completed	Number of studies	tbd	
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Other studies	Number of studies	tbd	High; Med; Low
Initiated	Number of studies	tbd	
Ongoing	Number of studies	tbd	
Completed	Number of studies	tbd	
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Publications	Number of publications	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Posters	Number of posters	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Digital Applications	Number of applications	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
Other External activities	Number of activities	tbd	High; Med; Low
Amount invested	Value in €uros	tbd	
Time spent	Number of hours	tbd	
External Customer feedback survey		yearly	High; Med; Low

Cross Product Involvement		Measurement (quantitative)	Frequency of collection	Impact (qualitative)
	Institutional Review (Public Affairs/Media)	Number of requests	tbd	High; Med; Low
	Time spent	Number of hours	tbd	
	Compliance Review			
	Quality of processes (SOPs; Guidelines; Norms)	Number of events	tbd	High; Med; Low
	Quality of Products; Recalls; Stock-outs	Number of events	tbd	High; Med; Low
	Contracts	Number of contracts	tbd	High; Med; Low
	Fair Market Value (FMV)	Number of FMV requests	tbd	High; Med; Low
	Transparency Platform	Number of reports	tbd	High; Med; Low
	Audits & Inspections	Number of events	tbd	High; Med; Low
	Time spent	Number of hours	tbd	High; Med; Low
	Reports	Number of reports	tbd	High; Med; Low
	Pharmacovigilance	Number of reports	tbd	High; Med; Low
	Medical Information	Number of reports	tbd	High; Med; Low
	Telephone	Number of reports	tbd	High; Med; Low
	Fuel	Number of reports	tbd	High; Med; Low
	Travel	Number of reports	tbd	High; Med; Low
	Time spent	Number of hours	tbd	High; Med; Low
	Requests	Number of requests	tbd	High; Med; Low
	Scientific Support	Number of requests	tbd	High; Med; Low
	Financial Support	Number of requests	tbd	High; Med; Low
	Time spent	Number of hours	tbd	High; Med; Low
	Personal Training	Number of sessions	tbd	High; Med; Low
	Time spent	Number of hours	tbd	
	Team Objectives			
	Setting	Number of hours	tbd	High; Med; Low
	Review	Number of hours	tbd	High; Med; Low
	Evaluation	Number of hours	tbd	High; Med; Low
	e-mail Management	Number of e-mails	tbd	High; Med; Low
	Time spent	Number of hours	tbd	
	Other Cross Product Activities	Number of activities	tbd	High; Med; Low
	Time spent	Number of hours	tbd	

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APPENDIX I

APPENDIX I – PHARMA AND CUSTOMERS' QUESTIONNAIRES

Questionnaire to professionals working for the Pharma Industry

The current questionnaire is part of a study "Contribution to an efficient Medical Management in Pharmaceutical Industry" which is being carried out by José Augusto Aleixo Dias MD at the University of Aveiro, within the Doctoral Program in Sciencies and Health Technologies, under the supervision of Professor José Manuel Calheiros. This questionnaire aims to collect the perception of the Medical Affairs (MA) contribution to the Pharmaceutical companies and to the customers they serve, in several dimensions. Your participation is voluntary and highly valuable to obtain a clear picture on how the work performed by these professionals is perceived, as well as, to identify areas of potential improvement. All the data collected is entirely confidential and will be treated anonymously, exclusively for the purpose of this study.
Thanks very much for your participation!

The investigator:
José Augusto Aleixo Dias, MD
Contacts: jose.a.dias@pfizer.com; Mobile: +351 91 725 47 26

* Required
1- In which condition do you answer this questionnaire? *

- o ☐ General Manager / Business Unit Director
- o ☐ Medical Affairs
- o ☐ Marketing / Customer Marketing
- o ☐ Regulatory
- o ☐ Safety / Pharmacovigilance
- o ☐ Medical Information
- o ☐ Quality of Products / Processes
- o ☐ Pharmacoeconomics / Access / Health & Value
- o ☐ Finance
- o ☐ Trade/ Distribution/ Logistics
- o ☐ Human Resources
- o ☐ Commercial
- o ☐ Legal
- o ☐ Business technology
- o ☐ Assistant
- o ☐ Other: ____

This is a required question
2- Gender *

- Male
- Female

This is a required question

3- Age *
Must be a whole number
This is a required question

4- Type of company you work to? *
Select one option

- Portuguese Company (If you chose this option, select "not applicable" in the following 2 questions)
- Multinational Company

This is a required question
5- In multinational companies, strategic Medical Affairs decisions should be taken preferably at: *
(If you work for a Portuguese Company, please select "not applicable")

- Global level
- Regional level
- Local level
- At all levels
- Not applicable

This is a required question
6- In multinational companies, Medical Affairs should preferably report: *
(If you work for a Portuguese Company, please select "not applicable")

- Centrally
- Locally to the General Manager
- Both
- Not applicable

This is a required question

7- How many people work in your Company in Portugal? *
Please fill with an entire number
Must be a number
This is a required question

8- How many Medical Affairs persons do you have in your Company in Portugal? *
Please fill with an entire number
Must be a number greater than 0
This is a required question

9- How important is for you the Medical Affairs contribution for the overall results of the Company? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

1	2	3	4	5
☐	☐	☐	☐	☐

This is a required question

10- How do you rate the Medical Affairs contribution to strategic activities, such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
Clinical Research	☐	☐	☐	☐	☐
Market access	☐	☐	☐	☐	☐
Operating Plans	☐	☐	☐	☐	☐
Product launch and support	☐	☐	☐	☐	☐
Safety and Pharmacovigilance	☐	☐	☐	☐	☐
Compliance	☐	☐	☐	☐	☐
KOL mapping	☐	☐	☐	☐	☐
Management of Customer relations	☐	☐	☐	☐	☐
Other (rate and describe bellow)	☐	☐	☐	☐	☐

Please enter one response per row

11- If "other" please describe

This is a required question

12- How do you rate the Medical Affairs contribution to operational activities, such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
Cross-functional meetings	☐	☐	☐	☐	☐

	1	2	3	4	5
Education Materials preparation and review	☐	☐	☐	☐	☐
Promotional Materials preparation and review	☐	☐	☐	☐	☐
Advisory Board preparation and management	☐	☐	☐	☐	☐
Symposium preparation, invitations and content review	☐	☐	☐	☐	☐
Contribution to reimbursement dossiers	☐	☐	☐	☐	☐
Internal training of Sales Force and other colleagues	☐	☐	☐	☐	☐
Presentations to customers	☐	☐	☐	☐	☐
Product related response to questions	☐	☐	☐	☐	☐
Safety reporting	☐	☐	☐	☐	☐
Digital and multichannel	☐	☐	☐	☐	☐
Other (rate and describe bellow)	☐	☐	☐	☐	☐

Please enter one response per row

13- If "other" please describe

This is a required question

14- What is your assessment of the Medical Affairs contribution for the digital & multichannel development and implementation processes? *

(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
Health Care Professionals	☐	☐	☐	☐	☐

	1	2	3	4	5
websites/Portals					
Preparing /reviewing materials for self detailing	☐	☐	☐	☐	☐
Training materials for Health Care Professionals (self education)	☐	☐	☐	☐	☐
Newsletters	☐	☐	☐	☐	☐
Webexe's	☐	☐	☐	☐	☐
Webinars live	☐	☐	☐	☐	☐
Webinars on demand	☐	☐	☐	☐	☐
Mobile Applications (e.g. disease awareness)	☐	☐	☐	☐	☐
Social media	☐	☐	☐	☐	☐
Other (rate and describe bellow)	☐	☐	☐	☐	☐

Please enter one response per row

15- If "other" please describe

This is a required question

16- When recruiting a Medical Affairs person, how do you value her/his personal characteristics? *

(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
Competence in a specific area	☐	☐	☐	☐	☐
Experience	☐	☐	☐	☐	☐
Flexibility	☐	☐	☐	☐	☐
Fluency in foreign languages	☐	☐	☐	☐	☐

	1	2	3	4	5
Pro-activeness	☐	☐	☐	☐	☐
Problem solving attitude	☐	☐	☐	☐	☐
Posture/Aspect	☐	☐	☐	☐	☐
Other (rate and describe bellow)	☐	☐	☐	☐	☐

Please enter one response per row

17- If "other" please describe

This is a required question

18- In general, what is the reasonable number of products a Medical Affairs FTE should have under her/his responsibility? *

(FTE - Full time equivalent)

Must be a number

This is a required question

19- How many Medical Affairs FTEs do you think would be needed to support a product during its life cycle? *

(Indicate the current number of FTEs)

	0	0,5	1	1,5	2	2,5	3	>3
1 year before the launch	☐	☐	☐	☐	☐	☐	☐	☐
6 months before the launch	☐	☐	☐	☐	☐	☐	☐	☐

	0	0,5	1	1,5	2	2,5	3	>3
At launch	☐	☐	☐	☐	☐	☐	☐	☐
6 months after the launch	☐	☐	☐	☐	☐	☐	☐	☐
1 year after the launch	☐	☐	☐	☐	☐	☐	☐	☐
2 year after the launch	☐	☐	☐	☐	☐	☐	☐	☐
3 to 5 years after launch	☐	☐	☐	☐	☐	☐	☐	☐
More than 5 years after launch	☐	☐	☐	☐	☐	☐	☐	☐

Please enter one response per row

20- In general, how many customers should a Medical Affairs person manage during her/his customer facing activity? *

This is a required question

21- How much do you value Medical Affairs activities, such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
Customer's scientific update	☐	☐	☐	☐	☐
Identification and response to customer's needs	☐	☐	☐	☐	☐
Capture insights and explore opportunities	☐	☐	☐	☐	☐
Incorporate new scientific arguments or differentiation messages	☐	☐	☐	☐	☐
Incentivize local research,	☐	☐	☐	☐	☐

	1	2	3	4	5
publications and posters					
Provide evidence for the customer's decision making process					
Respond to scientific/educational customer's requests					
Other (rate and describe bellow)					

Please enter one response per row

22- If "other" please describe

This is a required question

23- How do you see Medical Affairs resources being more efficient for the business? *

- Office based
- Home based
- Virtual
- Other:

This is a required question

24- How do you see Clinical Research being more efficient for the business? *

- Company resources
- Outsourced resources
- Both
- Other:

This is a required question

25- How do you value each of the following aspects impacting Medical Affairs retention? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5
R&D pipeline					
Salary and fringe					

	1	2	3	4	5
benefits					
Work conditions					
Team inclusiveness					
Opportunities for personal development					
Coaching					
Leadership					
Recognition					
Other (rate and describe bellow)					

Please enter one response per row

26- If "other" please describe

This is a required question

27- How do you assess Medical Affairs contribution for the Company reputation and credibility? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

1	2	3	4	5

This is a required question

28- How do you forsee MA contribution for the business operations evolving in the future? *

- o More of
- o About the same
- o Less of

This is a required question

29- Are there skills or services that are not offered currently by Medical Affairs, that you would like to see being explored?

This is a required question

30- Any other comment or suggestion on Medical Affairs activity that you would like to make?

This is a required question

Questionnaire to Customers

The current questionnaire is part of a study "Contribution to an efficient Medical Management in Pharmaceutical Industry" which is being carried out by José Augusto Aleixo Dias MD at the University of Aveiro, within the Doctoral Program in Sciencies and Health Technologies, under the supervision of Professor José Manuel Calheiros. This questionnaire aims to collect the perception of the Medical Affairs (MA) contribution to the Pharmaceutical companies and to the customers they serve in several dimensions.
Your participation is voluntary and highly valuable to obtain a clear picture on how the work performed by these professionals is perceived, as well as, to identify areas of potential improvement. All the data collected are entirely confidential and will be treated anonymously, exclusively for the purpose of this study. Thanks very much for your participation!

The investigator:
José Augusto Aleixo Dias, MD
Contacts: jose.a.dias@pfizer.com; Mobile: +351 917254726

* Required

1- Customer type: In which condition do you answer this questionnaire? *

- ☐ Physician
- ☐ Pharmacist
- ☐ Nurse
- ☐ Administration Board member (ARS, ECEs, USFs, ACSS, SPMS, etc…)
- ☐ Regulatory Authorities (Infarmed, DGS, Ministry of Health, etc…)
- ☐ Faculty (Professor, Investigator, etc…)
- ☐ Other: _____

2- Gender *

- ☐ Male
- ☐ Female

3- Age *

4- Type of Institution you work for? *

- ☐ National Health Service (SNS)
- ☐ State other than SNS
- ☐ Private
- ☐ Other: _____

5- How many people work for your Institution/Company in Portugal ? *

_____

6- How many people report directly to you ? *

7- How do you rate the value of your interactions with the following Pharmaceutical Industry representatives: *

	1	2	3	4	5	Don't know	Not applicable
Medical Affairs	☐	☐	☐	☐	☐	☐	☐
Sales Force representative	☐	☐	☐	☐	☐	☐	☐
Marketing Manager	☐	☐	☐	☐	☐	☐	☐
Key Account Manager	☐	☐	☐	☐	☐	☐	☐
Digital Marketing Manager	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

8- If you have selected "other" in the previous question, please rate and specify.

9- Based on your experience, how do you rate the scientific knowledge of Pfizer Medical Affairs ? *

	1	2	3	4	5	
Low	☐	☐	☐	☐	☐	High

10- How do you rate the Medical Affairs contribution to activities such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Education Materials Preparation and review	☐	☐	☐	☐	☐	☐	☐
Promotional Materials preparation and review	☐	☐	☐	☐	☐	☐	☐
Advisory Board preparation and management	☐	☐	☐	☐	☐	☐	☐
Symposium preparation, invitations and content	☐	☐	☐	☐	☐	☐	☐
Contribution to reimbursement dossiers	☐	☐	☐	☐	☐	☐	☐

	1	2	3	4	5	Don't know	Not applicable
Sales Force training	☐	☐	☐	☐	☐	☐	☐
Response to product related questions	☐	☐	☐	☐	☐	☐	☐
Safety Reporting and Pharmacovigilance	☐	☐	☐	☐	☐	☐	☐
Compliance of processes and procedures	☐	☐	☐	☐	☐	☐	☐
Management of Customer relations	☐	☐	☐	☐	☐	☐	☐
Digital & Multichannel development and support	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

11- If you have selected other in the previous question, please rate and specify.

12- How comfortable are you using digital communication channels, such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Emails	☐	☐	☐	☐	☐	☐	☐
Webex's	☐	☐	☐	☐	☐	☐	☐
Live Webinars	☐	☐	☐	☐	☐	☐	☐
On call webinars	☐	☐	☐	☐	☐	☐	☐
Social media (facebook, tweeter, etc.)	☐	☐	☐	☐	☐	☐	☐
Virtual Advisory Boards	☐	☐	☐	☐	☐	☐	☐
Health related Mobile Applications	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

13- If you have selected other in the previous question, please rate and specify.

14- What is your specific assessment of the Medical Affairs current contribution for the Digital & Multichanel development and implementation processes ? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Health Care Professionals Websites/Portals	☐	☐	☐	☐	☐	☐	☐
Preparing/reviewing materials for self-detailing	☐	☐	☐	☐	☐	☐	☐
Training Materials for Health Care Professionals (self-education)	☐	☐	☐	☐	☐	☐	☐
Newsletters	☐	☐	☐	☐	☐	☐	☐
Webinars (live)	☐	☐	☐	☐	☐	☐	☐
Webinars (on demand)	☐	☐	☐	☐	☐	☐	☐
Mobile Applications (e.g. disease awareness)	☐	☐	☐	☐	☐	☐	☐
Social Media (facebook; twitter; other?)	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

15- If you have selected other in the previous question, please rate and specify.

16- What is your specific assessment of the Medical Affairs future contribution for the Digital & Multichanel development and implementation processes ? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Health Care Professionals Websites/Portals	☐	☐	☐	☐	☐	☐	☐
Preparing/reviewing materials for self-detailing	☐	☐	☐	☐	☐	☐	☐
Training Materials for Health Care Professionals (self-education)	☐	☐	☐	☐	☐	☐	☐
Newsletters	☐	☐	☐	☐	☐	☐	☐
Webinars (live)	☐	☐	☐	☐	☐	☐	☐
Webinars (on demand)	☐	☐	☐	☐	☐	☐	☐
Mobile Applications (e.g. disease awareness)	☐	☐	☐	☐	☐	☐	☐

	1	2	3	4	5	Don't know	Not applicable
Social Media (facebook; twitter; other?)	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

17- If you have selected "other" in the previous question, please rate and specify.

18- In general, what is the reasonable number of medicines a Medical Affairs person should have under her/his responsibility? *

19- How many Medical Affairs persons do you think would be needed to support a medicine launch during its life cycle ? *
(indicate the number of Medical Affairs persons you think is reasonable at each stage; e.g. 0,5 means half person)

	0	0,5	1	1,5	2	2,5	3	>3	Don't know	Not applicable
1 year before launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6 months before launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
At launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6 Months after launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1 year after launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2 years after launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3 to 5 years after launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
More than 5 years after launch	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

20- In general, how many customers should a Medical Affairs person manage during her/his customer facing activity ? *

21- How much do you value the Medical Affairs activities such as: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Clinical Research	☐	☐	☐	☐	☐	☐	☐
Market access	☐	☐	☐	☐	☐	☐	☐
Operating Plans	☐	☐	☐	☐	☐	☐	☐
Product launch and support	☐	☐	☐	☐	☐	☐	☐
Safety and Pharmacovigilance	☐	☐	☐	☐	☐	☐	☐
Compliance	☐	☐	☐	☐	☐	☐	☐
KOL mapping	☐	☐	☐	☐	☐	☐	☐
Management of Customer relations	☐	☐	☐	☐	☐	☐	☐
Other (rate and describe bellow)	☐	☐	☐	☐	☐	☐	☐

22- If "other" please describe

23- Have you ever been involved in performing some of these studies? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Clinical Trials	☐	☐	☐	☐	☐	☐	☐
Investigator Initiated Research (IIRs)	☐	☐	☐	☐	☐	☐	☐
Other non-interventional studies	☐	☐	☐	☐	☐	☐	☐

24- How do you value the following Clinical Research type of projects ? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Clinical Trials	☐	☐	☐	☐	☐	☐	☐
Institutional Real World Data (Studies and Registries)	☐	☐	☐	☐	☐	☐	☐
Investigator Initiated Research	☐	☐	☐	☐	☐	☐	☐
Other non-interventional	☐	☐	☐	☐	☐	☐	☐

	1	2	3	4	5	Don't know	Not applicable
studies							

25- in order to make Clinical Research more efficient in Portugal what would be for you the most important driver ? *
(choose the most important one)

- ☐ Interest /perceived value
- ☐ Proper conditions
- ☐ Available time
- ☐ Available budget
- ☐ Other:

26- In your view, what are the major roadblocks for Clinical Trials implementation in Portugal ? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Lack of interest	☐	☐	☐	☐	☐	☐	☐
Lack of time	☐	☐	☐	☐	☐	☐	☐
Lack of resources	☐	☐	☐	☐	☐	☐	☐
Long approval timelines	☐	☐	☐	☐	☐	☐	☐
Difficult protocols	☐	☐	☐	☐	☐	☐	☐
Low Curriculum impact	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

27- If you have selected other in the previous question, please rate and specify.

28- What do you think is the contribution of the Medical Affairs in the implementation of the EFPIA disclosure code of transparency between the Pharmaceutical Industry and Health Care Professionals and healthcare organizations? *
(choose one)

- ☐ High
- ☐ Medium
- ☐ Low

29- How can patients benefit from the Medical Affairs activity? *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't Know	Not applicable
Contributing to develop more efficient treatment options	☐	☐	☐	☐	☐	☐	☐
Contributing to bring these medicines into our market	☐	☐	☐	☐	☐	☐	☐
Providing HCPs with updated information on available medicines so that they can make the best treatment choices for patients	☐	☐	☐	☐	☐	☐	☐
Stimulating patient's treatment adherence and compliance	☐	☐	☐	☐	☐	☐	☐
Contributing to raise disease awareness	☐	☐	☐	☐	☐	☐	☐
Support Patients Associations	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

30- If you have selected other in the previous question, please rate and specify.

31- In your opinion what has been the Pharmaceutical Industry Contribution to the health gains achieved so far ? *
(choose one)

- ☐ High
- ☐ Medium
- ☐ Low

32- What is your perception of the Pharmaceutical Industry image ? *
(choose one)

- ☐ Poor
- ☐ Fair
- ☐ Satisfactory
- ☐ Good
- ☐ Excellent

33- Why ? *
(please provide a short explanation)

34- How can the Medical Affairs contribute to improve the Pharmaceutical Industry image? *
(please choose the most important option)

- ☐ Promote a better understanding of the compliance rules under which it operates?
- ☐ Contribute to the transparency of the interactions with Health Care Professionals
- ☐ Provide scientific support for a better informed treatment choices (value of Medicines)
- ☐ Show independency from Marketing/Commercial interests
- ☐ Other:

35- In your opinion, do Medical Affairs provide unbiased scientific support? *
(choose one)

- ☐ Yes
- ☐ No

36- How do you value the outcomes resulting from your interaction with Medical Affairs in what regards: *
(rate 1 to 5, being 1 the lowest and 5 the highest)

	1	2	3	4	5	Don't know	Not applicable
Efficacy profile of medicines	☐	☐	☐	☐	☐	☐	☐
Safety profile of medicines	☐	☐	☐	☐	☐	☐	☐
Differentiation versus competitors	☐	☐	☐	☐	☐	☐	☐
Scientific update - New drug	☐	☐	☐	☐	☐	☐	☐

	1	2	3	4	5	Don't know	Not applicable
development							
Scientific update - Research Grants & IIRs (investigator Initiated Research)	☐	☐	☐	☐	☐	☐	☐
Scientific update - Congresses & Symposia	☐	☐	☐	☐	☐	☐	☐
Scientific update – Publications	☐	☐	☐	☐	☐	☐	☐
Scientific update - Webinars	☐	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐	☐

37- If "other" please rate and specify.

38- How do you see Medical Affairs evolving in the future? *
(choose one)

- ☐ More of
- ☐ About the same
- ☐ Less of

39- Are there any other comment/suggestion you would like to make, so that Medical Affairs can be more efficient?

Submit

APPENDIX II

APPENDIX II – BIVARIATE ANALYSIS

Independent Samples T-Test

Condition

Independent Samples T-Test

	W	p
V9	2873.000	0.108

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V9	Medical Affairs	0.673	< .001
	Other	0.767	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V9	0.144	1	0.705

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V9	Medical Affairs	38	4.474	0.647	0.105
	Other	131	4.282	0.705	0.062

Independent Samples T-Test

Gender

Independent Samples T-Test

	W	p
V9	3094.000	0.100

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V9	Male	0.762	< .001
	Female	0.743	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V9	0.032	1	0.859

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V9	Male	81	4.235	0.729	0.081
	Female	88	4.409	0.655	0.070

ANOVA

Age classes

ANOVA - V9

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.742	3.000	0.581	1.207	0.309
Residual	79.359	165.000	0.481		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.648	3.000	165.000	0.180

Descriptives

Descriptives - V9

Classes	Mean	SD	N
<=34	4.387	0.761	31.000
35-44	4.239	0.665	71.000
45-54	4.458	0.683	48.000
>=55	4.211	0.713	19.000

Independent Samples T-Test

Company type

Independent Samples T-Test

	W	p
V9	826.000	0.219

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V9	Portuguese Company	0.827	0.015
	Multinational Company	0.755	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V9	9.997	1	0.002

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V9	Portuguese Company	13	3.923	1.188	0.329
	Multinational Company	156	4.359	0.632	0.051

Independent Samples T-Test

Condition

Independent Samples T-Test

	W	p
V101	2471.000	0.943
V102	2428.500	0.800
V103	3058.000	0.020
V104	2939.000	0.044
V105	2437.000	0.833
V106	2896.500	0.096
V107	3028.000	0.024
V108	2886.500	0.105
Strategic_m	2959.000	0.076

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V101	Medical Affairs	0.776	< .001
	Other	0.756	< .001
V102	Medical Affairs	0.813	< .001
	Other	0.818	< .001
V103	Medical Affairs	0.833	< .001
	Other	0.846	< .001
V104	Medical Affairs	0.528	< .001
	Other	0.676	< .001
V105	Medical Affairs	0.786	< .001
	Other	0.792	< .001
V106	Medical Affairs	0.748	< .001
	Other	0.817	< .001
V107	Medical Affairs	0.639	< .001
	Other	0.757	< .001
V108	Medical Affairs	0.747	< .001
	Other	0.811	< .001
Strategic_m	Medical Affairs	0.936	0.030
	Other	0.967	0.003

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V101	0.337	1	0.563
V102	0.633	1	0.427
V103	0.067	1	0.796
V104	19.000	1	< .001
V105	2.483	1	0.117
V106	3.260	1	0.073
V107	3.754	1	0.054
V108	0.058	1	0.810
Strategic_m	0.586	1	0.445

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V101	Medical Affairs	38	4.263	0.891	0.145
	Other	131	4.290	0.855	0.075
V102	Medical Affairs	38	3.895	0.689	0.112
	Other	131	3.893	0.816	0.071
V103	Medical Affairs	38	4.053	0.837	0.136
	Other	131	3.733	0.773	0.068
V104	Medical Affairs	38	4.763	0.431	0.070
	Other	131	4.565	0.542	0.047
V105	Medical Affairs	38	4.184	0.926	0.150
	Other	131	4.275	0.713	0.062
V106	Medical Affairs	38	4.289	0.898	0.146
	Other	131	4.122	0.723	0.063
V107	Medical Affairs	38	4.632	0.589	0.096
	Other	131	4.313	0.814	0.071
V108	Medical Affairs	38	4.395	0.755	0.122
	Other	131	4.153	0.855	0.075
Strategic_m	Medical Affairs	38	4.311	0.483	0.078
	Other	131	4.170	0.453	0.040

Independent Samples T-Test

Gender

Independent Samples T-Test

	W	p
V101	3666.500	0.725
V102	3170.500	0.166
V103	2835.500	0.013
V104	3262.000	0.260
V105	3631.500	0.819
V106	3283.500	0.338
V107	2760.500	0.005
V108	2590.500	< .001
Strategic_m	2845.500	0.023

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V101	Male	0.751	< .001
	Female	0.773	< .001
V102	Male	0.840	< .001
	Female	0.784	< .001
V103	Male	0.854	< .001
	Female	0.823	< .001
V104	Male	0.664	< .001
	Female	0.634	< .001
V105	Male	0.784	< .001
	Female	0.785	< .001
V106	Male	0.825	< .001
	Female	0.784	< .001
V107	Male	0.778	< .001
	Female	0.681	< .001
V108	Male	0.843	< .001
	Female	0.745	< .001
Strategic_m	Male	0.963	0.018
	Female	0.967	0.026

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V101	0.552	1	0.459
V102	6.422	1	0.012
V103	2.404	1	0.123
V104	1.001	1	0.319
V105	1.007	1	0.317
V106	0.003	1	0.957
V107	3.078	1	0.081
V108	0.392	1	0.532
Strategic_m	0.785	1	0.377

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V101	Male	81	4.284	0.912	0.101
	Female	88	4.284	0.816	0.087
V102	Male	81	3.790	0.862	0.096
	Female	88	3.989	0.703	0.075
V103	Male	81	3.667	0.775	0.086
	Female	88	3.932	0.799	0.085
V104	Male	81	4.568	0.523	0.058
	Female	88	4.648	0.526	0.056
V105	Male	81	4.247	0.830	0.092
	Female	88	4.261	0.703	0.075
V106	Male	81	4.111	0.758	0.084
	Female	88	4.205	0.775	0.083
V107	Male	81	4.198	0.886	0.098
	Female	88	4.557	0.623	0.066
V108	Male	81	3.975	0.922	0.102
	Female	88	4.420	0.690	0.074
Strategic_m	Male	81	4.107	0.489	0.054
	Female	88	4.289	0.421	0.045

Independent Samples T-Test

Company type

Independent Samples T-Test

	W	p
V101	813.500	0.197
V102	914.000	0.511
V103	892.000	0.436
V104	1008.500	0.972
V105	1144.000	0.406
V106	885.500	0.412
V107	620.000	0.010
V108	891.500	0.436
Strategic_m	739.500	0.104

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V101	Portuguese Company	0.799	0.007
	Multinational Company	0.766	< .001
V102	Portuguese Company	0.429	< .001
	Multinational Company	0.831	< .001
V103	Portuguese Company	0.790	0.005
	Multinational Company	0.851	< .001
V104	Portuguese Company	0.628	< .001
	Multinational Company	0.654	< .001
V105	Portuguese Company	0.646	< .001
	Multinational Company	0.796	< .001
V106	Portuguese Company	0.627	< .001
	Multinational Company	0.809	< .001
V107	Portuguese Company	0.746	0.002
	Multinational Company	0.720	< .001
V108	Portuguese Company	0.857	0.035
	Multinational Company	0.792	< .001
Strategic_m	Portuguese Company	0.939	0.444
	Multinational Company	0.964	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V101	9.925	1	0.002
V102	0.024	1	0.877
V103	0.025	1	0.875
V104	0.114	1	0.736
V105	1.509	1	0.221
V106	4.962	1	0.027
V107	2.655	1	0.105
V108	0.605	1	0.438
Strategic_m	0.416	1	0.520

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V101	Portuguese Company	13	3.769	1.423	0.395
	Multinational Company	156	4.327	0.788	0.063
V102	Portuguese Company	13	3.692	0.855	0.237
	Multinational Company	156	3.910	0.782	0.063
V103	Portuguese Company	13	3.692	0.751	0.208
	Multinational Company	156	3.814	0.802	0.064
V104	Portuguese Company	13	4.615	0.506	0.140
	Multinational Company	156	4.609	0.528	0.042
V105	Portuguese Company	13	4.462	0.519	0.144
	Multinational Company	156	4.237	0.780	0.062
V106	Portuguese Company	13	4.000	0.707	0.196
	Multinational Company	156	4.173	0.772	0.062
V107	Portuguese Company	13	3.923	0.760	0.211
	Multinational Company	156	4.423	0.771	0.062
V108	Portuguese Company	13	4.000	1.000	0.277
	Multinational Company	156	4.224	0.824	0.066
Strategic_m	Portuguese Company	13	4.021	0.450	0.125
	Multinational Company	156	4.217	0.462	0.037

ANOVA

Age classes

ANOVA - V101

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.535	3.000	1.178	1.609	0.189
Residual	120.832	165.000	0.732		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.939	3.000	165.000	0.125

Descriptives

Descriptives - V101

Classes	Mean	SD	N
<=34	4.323	0.653	31.000
35-44	4.296	0.818	71.000
45-54	4.396	0.869	48.000
>=55	3.895	1.197	19.000

ANOVA

ANOVA - V102

Cases	Sum of Squares	df	Mean Square	F	p
Classes	4.624	3.000	1.541	2.557	0.057
Residual	99.459	165.000	0.603		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
2.337	3.000	165.000	0.076

Descriptives

Descriptives - V102

Classes	Mean	SD	N
<=34	3.613	0.882	31.000
35-44	3.887	0.708	71.000
45-54	4.104	0.722	48.000
>=55	3.842	0.958	19.000

ANOVA

ANOVA - V103

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.454	3.000	0.485	0.761	0.517
Residual	105.102	165.000	0.637		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.585	3.000	165.000	0.626

Descriptives

Descriptives - V103

Classes	Mean	SD	N
<=34	3.677	0.871	31.000
35-44	3.789	0.695	71.000
45-54	3.938	0.885	48.000
>=55	3.737	0.806	19.000

ANOVA

ANOVA - V104

Cases	Sum of Squares	df	Mean Square	F	p
Classes	2.100	3.000	0.700	2.618	0.053
Residual	44.124	165.000	0.267		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
6.671	3.000	165.000	< .001

Descriptives

Descriptives - V104

Classes	Mean	SD	N
<=34	4.419	0.620	31.000
35-44	4.592	0.523	71.000
45-54	4.750	0.438	48.000
>=55	4.632	0.496	19.000

ANOVA

ANOVA - V105

Cases	Sum of Squares	df	Mean Square	F	p
Classes	6.452	3.000	2.151	3.874	0.010
Residual	91.607	165.000	0.555		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.072	3.000	165.000	0.362

Post Hoc Tests

Post Hoc Comparisons - Classes

		Mean Difference	SE	t	p_{tukey}	p_{bonf}
<=34	35-44	-0.058	0.160	-0.363	0.983	1.000
	45-54	-0.466	0.172	-2.713	0.035	0.044
	>=55	-0.008	0.217	-0.039	1.000	1.000
35-44	45-54	-0.408	0.139	-2.927	0.020	0.023
	>=55	0.050	0.192	0.258	0.994	1.000
45-54	>=55	0.457	0.202	2.264	0.108	0.149

Descriptives

Descriptives - V105

Classes	Mean	SD	N
<=34	4.097	0.746	31.000
35-44	4.155	0.690	71.000
45-54	4.563	0.649	48.000
>=55	4.105	1.100	19.000

ANOVA

ANOVA - V106

Cases	Sum of Squares	df	Mean Square	F	p
Classes	5.186	3.000	1.729	3.050	0.030
Residual	93.501	165.000	0.567		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.649	3.000	165.000	0.180

Post Hoc Tests

Post Hoc Comparisons - Classes

		Mean Difference	SE	t	p_{tukey}	p_{bonf}
<=34	35-44	-0.181	0.162	-1.119	0.673	1.000
	45-54	-0.430	0.173	-2.480	0.065	0.085
	>=55	-0.518	0.219	-2.361	0.086	0.116
35-44	45-54	-0.249	0.141	-1.769	0.286	0.473
	>=55	-0.337	0.194	-1.731	0.305	0.512
45-54	>=55	-0.088	0.204	-0.430	0.973	1.000

Descriptives

Descriptives - V106

Classes	Mean	SD	N
<=34	3.903	0.831	31.000
35-44	4.085	0.692	71.000
45-54	4.333	0.834	48.000
>=55	4.421	0.607	19.000

ANOVA

ANOVA - V107

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.411	3.000	1.137	1.903	0.131
Residual	98.589	165.000	0.598		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.557	3.000	165.000	0.644

Descriptives

Descriptives - V107

Classes	Mean	SD	N
<=34	4.452	0.675	31.000
35-44	4.465	0.734	71.000
45-54	4.375	0.866	48.000
>=55	4.000	0.816	19.000

ANOVA

ANOVA - V108

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.556	3.000	0.519	0.736	0.532
Residual	116.196	165.000	0.704		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.995	3.000	165.000	0.397

Descriptives

Descriptives - V108

Classes	Mean	SD	N
<=34	4.355	0.608	31.000
35-44	4.183	0.833	71.000
45-54	4.229	0.951	48.000
>=55	4.000	0.882	19.000

ANOVA

ANOVA - Strategic_m

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.474	3.000	0.491	2.352	0.074
Residual	34.483	165.000	0.209		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.109	3.000	165.000	0.955

Descriptives

Descriptives - Strategic_m

Classes	Mean	SD	N
<=34	4.106	0.399	31.000
35-44	4.184	0.445	71.000
45-54	4.338	0.500	48.000
>=55	4.082	0.479	19.000

Independent Samples T-Test

Condition

Independent Samples T-Test

	W	p
V1201	2789.500	0.209
V1202	2819.000	0.138
V1203	2292.500	0.416
V1204	3160.500	0.003
V1205	2815.500	0.167
V1206	2555.000	0.785
V1207	2764.500	0.251
V1208	3293.500	< .001
V1209	2731.000	0.315
V1210	2766.000	0.267
V1211	2520.000	0.902
Operat_m	2995.500	0.056

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1201	Medical Affairs	0.799	< .001
	Other	0.802	< .001
V1202	Medical Affairs	0.550	< .001
	Other	0.681	< .001
V1203	Medical Affairs	0.757	< .001
	Other	0.762	< .001
V1204	Medical Affairs	0.456	< .001
	Other	0.716	< .001
V1205	Medical Affairs	0.662	< .001
	Other	0.718	< .001
V1206	Medical Affairs	0.814	< .001
	Other	0.812	< .001
V1207	Medical Affairs	0.637	< .001
	Other	0.770	< .001
V1208	Medical Affairs	0.589	< .001
	Other	0.788	< .001
V1209	Medical Affairs	0.673	< .001
	Other	0.766	< .001
V1210	Medical Affairs	0.768	< .001
	Other	0.829	< .001
V1211	Medical Affairs	0.874	< .001
	Other	0.853	< .001
Operat_m	Medical Affairs	0.914	0.007
	Other	0.959	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1201	2.446	1	0.120
V1202	9.877	1	0.002
V1203	1.607	1	0.207
V1204	22.567	1	< .001
V1205	0.126	1	0.723
V1206	0.118	1	0.731
V1207	3.464	1	0.064
V1208	1.946	1	0.165
V1209	0.008	1	0.929
V1210	0.144	1	0.704
V1211	2.320	1	0.130
Operat_m	0.227	1	0.634

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V1201	Medical Affairs	38	4.184	0.730	0.118
	Other	131	4.015	0.712	0.062
V1202	Medical Affairs	38	4.737	0.446	0.072
	Other	131	4.557	0.622	0.054
V1203	Medical Affairs	38	4.289	0.694	0.113
	Other	131	4.366	0.746	0.065
V1204	Medical Affairs	38	4.816	0.457	0.074
	Other	131	4.435	0.776	0.068
V1205	Medical Affairs	38	4.553	0.686	0.111
	Other	131	4.389	0.750	0.066
V1206	Medical Affairs	38	4.132	0.741	0.120
	Other	131	4.107	0.704	0.062
V1207	Medical Affairs	38	4.500	0.507	0.082
	Other	131	4.298	0.772	0.067
V1208	Medical Affairs	38	4.658	0.627	0.102
	Other	131	4.237	0.773	0.068
V1209	Medical Affairs	38	4.421	0.826	0.134
	Other	131	4.321	0.757	0.066
V1210	Medical Affairs	38	4.263	0.795	0.129
	Other	131	4.092	0.827	0.072
V1211	Medical Affairs	38	3.658	1.047	0.170
	Other	131	3.679	0.853	0.075
Operat_m	Medical Affairs	38	4.384	0.458	0.074
	Other	131	4.227	0.489	0.043

Independent Samples T-Test

Gender

Independent Samples T-Test

	W	p
V1201	2921.500	0.025
V1202	3556.500	0.979
V1203	3286.000	0.336
V1204	2801.500	0.005
V1205	2874.500	0.015
V1206	3594.000	0.918
V1207	3121.000	0.123
V1208	3224.000	0.240
V1209	3572.500	0.978
V1210	3371.500	0.519
V1211	3175.000	0.190
Operat_m	2971.500	0.062

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1201	Male	0.813	< .001
	Female	0.787	< .001
V1202	Male	0.661	< .001
	Female	0.655	< .001
V1203	Male	0.787	< .001
	Female	0.730	< .001
V1204	Male	0.745	< .001
	Female	0.594	< .001
V1205	Male	0.749	< .001
	Female	0.679	< .001
V1206	Male	0.822	< .001
	Female	0.783	< .001
V1207	Male	0.771	< .001
	Female	0.737	< .001
V1208	Male	0.784	< .001
	Female	0.750	< .001
V1209	Male	0.729	< .001
	Female	0.766	< .001
V1210	Male	0.796	< .001
	Female	0.817	< .001
V1211	Male	0.862	< .001
	Female	0.846	< .001
Operat_m	Male	0.960	0.013
	Female	0.952	0.003

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1201	1.409	1	0.237
V1202	0.278	1	0.599
V1203	2.055	1	0.154
V1204	22.040	1	< .001
V1205	2.915	1	0.090
V1206	1.918	1	0.168
V1207	0.282	1	0.596
V1208	1.069	1	0.303
V1209	0.904	1	0.343
V1210	0.083	1	0.773
V1211	0.664	1	0.416
Operat_m	0.847	1	0.359

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V1201	Male	81	3.938	0.677	0.075
	Female	88	4.159	0.741	0.079
V1202	Male	81	4.605	0.563	0.063
	Female	88	4.591	0.618	0.066
V1203	Male	81	4.284	0.778	0.086
	Female	88	4.409	0.689	0.073
V1204	Male	81	4.333	0.866	0.096
	Female	88	4.693	0.533	0.057
V1205	Male	81	4.272	0.837	0.093
	Female	88	4.568	0.603	0.064
V1206	Male	81	4.099	0.784	0.087
	Female	88	4.125	0.640	0.068
V1207	Male	81	4.247	0.783	0.087
	Female	88	4.432	0.657	0.070
V1208	Male	81	4.247	0.830	0.092
	Female	88	4.409	0.689	0.073
V1209	Male	81	4.321	0.849	0.094
	Female	88	4.364	0.698	0.074
V1210	Male	81	4.099	0.800	0.089
	Female	88	4.159	0.843	0.090
V1211	Male	81	3.605	0.817	0.091
	Female	88	3.739	0.965	0.103
Operat_m	Male	81	4.187	0.508	0.056
	Female	88	4.332	0.456	0.049

Independent Samples T-Test

Company type

Independent Samples T-Test

	W	p
V1201	628.500	0.012
V1202	807.500	0.147
V1203	996.500	0.912
V1204	810.000	0.157
V1205	1019.000	0.976
V1206	991.500	0.886
V1207	1102.500	0.565
V1208	718.500	0.056
V1209	1204.500	0.216
V1210	1030.500	0.920
V1211	1092.000	0.624
Operat_m	883.000	0.440

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1201	Portuguese Company	0.628	< .001
	Multinational Company	0.805	< .001
V1202	Portuguese Company	0.772	0.003
	Multinational Company	0.646	< .001
V1203	Portuguese Company	0.776	0.004
	Multinational Company	0.766	< .001
V1204	Portuguese Company	0.787	0.005
	Multinational Company	0.662	< .001
V1205	Portuguese Company	0.750	0.002
	Multinational Company	0.716	< .001
V1206	Portuguese Company	0.799	0.007
	Multinational Company	0.804	< .001
V1207	Portuguese Company	0.750	0.002
	Multinational Company	0.755	< .001
V1208	Portuguese Company	0.820	0.012
	Multinational Company	0.754	< .001
V1209	Portuguese Company	0.628	< .001
	Multinational Company	0.753	< .001
V1210	Portuguese Company	0.757	0.002
	Multinational Company	0.807	< .001
V1211	Portuguese Company	0.812	0.010
	Multinational Company	0.858	< .001
Operat_m	Portuguese Company	0.956	0.690
	Multinational Company	0.954	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1201	0.081	1	0.776
V1202	0.535	1	0.466
V1203	4.092	1	0.045
V1204	0.973	1	0.325
V1205	0.129	1	0.720
V1206	2.122	1	0.147
V1207	0.056	1	0.813
V1208	2.224	1	0.138
V1209	1.877	1	0.172
V1210	0.063	1	0.802
V1211	0.240	1	0.625
Operat_m	0.052	1	0.820

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V1201	Portuguese Company	13	3.615	0.506	0.140
	Multinational Company	156	4.090	0.722	0.058
V1202	Portuguese Company	13	4.385	0.650	0.180
	Multinational Company	156	4.615	0.584	0.047
V1203	Portuguese Company	13	4.231	1.013	0.281
	Multinational Company	156	4.359	0.709	0.057
V1204	Portuguese Company	13	4.231	0.927	0.257
	Multinational Company	156	4.545	0.712	0.057
V1205	Portuguese Company	13	4.462	0.660	0.183
	Multinational Company	156	4.423	0.745	0.060
V1206	Portuguese Company	13	4.077	0.862	0.239
	Multinational Company	156	4.115	0.700	0.056
V1207	Portuguese Company	13	4.462	0.660	0.183
	Multinational Company	156	4.333	0.730	0.058
V1208	Portuguese Company	13	4.000	0.707	0.196
	Multinational Company	156	4.359	0.762	0.061
V1209	Portuguese Company	13	4.615	0.506	0.140
	Multinational Company	156	4.321	0.787	0.063
V1210	Portuguese Company	13	4.077	1.038	0.288
	Multinational Company	156	4.135	0.804	0.064
V1211	Portuguese Company	13	3.846	0.801	0.222
	Multinational Company	156	3.660	0.905	0.072
Operat_m	Portuguese Company	13	4.182	0.446	0.124
	Multinational Company	156	4.269	0.490	0.039

ANOVA

Age classes

ANOVA - V1201

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.934	3.000	1.311	2.620	0.053
Residual	82.587	165.000	0.501		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.447	3.000	165.000	0.720

Descriptives

Descriptives - V1201

Classes	Mean	SD	N
<=34	3.806	0.792	31.000
35-44	4.169	0.632	71.000
45-54	4.125	0.733	48.000
>=55	3.842	0.765	19.000

ANOVA

ANOVA - V1202

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.213	3.000	0.404	1.162	0.326
Residual	57.426	165.000	0.348		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
3.163	3.000	165.000	0.026

Descriptives

Descriptives - V1202

Classes	Mean	SD	N
<=34	4.516	0.677	31.000
35-44	4.535	0.629	71.000
45-54	4.708	0.504	48.000
>=55	4.684	0.478	19.000

ANOVA

ANOVA - V1203

Cases	Sum of Squares	df	Mean Square	F	p
Classes	0.062	3.000	0.021	0.037	0.990
Residual	90.341	165.000	0.548		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.082	3.000	165.000	0.358

Descriptives

Descriptives - V1203

Classes	Mean	SD	N
<=34	4.323	0.791	31.000
35-44	4.366	0.702	71.000
45-54	4.333	0.808	48.000
>=55	4.368	0.597	19.000

ANOVA

ANOVA - V1204

Cases	Sum of Squares	df	Mean Square	F	p
Classes	0.938	3.000	0.313	0.578	0.630
Residual	89.240	165.000	0.541		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.743	3.000	165.000	0.528

Descriptives

Descriptives - V1204

Classes	Mean	SD	N
<=34	4.452	0.675	31.000
35-44	4.535	0.693	71.000
45-54	4.604	0.765	48.000
>=55	4.368	0.895	19.000

ANOVA

ANOVA - V1205

Cases	Sum of Squares	df	Mean Square	F	p
Classes	2.350	3.000	0.783	1.453	0.229
Residual	88.975	165.000	0.539		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.227	3.000	165.000	0.302

Descriptives

Descriptives - V1205

Classes	Mean	SD	N
<=34	4.516	0.626	31.000
35-44	4.437	0.649	71.000
45-54	4.479	0.825	48.000
>=55	4.105	0.937	19.000

ANOVA

ANOVA - V1206

Cases	Sum of Squares	df	Mean Square	F	p
Classes	2.704	3.000	0.901	1.810	0.147
Residual	82.160	165.000	0.498		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.391	3.000	165.000	0.247

Descriptives

Descriptives - V1206

Classes	Mean	SD	N
<=34	3.871	0.670	31.000
35-44	4.141	0.639	71.000
45-54	4.146	0.772	48.000
>=55	4.316	0.820	19.000

ANOVA

ANOVA - V1207

Cases	Sum of Squares	df	Mean Square	F	p
Classes	4.762	3.000	1.587	3.143	0.027
Residual	83.333	165.000	0.505		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.718	3.000	165.000	0.542

Post Hoc Tests

Post Hoc Comparisons - Classes

		Mean Difference	SE	t	p_{tukey}
<=34	35-44	-0.465	0.153	-3.038	0.014
	45-54	-0.375	0.164	-2.290	0.102
	>=55	-0.368	0.207	-1.779	0.281
35-44	45-54	0.090	0.133	0.676	0.904
	>=55	0.096	0.184	0.525	0.952
45-54	>=55	0.007	0.193	0.034	1.000

Descriptives

Descriptives - V1207

Classes	Mean	SD	N
<=34	4.000	0.856	31.000
35-44	4.465	0.629	71.000
45-54	4.375	0.789	48.000
>=55	4.368	0.496	19.000

ANOVA

ANOVA - V1208

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.285	3.000	1.095	1.919	0.128
Residual	94.159	165.000	0.571		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.385	3.000	165.000	0.764

Descriptives

Descriptives - V1208

Classes	Mean	SD	N
<=34	4.065	0.772	31.000
35-44	4.338	0.696	71.000
45-54	4.479	0.825	48.000
>=55	4.368	0.761	19.000

ANOVA

ANOVA - V1209

Cases	Sum of Squares	df	Mean Square	F	p
Classes	6.674	3.000	2.225	3.930	0.010
Residual	93.420	165.000	0.566		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.866	3.000	165.000	0.137

Post Hoc Tests

Post Hoc Comparisons - Classes

		Mean Difference	SE	t	p_{tukey}
<=34	35-44	-0.501	0.162	-3.094	0.012
	45-54	-0.544	0.173	-3.136	0.011
	>=55	-0.380	0.219	-1.735	0.303
35-44	45-54	-0.043	0.141	-0.303	0.990
	>=55	0.121	0.194	0.622	0.923
45-54	>=55	0.163	0.204	0.801	0.851

Descriptives

Descriptives - V1209

Classes	Mean	SD	N
<=34	3.935	0.998	31.000
35-44	4.437	0.603	71.000
45-54	4.479	0.652	48.000
>=55	4.316	1.003	19.000

ANOVA

ANOVA - V1210

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.479	3.000	1.160	1.745	0.160
Residual	109.657	165.000	0.665		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.588	3.000	165.000	0.624

Descriptives

Descriptives - V1210

Classes	Mean	SD	N
<=34	3.871	0.922	31.000
35-44	4.113	0.803	71.000
45-54	4.292	0.743	48.000
>=55	4.211	0.855	19.000

ANOVA

ANOVA - V1211

Cases	Sum of Squares	df	Mean Square	F	p
Classes	6.723	3.000	2.241	2.880	0.038
Residual	128.378	165.000	0.778		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.385	3.000	165.000	0.764

Post Hoc Tests

Post Hoc Comparisons - Classes

		Mean Difference	SE	t	p_{tukey}
<=34	35-44	-0.488	0.190	-2.572	0.051
	45-54	-0.513	0.203	-2.523	0.058
	>=55	-0.584	0.257	-2.273	0.106
35-44	45-54	-0.024	0.165	-0.148	0.999
	>=55	-0.096	0.228	-0.420	0.974
45-54	>=55	-0.071	0.239	-0.298	0.991

Descriptives

Descriptives - V1211

Classes	Mean	SD	N
<=34	3.258	0.965	31.000
35-44	3.746	0.840	71.000
45-54	3.771	0.857	48.000
>=55	3.842	0.958	19.000

ANOVA

ANOVA - Operat_m

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.742	3.000	0.581	2.529	0.059
Residual	37.886	165.000	0.230		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.400	3.000	165.000	0.753

Descriptives

Descriptives - Operat_m

Classes	Mean	SD	N
<=34	4.056	0.469	31.000
35-44	4.299	0.473	71.000
45-54	4.345	0.501	48.000
>=55	4.254	0.461	19.000

Independent Samples T-Test

Condition

Independent Samples T-Test

	W	p
V1401	2239.000	0.312
V1402	2549.500	0.807
V1403	2609.000	0.625
V1404	2590.000	0.684
V1405	2314.500	0.474
V1406	2268.500	0.376
V1407	2131.000	0.150
V1408	2480.000	0.973
V1409	2256.000	0.350
Digital_m	2320.500	0.526

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1401	Medical Affairs	0.858	< .001
	Other	0.850	< .001
V1402	Medical Affairs	0.767	< .001
	Other	0.808	< .001
V1403	Medical Affairs	0.699	< .001
	Other	0.799	< .001
V1404	Medical Affairs	0.852	< .001
	Other	0.845	< .001
V1405	Medical Affairs	0.863	< .001
	Other	0.816	< .001
V1406	Medical Affairs	0.848	< .001
	Other	0.800	< .001
V1407	Medical Affairs	0.875	< .001
	Other	0.811	< .001
V1408	Medical Affairs	0.843	< .001
	Other	0.859	< .001
V1409	Medical Affairs	0.869	< .001
	Other	0.865	< .001
Digital_m	Medical Affairs	0.879	< .001
	Other	0.942	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1401	6.569	1	0.011
V1402	5.782	1	0.017
V1403	2.677	1	0.104
V1404	5.638	1	0.019
V1405	5.157	1	0.024
V1406	10.064	1	0.002
V1407	6.965	1	0.009
V1408	1.678	1	0.197
V1409	1.007	1	0.317
Digital_m	2.207	1	0.139

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V1401	Medical Affairs	38	3.632	1.125	0.183
	Other	131	3.885	0.829	0.072
V1402	Medical Affairs	38	4.132	1.070	0.174
	Other	131	4.206	0.741	0.065
V1403	Medical Affairs	38	4.184	1.136	0.184
	Other	131	4.244	0.785	0.069
V1404	Medical Affairs	38	3.816	1.136	0.184
	Other	131	3.840	0.840	0.073
V1405	Medical Affairs	38	3.684	1.068	0.173
	Other	131	3.863	0.830	0.073
V1406	Medical Affairs	38	3.763	1.218	0.198
	Other	131	4.015	0.894	0.078
V1407	Medical Affairs	38	3.605	1.175	0.191
	Other	131	3.901	0.927	0.081
V1408	Medical Affairs	38	3.684	1.093	0.177
	Other	131	3.725	0.912	0.080
V1409	Medical Affairs	38	3.316	1.093	0.177
	Other	131	3.511	0.915	0.080
Digital_m	Medical Affairs	38	3.758	0.930	0.151
	Other	131	3.910	0.689	0.060

Independent Samples T-Test

Gender

Independent Samples T-Test

	W	p
V1401	894.500	0.450
V1402	830.000	0.242
V1403	811.000	0.195
V1404	1151.500	0.385
V1405	1074.000	0.701
V1406	953.000	0.703
V1407	988.000	0.872
V1408	852.500	0.310
V1409	973.000	0.799
Digital_m	912.000	0.548

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1401	Portuguese Company	0.891	0.099
	Multinational Company	0.845	< .001
V1402	Portuguese Company	0.820	0.012
	Multinational Company	0.794	< .001
V1403	Portuguese Company	0.720	< .001
	Multinational Company	0.778	< .001
V1404	Portuguese Company	0.675	< .001
	Multinational Company	0.857	< .001
V1405	Portuguese Company	0.791	0.005
	Multinational Company	0.832	< .001
V1406	Portuguese Company	0.791	0.005
	Multinational Company	0.817	< .001
V1407	Portuguese Company	0.821	0.012
	Multinational Company	0.831	< .001
V1408	Portuguese Company	0.846	0.025
	Multinational Company	0.858	< .001
V1409	Portuguese Company	0.688	< .001
	Multinational Company	0.868	< .001
Digital_m	Portuguese Company	0.909	0.180
	Multinational Company	0.919	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1401	0.003	1	0.956
V1402	1.915	1	0.168
V1403	0.467	1	0.495
V1404	6.533	1	0.011
V1405	0.101	1	0.751
V1406	0.011	1	0.916
V1407	1.117	1	0.292
V1408	1.135	1	0.288
V1409	0.046	1	0.831
Digital_m	0.048	1	0.827

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE
V1401	Portuguese Company	13	3.692	0.855	0.237
	Multinational Company	156	3.840	0.912	0.073
V1402	Portuguese Company	13	4.000	0.707	0.196
	Multinational Company	156	4.205	0.833	0.067
V1403	Portuguese Company	13	3.923	1.038	0.288
	Multinational Company	156	4.256	0.857	0.069
V1404	Portuguese Company	13	4.077	0.494	0.137
	Multinational Company	156	3.814	0.935	0.075
V1405	Portuguese Company	13	3.846	1.068	0.296
	Multinational Company	156	3.821	0.876	0.070
V1406	Portuguese Company	13	3.846	1.068	0.296
	Multinational Company	156	3.968	0.973	0.078
V1407	Portuguese Company	13	3.846	0.801	0.222
	Multinational Company	156	3.833	1.009	0.081
V1408	Portuguese Company	13	3.385	1.121	0.311
	Multinational Company	156	3.744	0.936	0.075
V1409	Portuguese Company	13	3.385	0.870	0.241
	Multinational Company	156	3.474	0.967	0.077
Digital_m	Portuguese Company	13	3.779	0.730	0.202
	Multinational Company	156	3.884	0.753	0.060

Independent Samples T-Test

Company type

Independent Samples T-Test

	W	p
V1401	894.500	0.450
V1402	830.000	0.242
V1403	811.000	0.195
V1404	1151.500	0.385
V1405	1074.000	0.701
V1406	953.000	0.703
V1407	988.000	0.872
V1408	852.500	0.310
V1409	973.000	0.799
Digital_m	912.000	0.548

Note. Mann-Whitney U test.

Assumption Checks

Test of Normality (Shapiro-Wilk)

		W	p
V1401	Portuguese Company	0.891	0.099
	Multinational Company	0.845	< .001
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	Multinational Company	0.857	< .001
V1405	Portuguese Company	0.791	0.005
	Multinational Company	0.832	< .001
V1406	Portuguese Company	0.791	0.005
	Multinational Company	0.817	< .001
V1407	Portuguese Company	0.821	0.012
	Multinational Company	0.831	< .001
V1408	Portuguese Company	0.846	0.025
	Multinational Company	0.858	< .001
V1409	Portuguese Company	0.688	< .001
	Multinational Company	0.868	< .001
Digital_m	Portuguese Company	0.909	0.180
	Multinational Company	0.919	< .001

Note. Significant results suggest a deviation from normality.

Test of Equality of Variances (Levene's)

	F	df	p
V1401	0.003	1	0.956
V1402	1.915	1	0.168
V1403	0.467	1	0.495
V1404	6.533	1	0.011
V1405	0.101	1	0.751
V1406	0.011	1	0.916
V1407	1.117	1	0.292
V1408	1.135	1	0.288
V1409	0.046	1	0.831
Digital_m	0.048	1	0.827

Descriptives

Group Descriptives

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V1403	Portuguese Company	13	3.923	1.038	0.288
	Multinational Company	156	4.256	0.857	0.069
V1404	Portuguese Company	13	4.077	0.494	0.137
	Multinational Company	156	3.814	0.935	0.075
V1405	Portuguese Company	13	3.846	1.068	0.296
	Multinational Company	156	3.821	0.876	0.070
V1406	Portuguese Company	13	3.846	1.068	0.296
	Multinational Company	156	3.968	0.973	0.078
V1407	Portuguese Company	13	3.846	0.801	0.222
	Multinational Company	156	3.833	1.009	0.081
V1408	Portuguese Company	13	3.385	1.121	0.311
	Multinational Company	156	3.744	0.936	0.075
V1409	Portuguese Company	13	3.385	0.870	0.241
	Multinational Company	156	3.474	0.967	0.077
Digital_m	Portuguese Company	13	3.779	0.730	0.202
	Multinational Company	156	3.884	0.753	0.060

ANOVA

ANOVA - V1401

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.788	3.000	1.263	1.552	0.203
Residual	134.236	165.000	0.814		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.808	3.000	165.000	0.491

Descriptives

Descriptives - V1401

Classes	Mean	SD	N
<=34	3.806	0.980	31.000
35-44	3.887	0.803	71.000
45-54	3.917	0.919	48.000
>=55	3.421	1.071	19.000

ANOVA

ANOVA - V1402

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.016	3.000	1.005	1.495	0.218
Residual	110.925	165.000	0.672		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.690	3.000	165.000	0.171

Descriptives

Descriptives - V1402

Classes	Mean	SD	N
<=34	3.968	0.795	31.000
35-44	4.324	0.692	71.000
45-54	4.125	0.914	48.000
>=55	4.211	1.032	19.000

ANOVA

ANOVA - V1403

Cases	Sum of Squares	df	Mean Square	F	p
Classes	2.150	3.000	0.717	0.939	0.423
Residual	125.850	165.000	0.763		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.253	3.000	165.000	0.859

Descriptives

Descriptives - V1403

Classes	Mean	SD	N
<=34	4.129	0.806	31.000
35-44	4.338	0.774	71.000
45-54	4.229	0.905	48.000
>=55	4.000	1.202	19.000

ANOVA

ANOVA - V1404

Cases	Sum of Squares	df	Mean Square	F	p
Classes	3.992	3.000	1.331	1.622	0.186
Residual	135.369	165.000	0.820		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.746	3.000	165.000	0.526

Descriptives

Descriptives - V1404

Classes	Mean	SD	N
<=34	3.548	0.961	31.000
35-44	3.944	0.876	71.000
45-54	3.792	0.874	48.000
>=55	4.000	1.000	19.000

ANOVA

ANOVA - V1405

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.618	3.000	0.539	0.679	0.566
Residual	131.057	165.000	0.794		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.412	3.000	165.000	0.745

Descriptives

Descriptives - V1405

Classes	Mean	SD	N
<=34	3.677	1.013	31.000
35-44	3.915	0.824	71.000
45-54	3.750	0.838	48.000
>=55	3.895	1.049	19.000

ANOVA

ANOVA - V1406

Cases	Sum of Squares	df	Mean Square	F	p
Classes	2.078	3.000	0.693	0.721	0.541
Residual	158.632	165.000	0.961		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.922	3.000	165.000	0.128

Descriptives

Descriptives - V1406

Classes	Mean	SD	N
<=34	3.839	1.098	31.000
35-44	4.056	0.924	71.000
45-54	3.979	0.838	48.000
>=55	3.737	1.284	19.000

ANOVA

ANOVA - V1407

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.781	3.000	0.594	0.599	0.617
Residual	163.580	165.000	0.991		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
1.929	3.000	165.000	0.127

Descriptives

Descriptives - V1407

Classes	Mean	SD	N
<=34	3.710	1.071	31.000
35-44	3.944	0.969	71.000
45-54	3.813	0.842	48.000
>=55	3.684	1.293	19.000

ANOVA

ANOVA - V1408

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.964	3.000	0.655	0.718	0.542
Residual	150.402	165.000	0.912		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.588	3.000	165.000	0.623

Descriptives

Descriptives - V1408

Classes	Mean	SD	N
<=34	3.516	1.029	31.000
35-44	3.803	0.872	71.000
45-54	3.750	0.978	48.000
>=55	3.632	1.065	19.000

ANOVA

ANOVA - V1409

Cases	Sum of Squares	df	Mean Square	F	p
Classes	6.178	3.000	2.059	2.298	0.079
Residual	147.893	165.000	0.896		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
2.252	3.000	165.000	0.084

Descriptives

Descriptives - V1409

Classes	Mean	SD	N
<=34	3.065	1.181	31.000
35-44	3.549	0.824	71.000
45-54	3.563	0.873	48.000
>=55	3.579	1.121	19.000

ANOVA

ANOVA - Digital_m

Cases	Sum of Squares	df	Mean Square	F	p
Classes	1.799	3.000	0.600	1.069	0.364
Residual	92.568	165.000	0.561		

Note. Type III Sum of Squares

Assumption Checks

Test for Equality of Variances (Levene's)

F	df1	df2	p
0.254	3.000	165.000	0.858

Descriptives

Descriptives - Digital_m

Classes	Mean	SD	N
<=34	3.696	0.804	31.000
35-44	3.974	0.679	71.000
45-54	3.880	0.743	48.000
>=55	3.796	0.913	19.000

APPENDIX III

APPENDIX III – LOGISTIC REGRESSION

123 vs 45

Model summary

Model	Deviance	AIC	BIC	df	X^2	p	McFadden R^2
H_0	101.283	103.283	106.413	168			
H_1	25.675	83.675	174.442	140	75.608	< .001	0.747

Coefficients

	Estimate	Robust Standard Error	Standardized⁺	Odds Ratio	z	p	95% Confidence interval	
							Lower bound	Upper bound
(Intercept)	-76.125	40.020	16.331	8.694e -34	-1.902	0.057	-154.564	2.313
V101	5.536	3.316	4.763	253.718	1.669	0.095	-0.964	12.036
V102	-0.149	1.183	-0.117	0.862	-0.126	0.900	-2.468	2.170
V103	5.292	3.579	4.214	198.711	1.478	0.139	-1.723	12.307
V104	9.432	5.652	4.948	12483.203	1.669	0.095	-1.645	20.509
V105	-6.539	4.149	-4.996	0.001	-1.576	0.115	-14.671	1.593
V106	-1.021	0.922	-0.782	0.360	-1.108	0.268	-2.827	0.786
V107	0.759	0.894	0.592	2.137	0.849	0.396	-0.993	2.512
V108	4.354	3.263	3.645	77.815	1.335	0.182	-2.040	10.749
V1201	2.721	2.452	1.953	15.193	1.110	0.267	-2.085	7.527
V1202	-3.992	2.263	-2.358	0.018	-1.764	0.078	-8.427	0.443
V1203	1.323	0.772	0.971	3.756	1.715	0.086	-0.189	2.835
V1204	2.848	1.683	2.086	17.246	1.692	0.091	-0.451	6.146
V1205	-3.501	2.639	-2.581	0.030	-1.327	0.185	-8.672	1.671
V1206	-0.362	0.844	-0.257	0.697	-0.428	0.668	-2.016	1.293
V1207	-1.098	1.682	-0.795	0.334	-0.653	0.514	-4.394	2.198
V1208	3.615	4.162	2.754	37.169	0.869	0.385	-4.541	11.772
V1209	1.786	0.755	1.379	5.966	2.366	0.018	0.307	3.265
V1210	6.854	3.857	5.624	947.524	1.777	0.076	-0.706	14.414
V1211	3.438	2.267	3.083	31.130	1.516	0.129	-1.006	7.882
V1401	7.156	2.933	6.486	1281.382	2.440	0.015	1.408	12.904
V1402	-3.546	1.520	-2.920	0.029	-2.333	0.020	-6.524	-0.567
V1403	-3.024	1.962	-2.640	0.049	-1.542	0.123	-6.869	0.821
V1404	-7.195	4.498	-6.553	7.501e -4	-1.600	0.110	-16.012	1.621

Coefficients

	Estimate	Robust Standard Error	Standardized[+]	Odds Ratio	z	p	95% Confidence interval	
							Lower bound	Upper bound
V1405	-3.428	1.758	-3.046	0.032	-1.950	0.051	-6.873	0.018
V1406	-1.817	3.649	-1.777	0.162	-0.498	0.618	-8.969	5.335
V1407	4.324	3.335	4.290	75.480	1.297	0.195	-2.212	10.860
V1408	3.392	1.197	3.231	29.738	2.834	0.005	1.046	5.739
V1409	-5.432	2.287	-5.202	0.004	-2.375	0.018	-9.915	-0.948

[+] Standardized estimates represent estimates where the continuous predictors are standardized (X-standardization).

Note. V9a level '1' coded as class 1.

Performance Diagnostics

Confusion matrix

	Predicted	
Observed	0	1
0	14.000	1.000
1	0.000	154.000

Performance metrics

	Value
AUC	0.982
Sensitivity	1.000
Specificity	0.933
Precision	0.994

1234 vs 5

Model summary

Model	Deviance	AIC	BIC	df	X^2	p	McFadden R^2
H_0	231.144	233.144	236.274	168			
H_1	161.232	219.232	309.999	140	69.912	< .001	0.302

Coefficients

							95% Confidence interval	
	Estimate	Robust Standard Error	Standardized[+]	Odds Ratio	z	p	Lower bound	Upper bound
(Intercept)	-13.697	3.100	-0.535	1.126e-6	-4.418	< .001	-19.773	-7.621
V101	0.431	0.302	0.371	1.539	1.428	0.153	-0.161	1.023
V102	-0.503	0.385	-0.396	0.605	-1.305	0.192	-1.258	0.252
V103	0.075	0.349	0.059	1.077	0.214	0.831	-0.610	0.759
V104	0.188	0.522	0.099	1.207	0.361	0.718	-0.835	1.211
V105	0.717	0.484	0.548	2.048	1.480	0.139	-0.232	1.666
V106	0.254	0.367	0.195	1.289	0.692	0.489	-0.465	0.973
V107	0.296	0.451	0.231	1.344	0.656	0.512	-0.588	1.180
V108	1.055	0.448	0.884	2.873	2.357	0.018	0.178	1.933
V1201	-0.001	0.415	-0.001	0.999	-0.002	0.998	-0.815	0.813
V1202	0.831	0.562	0.491	2.297	1.480	0.139	-0.269	1.932
V1203	-1.581	0.446	-1.160	0.206	-3.548	< .001	-2.455	-0.708
V1204	-0.222	0.420	-0.163	0.801	-0.529	0.597	-1.044	0.601
V1205	0.750	0.500	0.553	2.117	1.500	0.134	-0.230	1.730
V1206	0.573	0.409	0.407	1.773	1.400	0.162	-0.229	1.375
V1207	-0.666	0.391	-0.483	0.514	-1.704	0.088	-1.433	0.100
V1208	0.271	0.469	0.206	1.311	0.577	0.564	-0.649	1.191
V1209	0.661	0.393	0.510	1.937	1.685	0.092	-0.108	1.431
V1210	-0.783	0.381	-0.642	0.457	-2.053	0.040	-1.530	-0.036
V1211	-0.291	0.449	-0.261	0.748	-0.648	0.517	-1.171	0.589
V1401	0.491	0.427	0.445	1.635	1.151	0.250	-0.345	1.328
V1402	0.442	0.465	0.364	1.555	0.949	0.342	-0.470	1.353
V1403	-0.336	0.540	-0.293	0.715	-0.623	0.533	-1.394	0.722
V1404	-0.413	0.459	-0.376	0.662	-0.899	0.369	-1.313	0.487
V1405	0.470	0.469	0.418	1.601	1.002	0.316	-0.449	1.390
V1406	0.078	0.494	0.076	1.081	0.158	0.875	-0.891	1.047
V1407	0.250	0.337	0.248	1.285	0.743	0.458	-0.410	0.911
V1408	0.116	0.415	0.111	1.123	0.281	0.779	-0.696	0.929
V1409	-0.119	0.403	-0.114	0.888	-	0.769	-0.909	0.672

Coefficients

	Estimate	Robust Standard Error	Standardized[+]	Odds Ratio	z	p	95% Confidence interval	
							Lower bound	Upper bound
					0.294			

[+] Standardized estimates represent estimates where the continuous predictors are standardized (X-standardization).

* Vovk-Sellke Maximum *p* -Ratio: Based on the *p* -value, the maximum possible odds in favor of H_1 over H_0 equals 1/(-e *p* log(*p*)) for *p* ≤ .37 (Sellke, Bayarri, & Berger, 2001).

Note. V9b level '1' coded as class 1.

Performance Diagnostics

Confusion matrix

	Predicted	
Observed	0	1
0	79.000	17.000
1	17.000	56.000

Performance metrics

	Value
AUC	0.848
Sensitivity	0.767
Specificity	0.823
Precision	0.767