



Enhancing MSLs Competence

————— MEDICAL SERIES —————

Benchmarking Study

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Smart Pharma carried out a benchmarking study regarding MSLS' best practices, the key outcomes of which are shared in this position paper

Objective

- Identify MSLS best practices, with a focus on:
 - Their **activities** (roles and responsibilities) from both a **quantitative** and **qualitative** perspective
 - The **planning, monitoring** and **assessment** of their activity
 - Their degree of **coordination** with other departments (e.g., marketing, sales forces)
 - The way they maintain **regular interactions** with **KOLs**
 - Possible **evolutions** of their role

method

- **Smart Pharma Consulting in-house knowledge:**
 - Previous projects related to MSLS' activity
 - Position paper published in 2017 on MSLS
- **External interviews with 7 experts...**
 - 4 MSL Managers
 - 2 Franchise Medical Heads
 - 1 Deputy Medical Director
- **... from 4 pharmaceutical companies:**

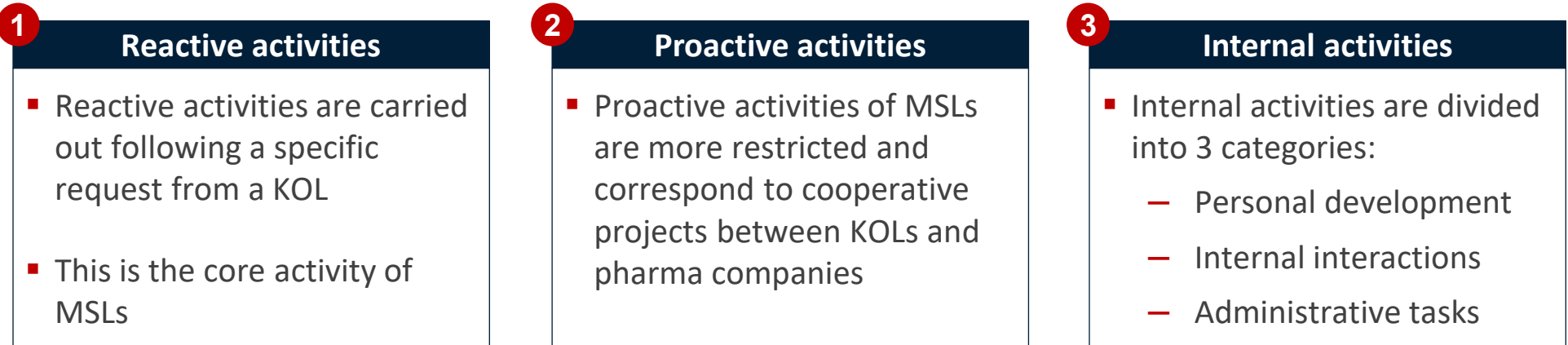
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The activity of MSLs, medical field teams dedicated to scientific communication, is divided into 3 main categories: reactive, proactive and internal activities

MSLs' activities segmentation

- MSLs are one of pharma companies' **field teams** dedicated to enhance the **full exchange of scientific information** with HCPs, especially with KOLs (Key Opinion Leaders)...
- ... and to **build strong relationships and partnerships** with them
- MSLs have a **major role** in medical expertise and their activities are divided into **3 main categories**:



Reactive interactions are MSLs’ core activity and consist in responding to requests for information from KOLs, supporting Investigator-Initiated Studies (IIS) and Early Access Programs (EAP)

MSLs’ reactive activities

1

Reactive activities

Provision of scientific information

- MSLs provide medical information to KOLs upon request (e.g., new clinical data, off-label use)
- The interaction can be remote, face-to-face or through medical staff

IIS

- MSLs respond (positively or not depending on the medical strategy) to requests for collaboration on investigator-initiated studies
- Decisions are more and more made at global level

EAP

- MSLs also accompany expert centers during Early Access Programs (e.g., information on the set-up and eligibility of patients)

Comments from experts interviewed

- “This represents the major part of the activity but the repartition between the reactive actions is extremely variable according to the product life-cycle”*
- “The reactive activity represents about 75% of the MSL actions”*
- “Although it is the result of a request from the KOL, the interaction is not top-down, it is really a discussion that allows MSL to gather insights (e.g., potential new indications)”*
- “EAPs support can represent up to 90% of the activity during the first 6 months of the program's launch”*

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

Proactive activities correspond to the organization of medical events (e.g., ad boards, congresses, symposiums) and the follow-up of phase I, II, III clinical trials and RWE studies

MSLs' proactive activities

<p>2</p>	<p>Proactive activities</p>
<p><u>Medical events organization</u></p> <ul style="list-style-type: none"> ▪ MSLs participate in the organization of medical events such as ad boards, congresses, symposiums, staff meetings, other medical meetings at local or region levels 	
<p><u>Clinical studies</u></p> <ul style="list-style-type: none"> ▪ MSLs are also involved in the execution of phase I, II and III studies, from selection of investigation centers to the follow-up of the implementation 	
<p><u>RWE</u></p> <ul style="list-style-type: none"> ▪ More recently, MSLs have also participated in Real World Evidence studies (RWE), especially in implementation and data collection 	

<p>Comments from experts interviewed</p>
<ul style="list-style-type: none"> ▪ <i>“MSLs are mostly involved in regional events, whereas headquarters medical team takes the lead for national events”</i> ▪ <i>“MSLs are actively involved in medical education events re. improving patient care, treatments, etc.”</i> ▪ <i>“RWE is a historical activity for us with MSLs setting up and then relaying to the CRA¹ or a CRO²”</i> ▪ <i>“MSLs are involved in RWE studies, while for phase I to III clinical studies their contribution is limited to centers identification”</i> ▪ <i>“Our MSLs are involved in clinical studies”</i>

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ Clinical Research Associate – ² Contract Research Organization

The internal activities of MSLs include their personal development, essential to their activity, the sharing of insights with other departments, as well as the associated administrative tasks

MSLs' internal activities

3 Internal activities

Personal development

- Personal development is an important activity for MSLs who must continuously update their scientific knowledge and soft skills (e.g., communication, project organization)

Internal interactions

- Internal interactions are essential to share the insights gathered in the field activity after analysis and synthesis
- Depending on pharmaceutical companies, MSLs can participate in the training of med reps

Administrative tasks

- Administrative tasks represent a significant part of MSLs' daily activity (e.g., planning of interactions with KOLs, filing information in the CRM software)

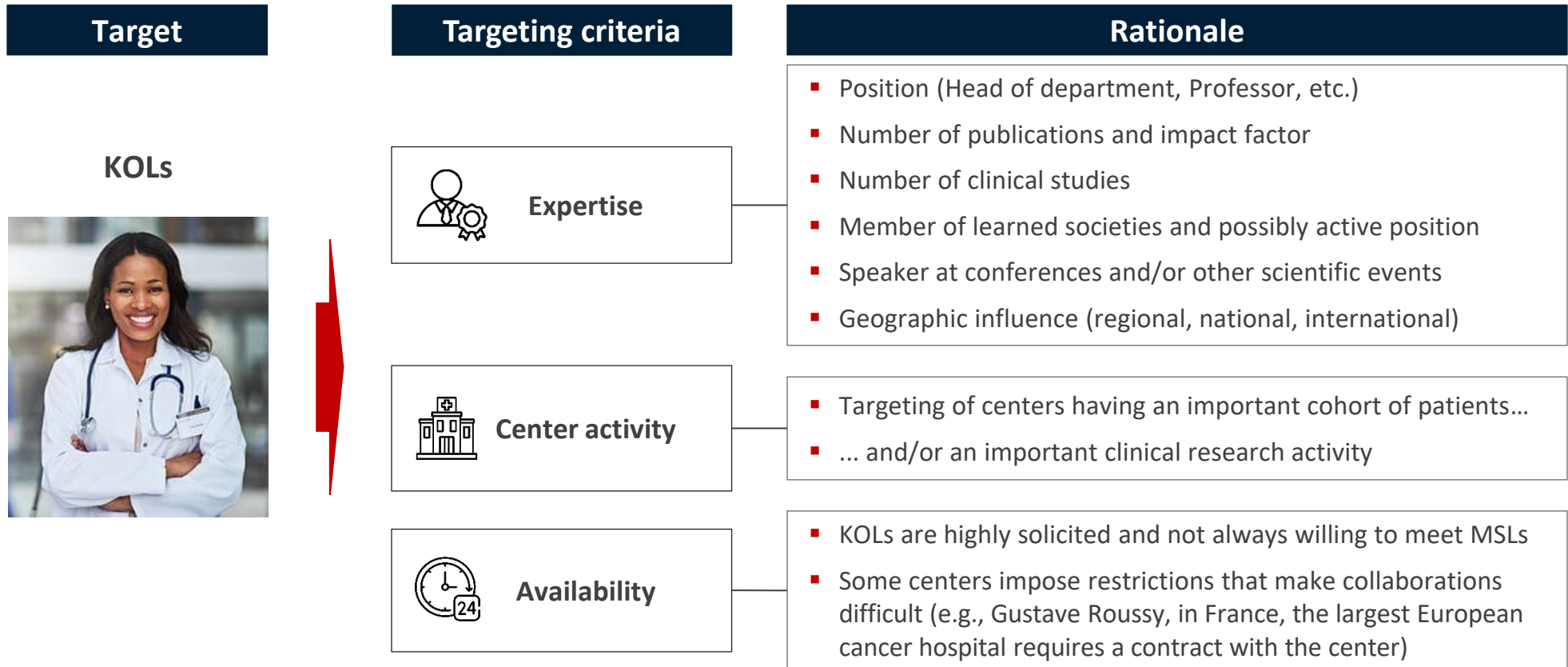
Comments from experts interviewed

- *“Personal development accounts for about 10-15% of MSLs’ activity, but much of it is included in daily activities (e.g., conferences and congresses)”*
- *“MSLs can act as a one-time referent to med reps but we have a Training department independent from the Medical department”*
- *“MSLs complain they don't have enough time for their personal development”*
- *“Interactions between MSLs and med reps and/or the headquarters team are important to have a complete knowledge of each expert center (e.g., change of position of a KOL within the center)”*

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

KOLs, main target and privileged interlocutors of MSLs, are targeted and segmented based on their expertise, the activity of the center where they operate and their availability to collaborate

MSLs' target segmentation



Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

MSLs' activity is strongly regulated with the obligation to have non-promotional speeches and to document the reactive aspect of their interactions

MSLs' compliance rules

Compliance of interactions¹

Non-promotional

- MSLs' scientific communication **cannot promote the company's product** and they must **disseminate messages** in an **objective manner**

Traceability of reactive interactions

- The reactivity of interactions must be **documented in the CRM** (e.g., request by email from physicians, solicitation by a med rep)
- In the case of an unexpected request (e.g., question during a congress), a summary e-mail is sent afterwards
- Only exception: the MSL can introduce himself proactively for his **first meeting**, in order to make himself known to KOLs

Comments from experts interviewed

- "There are regular internal audits and audits carried out by authorities on the respect of compliance rules by MSLs (interviews, verification of supports, etc.)"*
- "It is very strict, when MSLs communicate on off-label use, it must absolutely be documented"*
- "Lots of very strict procedures, proactive activities are only done under contract"*
- "We use Veeva software for events and Interact for contacts"*
- "We use Links as our CRM"*

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ These rules are becoming progressively similar and stricter across European countries

MSLs acting mainly on demand, no frequency objective is defined, and activity is enhanced by the added-value of interactions, sales force involvement and digital communication channels

MSLs' frequency of interactions



Objective of interactions

As most MSLs interactions are performed in a reactive way, **no interaction objective is defined by Medical teams**

How to maintain interactions



Added-value content

- Since **KOLs have little time to spare**, it is important to ensure the **quality of interactions...**
- ... and propose a large range of **high value-added** collaborations

Sales force involvement

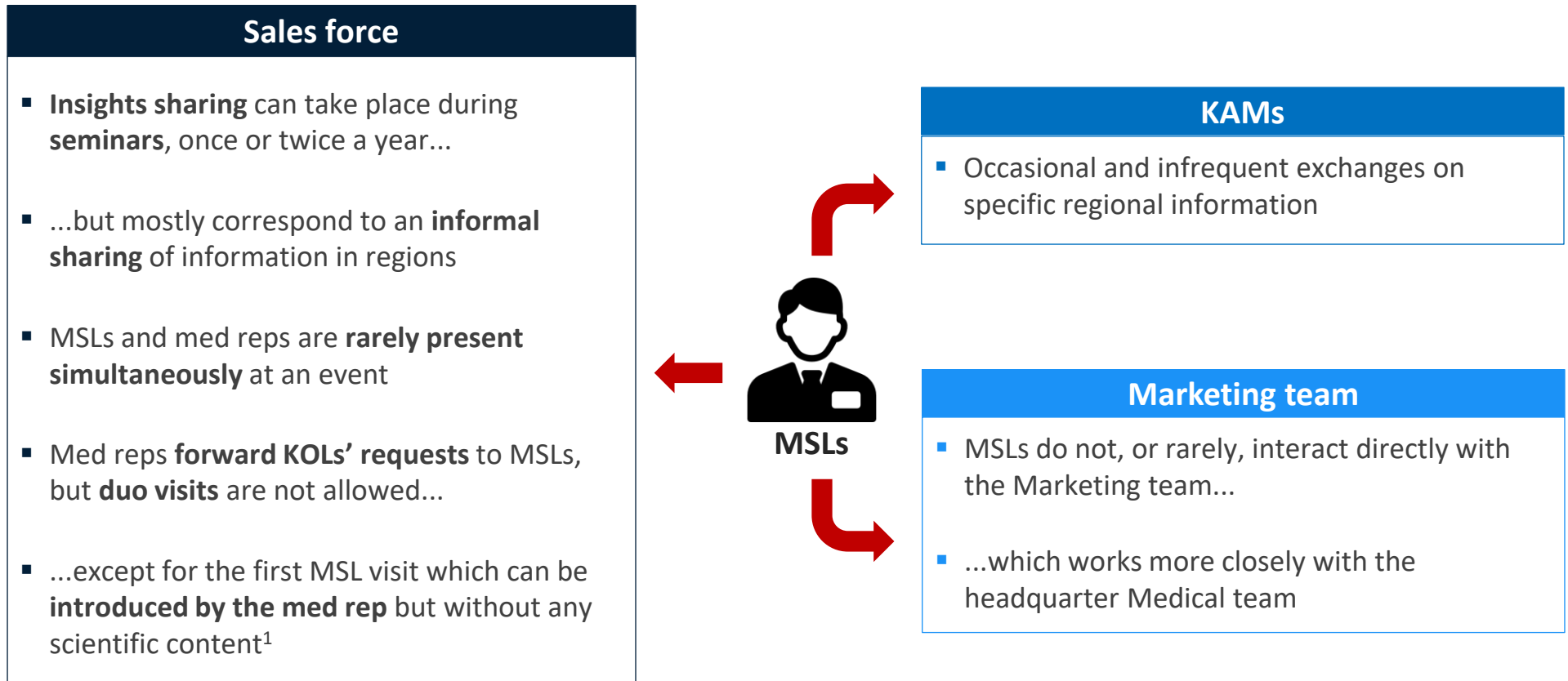
- The **involvement level of sales force** impacts the activity of MSLs by being a **vector of solicitations from KOLs**

Digital communications

- Digital has helped **maintain relationships with KOLs** during the Covid-19 pandemic and...
- ... has **facilitated efficiency and access** to hard-to-meet HCPs

MSLs interact internally with med reps to share insights, during seminars or informal exchanges, but interact little or not at all with Key Account Managers (KAMs) nor the Marketing team

MSLs' interactions with internal departments



Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ These rules are becoming progressively similar and stricter across European countries

MSL's action plan is part of the overall medical strategy, but it is established, personalized and implemented regionally according to KOLs' specific needs

MSLs' action plan definition

"How is MSLs' action plan established?"

Established
by MSLs

7

- *"The medical strategy is established and implemented by the MSL who adapts it according to the granularity and needs of his region"*
- *"Instructions from the Medical direction allow the activity to be framed in the strategy, but the MSL adapts it in the region to best meet specific needs"*
- *"The medical communication is necessarily oriented by the Medical direction, but the MSL adapts the action plan according to the regional activity"*

MSLs' action plans are part of the same global strategy but are developed independently of sales force plans and formalized as a roadmap

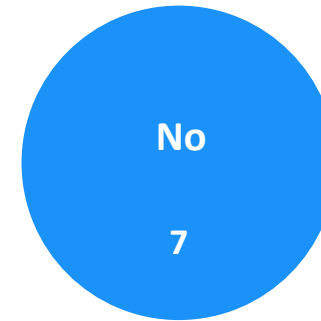
MSLs' action plan crafting

"Is MSL action plan written?"



- *"MSLs' action plans are written on an annual basis and are updated as the activities progress"*
- *"Once written and presented, these action plans serve as a roadmap throughout the year"*

"Is MSLs' action plan defined in link to sales force plans?"



- *"The strategic basis is common, but the action plans are defined in total independence"*
- *"Although they have a common goal, MSLs and med reps are two separate channels"*
- *"The timelines of the plans are different"*

MSLs’ activity can be assessed quantitatively with field time and number of experts engaged or projects conducted and qualitatively by characterizing the nature of the interactions

MSLs’ performance metrics (1/2)



Activity



Quantitative indicators

- MSLs’ activity can be quantified by measuring:
 - **Field time**, which is the total amount of **interactions with KOLs** (categorized by proactive / reactive, remote / face-to-face)
 - Number of **experts engaged** (contributing to clinical trials, giving lectures, etc.)
 - The number of **projects conducted** (e.g., ad boards)
 - The number of **insights collected** from interactions with KOLs

Qualitative indicators

- From a qualitative point of view, MSLs’ activity corresponds to:
 - The typology of **medical communication topics** (e.g., safety, off-label use)
 - The **relevance, quality** and **diversity** of the **insights** gathered (high value-added insights for the strategy)
 - The **ability to share** these **insights** in a rigorous and systematic way internally

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

The impact of MSLs' activity is much more difficult to quantify and can essentially be assessed on qualitative criteria

MSLs' performance metrics (2/2)



Impact



Quantitative indicators

- It is **difficult to define quantitative indicators** to measure the impact of MSLs...
- ...and the pharma companies interviewed do not use those indicators to assess MSLs' impact
- Therefore, the **variable part of MSLs' remuneration is not based on quantitative objectives...**
- ...but is linked to the **follow-up of the roadmap** and to **MSLs' individual assessment** (e.g., behavior, initiatives taken)

Qualitative indicators

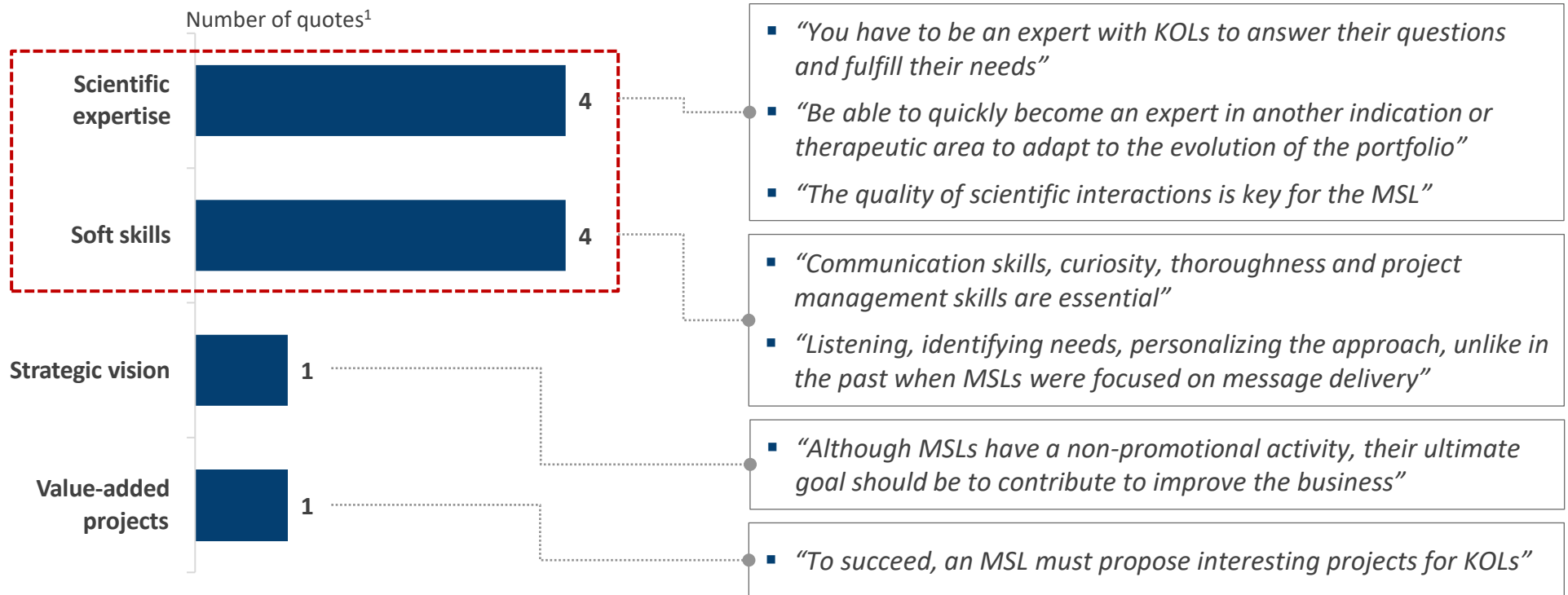
- Concerning the qualitative aspect of the impact, it is possible to evaluate:
 - The **perception of medical communication** by KOLs through a questionnaire
 - The "unlocking" of centers with whom it was not **possible to collaborate** previously
 - The **success of a project conducted** (e.g., recommendations published as a result of an Ad Board to address a given issue)

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

Scientific expertise and soft skills are the key success factors for MSLs to be a complete expert with KOLs they interact with, especially in terms of communication and project management skills

MSLs' key success factors

“What are the key success factors for MSLs?”



Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ Several answers possible

MSLs have an increasingly important role to play within pharmaceutical companies, in a context of restricted access to HCPs and of very strict regulatory framework

MSLs' challenges & evolution

MSLs' challenges

- Although this is **less the case than for med reps**, access to **HCPs is increasingly restricted** as they have less and less time to spare...
- ...which reinforces the need to offer **high value-added interactions** and **projects** for **KOLs**
- Especially since HCPs now have **easier access to information** through the Internet (e.g., PubMed, congresses summary, products SmPCs¹)
- On the regulatory aspect, MSLs' activity is strongly **supervised and limited** by authorities...
- ...as well as more and more by **time-consuming internal procedures** to ensure compliance

MSLs' evolution






- MSLs have an **increasingly central role** in leading-edge therapeutic areas...
- ...and have a growing role in **Early Access Programs support** and **RWE² data generation**, that is increasingly valued in Market Access and required by health authorities
- **Digital** technologies will also impact furthermore MSLs' activity with the **flexibility** offered by the different **communication channels**...
- ...and by the development of **tools based on Artificial Intelligence** likely to transform the patient pathway (e.g., diagnostic algorithm in oncology)

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ Summary of Product Characteristics – ² Real World Evidence

MSLs' activities are quite homogeneous across Europe, although some adaptations may be required to local specificities

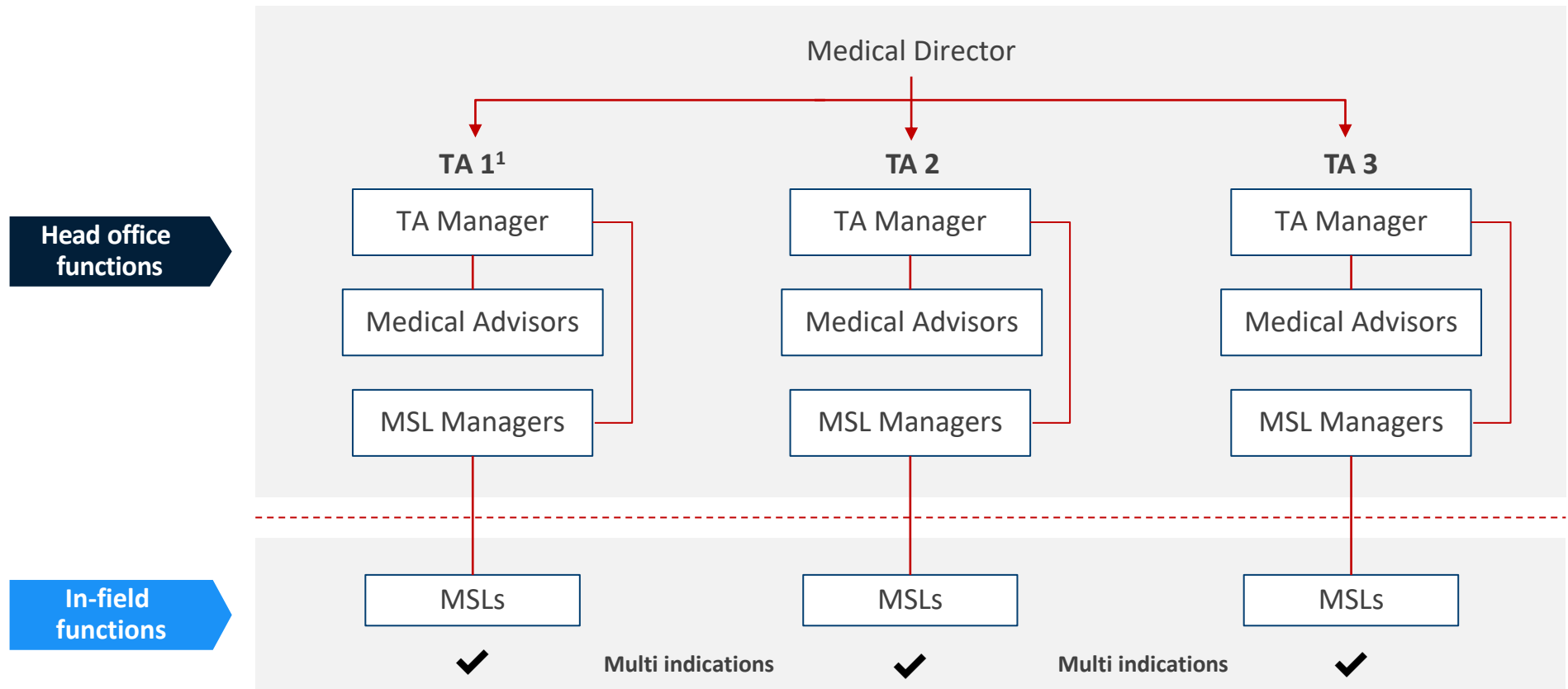
MSLs' activities international landscape

MSLs' activities					
Introduction to HCPs (first contact)	✓	✓	✓	✓	✓
Invitation to congresses	✓	✓		✓	✓
Invitation to Ad boards	✓	✓		✓	✓
Proposal / Support for clinical studies	✓	✓	✓	✓	✓
Comments		<ul style="list-style-type: none"> Access to private-based HCPs is difficult 	<ul style="list-style-type: none"> MSLs cannot be proactive for RWE studies Ad boards are difficult to organize in the UK (due to regulation) 	<ul style="list-style-type: none"> MSLs can be proactive since end of 2021 	<ul style="list-style-type: none"> Low concentration of expert centers Proactivity allowed for new data

Sources: Smart Pharma Consulting analyses, based on interviews with Medical Teams in Europe (May 2022)

In general, MSLs report to an MSL Manager, covering multiple indications, and are the only in-field function of the Medical Affairs department of Pharma companies' affiliates

MSL Teams within Medical Affairs department – Most common structure



Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

¹ Therapeutic Area

To keep on interacting regularly with KOLs, in a context of regulatory constraints and post-Covid-19 crisis, MSLs must propose high quality content and/or co-develop highly valued projects

Key learnings

MSL role

- MSLs are pharma companies **in-field collaborators** dedicated to **exchange scientific information** with HCPs, especially with **KOLs** (most often for multi-indications in a specific therapeutic area)
- MSLs play a **major role in medical expertise** and their activities are split into **3 main categories**:
 - **Reactive activities** which are their core activities (e.g., response to solicitations)
 - **Proactive activities** which are done under contract (e.g., speaker partnership, ad boards participation)
 - **Internal activities** (e.g., personal development, insights sharing, administrative tasks)

MSL activity planning & monitoring

- MSLs, who establish their **action plan** according to **regional needs and specificities**, do not have defined interaction objectives due to the reactive nature of their core activities
- MSL activity can be monitored with **quantitative indicators** (e.g., number of interactions) or **qualitative indicators** (e.g., quality of insights gathered)...
- but **measuring the impact** of these activities is **complicated** and **not** always **relevant** considering the regulatory constraints

MSL challenges & evolution

- MSL activities being **non-promotional**, their reactive activities **must be documented**
- Their role being key, they must propose **high value-added content** to HCPs to maintain interactions and...
- ... strengthen their role in **RWE studies** and their use of **digital tools** that are impacting Medical Affairs

Sources: Interviews with 7 experts from 4 pharmaceutical companies (AbbVie, BMS, Novartis, Pfizer) – Smart Pharma Consulting analyses

Consulting firm dedicated to the pharmaceutical sector operating in the complementary domains of strategy, management and organization

Medical Series

- The Medical Series covers different topics related to Medical Affairs, either at Corporate or Affiliates level
- Depending on issues, Smart Pharma Consulting shares:
 - Strategic, tactical and organizational thoughts and recommendations
 - Well-documented facts and figures, including outcomes of recent benchmarking studies
 - Practical methods and tools
- Each issue is designed to be read in 15 to 20 minutes and not to exceed 24 pages

Enhancing **MSLs Competence** Benchmarking Study

- This study based on Smart Pharma Consulting experience and a benchmarking study carried out through interviews of 7 senior executives from 4 leading pharma companies provides insights re.:
 - MSLs activities planning
 - MSLs coordination with other Pharma companies' departments
 - The way to keep regular interactions with KOLs
 - Possible evolutions of MSLs role

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching activities in advanced masters (ESSEC B-school, Paris Faculty of Pharmacy)
 - Training activities for pharma executives
 - The publication of articles, booklets, books and expert reports
- Our publications can be downloaded from our website:
 - 41 articles
 - 65 position papers covering the following topics:

1. Market Insights	5. Marketing
2. Strategy	6. Sales Force Effectiveness
3. Market Access	7. Management & Trainings
4. Medical Affairs	
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny