

2016 – 2023

Medical Affairs

1. Enhancing MSLs Competence
2. High-Performance Strategic Medical Plans
3. Medical Affairs Best Practices
4. Best-in-class Medical Science Liaisons
5. Strategic KOL Engagement Planning

Insights - Concepts - Methods - Tools

This e-book is the collection of the position papers re. Medical Affairs published by Smart Pharma Consulting, in line with its commitment to share knowledge and thoughts

Presentation of the 2016 – 2023 Publications re. Medical Affairs

- Smart Pharma Consulting has compiled five position papers addressing issues relative to Medical Affairs
 - These publications propose effective and practical solutions to help pharma companies improve their performance
 - For so doing, we share openly:
 - Business insights
 - Concepts
 - Methods
 - Tools
- } The majority of which have been developed by Smart Pharma Consulting
- The topics covered are the following:
 1. Enhancing MSLs Competence p.16
 2. High-Performance Strategic Medical Plans p.35
 3. Medical Affairs Best Practices p.53
 4. Best-in-class Medical Science Liaisons p.71
 5. Strategic KOL Engagement Planning p.106
 - We have also included examples of training programs we propose p.147
 - We hope that this collection will be of high value to you

Jean-Michel Peny

Smart Pharma **Expertise**

CORPORATE PRESENTATION

Capabilities & Experience

What does make us so unique?

Smart Pharma Consulting has been created in 2001 to deliver pharma and MedTech companies high-end services in strategy, management and organization; and to redistribute opportunities

Smart Pharma Consulting in a nutshell

Key Facts & Figures

- 23rd anniversary
- 144 clients, of which 109 pharma / MedTech companies
- ~1,250 missions (i.e., 55 p.a.)
- ~40% of international projects
- 1,150 executives trained
- 2,100 students have been taught strategy & marketing
- More than 100 publications
- Since 2005, €5.5M donation to humanitarian projects

Core priorities to deliver unmatched services

- Smart Pharma Consulting strives to:
 - Generate and disseminate high quality insights
 - Offer innovative concepts, methods, tools and solutions
 - Share knowledge and thoughts through consulting, training, teaching and publishing activities

Corporate societal engagement to redistribute opportunities

- **Solving, Serving & Sharing** is in our **DNA**
- Smart Pharma Consulting is engaged to “Protect & Raise” the most vulnerable children
- Since 2005, we partner through our department “Smart Pharma Care” with 4 reputable NGOs in Africa
- In 2006, we have started our own program in Nepal, which today supports more than 200 disadvantaged children

Smart Pharma Consulting has an in-depth knowledge and understanding of the pharma and MedTech markets based on three decades of specialization and experience of its consultants

Experiences & competencies

- Smart Pharma consultants have an in-depth knowledge and understanding of the pharma and MedTech markets as shown by:
 - More than 35 years of experience
 - A dedication to strategic, management and organizational issues for pharma and MedTech companies
 - A list of 136 clients (of which 103 pharma and MedTech companies)
 - More than 100 publications¹ (e.g., reports, position papers, articles and books)
 - Operational experience in pharma companies:
 - In various countries: Africa, France, India, Middle-East, Pakistan, Turkey, Sri Lanka
 - At positions such as: country manager, product manager, sales manager, business intelligence manager, portfolio and operation manager
- Smart Pharma Consulting is also strongly involved in sharing experiences and competencies through:
 - Trainings of executives and teaching of students
 - Regular publications of “position papers” including innovative concepts, methodologies and tools

Our triple expertise provides us with a unique positioning on the consulting market and enables us to create synergies to deliver our clients Smarter Services

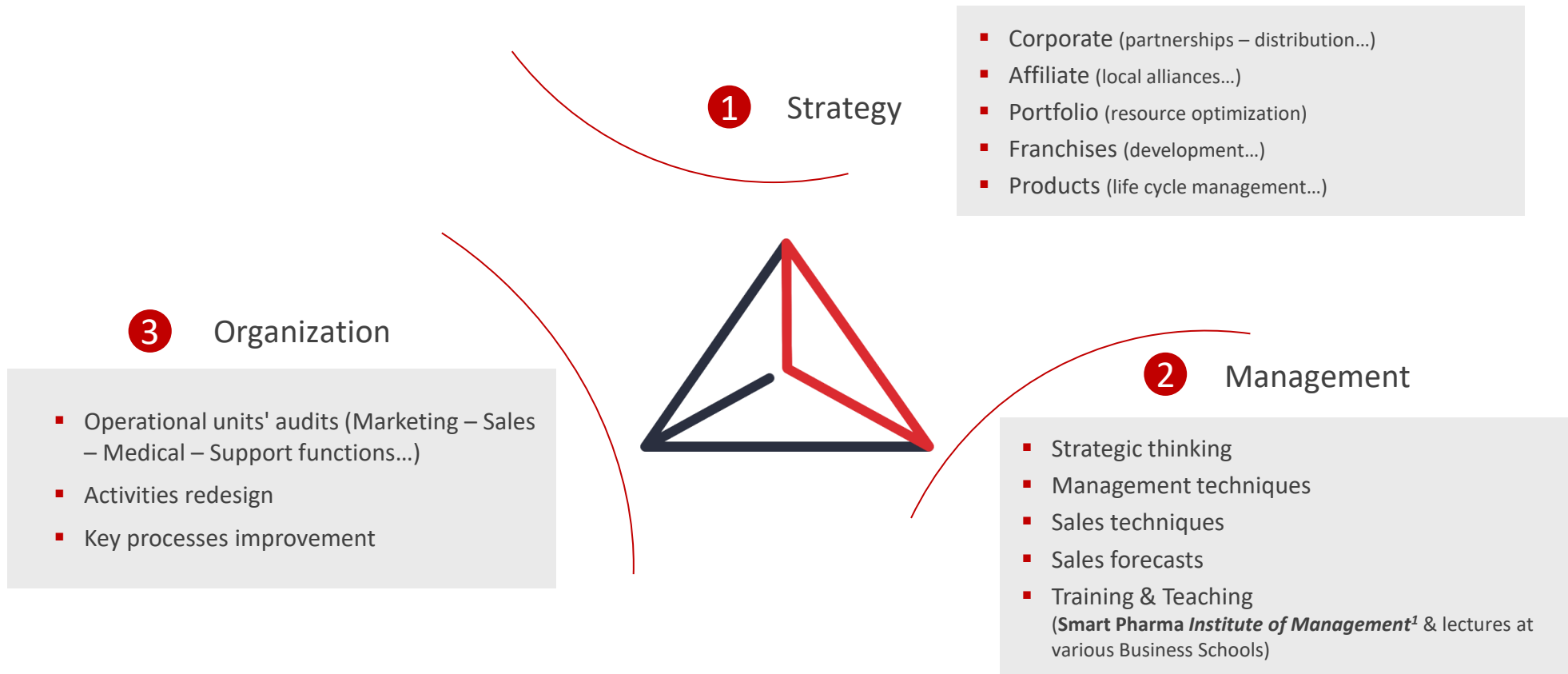
Smart Pharma Consulting unique positioning



Smart Pharma Consulting is officially registered as a training organization by the French government since 2002

Dedicated to the pharmaceutical sector, Smart Pharma Consulting operates in the three complementary domains of Strategy, Management and Organization since 2001

Smart Pharma Consulting core capabilities



Beyond its excellent pharma market insights, Smart Pharma Consulting is known and recognized for its methodological skills and the rigor of its analyses and advice

Specific expertise

1 In-depth knowledge and understanding of the pharma market as shown by our most recent reports

- French healthcare system and pharmaceutical market (2023, 2021, 2019, 2017, 2015, 2014)
- Generics market (2017, 2016, 2014)
- Global biosimilars drugs market (2019, 2021, 2017, 2015)
- Drug value & Market access optimization (2016)
- Best pharma performers (2021, 2019, 2015)
- Pharma distribution (2015)

2 Development of innovative and practical concepts, methodologies and tools to improve the relevance of strategies and tactics, and the quality of their execution

- Publication of 41 articles...
- ... 7 books (of which 3 on Marketing)
- ~10 position papers p.a.
- Participation in conferences

1

2

4

3

Smart Pharma
Competitive
Advantages

Knowledge of and access to stakeholders

- Pharma & MedTech companies: missions carried out for 109 companies since 2001
- Interviews of:
 - ~35 companies (benchmarking studies) p.a.
 - ~40 KOLs p.a.
 - ~100 physicians (specialists & GPs) p.a.
 - ~100 retail and hospital pharmacists p.a.
 - ~200 patients p.a.
 - ~15 health authorities, payers, PAGs¹ p.a.

Experience in multiple strategic segments, including:

- Rx-bound products (R&D-based, biologics, generics and biosimilars) in 16 therapeutic areas
 - Vaccines
 - OTCs and food supplements
 - Medical devices
- for various companies across the world

We partner with companies wishing to optimize their current and future business based on best-of-class consulting services

Key clients (2001-2021) – (1/2)

« Pharma & MedTech companies »

<ul style="list-style-type: none"> • Abbott • AbbVie • Actelion (Janssen) • Aga Linde • AJ Pharma • Alfasigma • ALK • Allergan (AbbVie) • Almirall • Arkopharma • Aspen • Astellas • AstraZeneca • B. Braun • Bayer • Becton Dickinson 	<ul style="list-style-type: none"> • Bioprojet • BMS • Boehringer Ingelheim • Chiesi • Daiichi-Sankyo • Delbert • Diaxonhit • Diepharmex • Dynavie • Effik • Eisai • Esteve • Ethypharm • Expanscience • Fresenius Kabi • Galderma • Gilead 	<ul style="list-style-type: none"> • Grünenthal • GSK • Hartmann • HRA Pharma • Indivior • Innothera • Insulet • Invacare • IPRAD (Biocodex) • IPSEN • Janssen • Keocyt (Esteve) • Leo Pharma • Lilly • LFB • Lundbeck 	<ul style="list-style-type: none"> • Menarini • Merck AG • MSD • Mundipharma • Naos • Nemera • Nobel Biocare • Nordic Pharma • Norgine • Novartis • Novo-Nordisk • Nuvamid • Organon • Otsuka • Pfizer • Pierre Fabre • Reckitt-Benckiser 	<ul style="list-style-type: none"> • Recordati • Roche • Sanofi • Schwabe • Servier • Sinclair Pharma • SOBI • Takeda • The Medicine Co. • Therabel • Tillotts Pharma • UCB pharma • UPSA • Urgo • Vifor Fresenius • Zambon • Wellspect
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We partner with companies wishing to optimize their current and future business based on best-of-class consulting services

Key clients (2001-2021) – (2/2)

Biotech companies	Generics companies	Distributors	Investors	Miscellaneous
<ul style="list-style-type: none"> Alexion (AstraZeneca) Amgen Biogen Celgene (BMS) Genzyme (Sanofi) GSK Biologicals Innavirvax Sanofi-Pasteur 	<ul style="list-style-type: none"> Accord Health Biogaran (Servier) Dr Reddy's EG Labo (Stada) Gedeon Richter Glenmark Hospira Polymedic Sandoz (Novartis) Sothema Teva Viatrix Wockhardt Zentiva Zydus 	<ul style="list-style-type: none"> Alliance Healthcare Ceido Collectif des groupements (CNGPO) FM Logistic Giphar Pharma Référence PharmaVie (Phoenix) 	<ul style="list-style-type: none"> Alma Capital Astorg Cinven Exane Keensight Capital PAI Rothschild Sagard Valpre Weinberg Capital <div> Lawyers <ul style="list-style-type: none"> Jones Day Simmons & Simmons Véron & Associés </div>	<ul style="list-style-type: none"> Celtipharm CEGEDIM Cosmétique Active¹ CRIP Datapharm DDB health Fondation Deniker GEMME MedToMed Osalia PMC-Isochem Preciphar Unilever Zoetis

We have published 41 articles in national and international specialized magazines, addressing key pharmaceutical market issues

Published articles¹

Strategy: Ethical products

- Building prescriber loyalty (1993)
- ACE-inhibitors - an analysis of marketing strategy (1994)
- Are generic defense strategies worth the effort? (1996)
- Winning strategies in the French hospital market (1996)
- Making the most of maturity (2003)
- The end of the back-up brands? (2005)
- Financial requirements of immunisation programmes in developing countries: 2004-2014 perspective (2005)²
- Nosocomial Rotavirus infection in European countries (2006)⁴
- Les marques sont-elles condamnées à mourir ? (2007)⁵
- Le BPS, pour la "justesse de voix" (2008)⁵
- La réputation d'entreprise – Un nouvel enjeu stratégique (2008)⁵

Effectiveness and Operational organization

- Heading for change: marketing and sales trends in France (1995)
- Counting the cost of purchase (1997)
- The brave new world of corporate marketing (2000)
- Talking up sales (2002)
- How can customer-centricity increase brand preference? (2009)

Environment (international)

- Drug reimbursement harmonization in Europe (1994)
- Working with the authorities (2002)
- The Evolution of the global pharma industry (2012)⁶

Strategy: Generics

- Entering the French generics market (1997)
- Is the sun rising for Japanese generics? (1998)
- Can generics really help to curb French healthcare costs? (1999)
- Lighting fire from wet timber in French generics market (2001)
- How bright is the future for generics? (2003)
- Barriers to substitution (2005)
- What is the value of authorized generic agreements? (2006)³
- Princeps-génériques: Faut-il pactiser avec l'ennemi ? (2007)⁵
- Quelles perspectives pour les génériques ? (2007)⁴
- Les génériques, ce n'est plus automatique (2011)⁶
- What future for the French retail generic market? (2015)³

Strategy: OTC & Dietary Supplements

- Assessing the OTC market in France (1997)
- How bright are the prospects for self-medication in France? (1999)
- Thin pickings in dietary supplements (1999)
- Should big pharma sell its OTC business? (2004)
- Automédication: Quel attrait pour le marché mondial ? (2006)⁵
- Des stratégies opposées pour les « big pharma » (2006)⁵
- Le switch: solution ou danger (2006)⁵
- Le médicament en libre accès: La grande illusion (2007)

Environment (national)

- Disease management opportunities in France (1997)
- Survival strategies in contract sales organizations (2002)
- Changes at the French pharmacy (2004)

Consultants working at Smart Pharma Consulting benefit from a double experience, in pharmaceutical companies and specialized consulting firms

Senior Management Team

Jean-Michel Peny

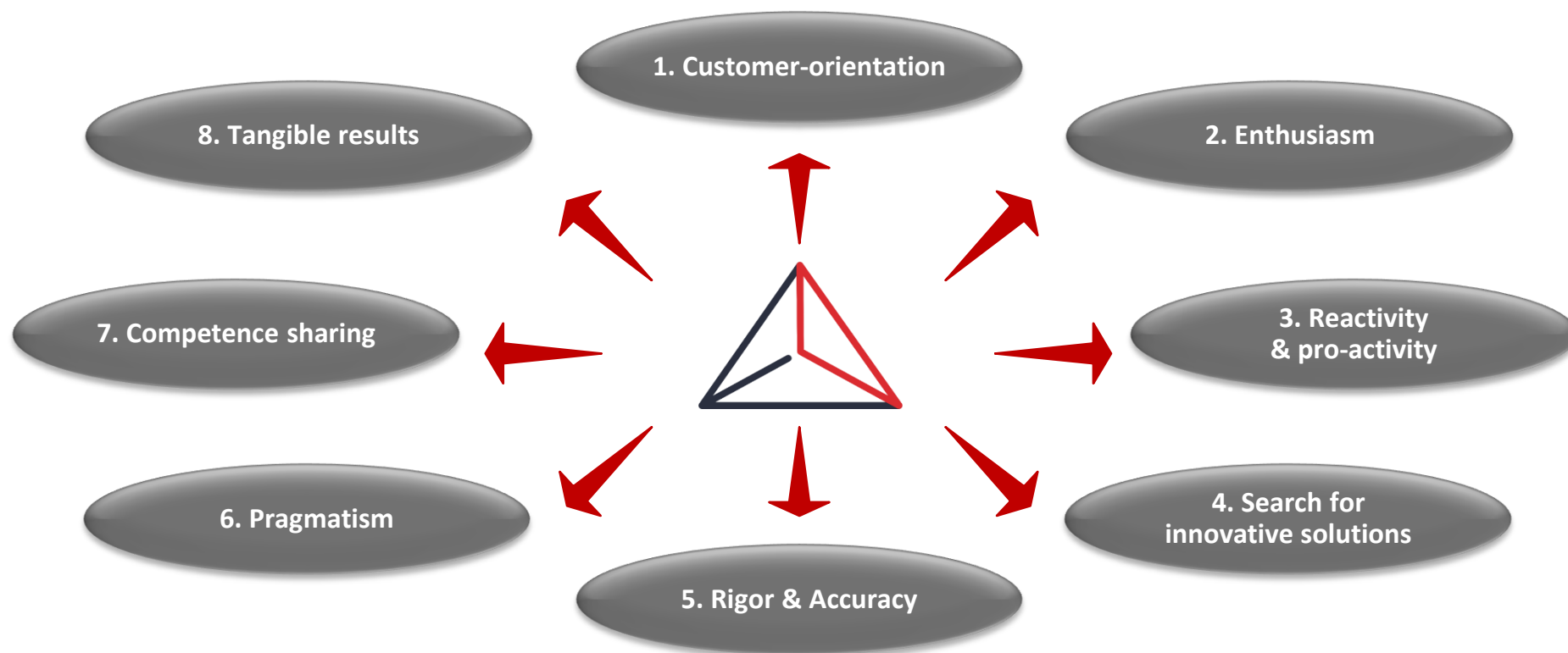
- **President**
- **Pharm. D. (Nantes)**
- **MBA – HEC Business School (Paris)**
- **Master degree in International Business (Lyon)**
- **Senior Executive Programs:** Harvard Business School – Stanford Business School – Sloan School – Wharton (USA)
- **Pharmacist at Begin hospital (Paris area) – 1 year**
- **General Manager for pharmaceutical companies:**
 - 3 years in Sri Lanka (Servier)
 - 3 years in India (Servier)
 - 1 year in France (Novartis Generics)
- **31-year experience in Strategy and Management consulting for the pharmaceutical sector** (Bain & Co, Arthur D. Little, Kearney, ISO Health Care Consulting)
- **32-year teaching experience**
 Lecturer (ESCP & ESSEC B-schools - Paris Pharmaceutical and Medical Universities)
 Former affiliate Professor (HEC B-school)

Laurent Chesnel

- **Senior Manager**
- **Graduated from KEDGE Business School (Bordeaux)**
 Specialization in audit, law and management control
- **10-year operational experience in Financial Audit at KPMG**
 - 3 years as a Manager
 - Audit of statutory and consolidated financial statements, in French GAAP, IFRS or US GAAP
 - Specialization in the Technology Media & Telecommunication (TMT) practice
 - “Key accounts” clients (Capgemini, SFR, TF1, Vivendi)
- **9-year consulting experience with Smart Pharma Consulting**

Smart Pharma Consulting delivers a unique service based on eight commitments which are determinant to ensure a service delivery, second to none

The eight commitments of Smart Pharma Consulting



Smart Pharma Consulting partners with four reputable NGOs on projects located in Africa and runs its own project in Nepal to protect and raise the most disadvantaged children

Smart Pharma Consulting's engagement in humanitarian actions

- We are strongly engaged, through our "Smart Pharma Care" department, to help the world's most vulnerable children
- This engagement is a pillar of our societal commitment to redistribute opportunities and wealth

African Programs

We partner, since 2005, with 4 NGOs to protect children against violence, diseases; and to secure their access to water and food



Nepalese Program

- In 2006, we started our own program in Nepal to protect and educate children at risk
- The project is founded and managed by Smart Pharma, with the help of FSNB Health & Care¹
- The Nepalese NGO Saathi ensures the operational activities of this project including > 200 children



"Our ambition is to protect and help children build a better future"

3. Medical Affairs



Enhancing **MSLs Competence**

MEDICAL SERIES

Benchmarking Study

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

Introduction

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:**

abbvie

 Bristol Myers Squibb™ NOVARTIS Pfizer

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:

1

Reactive activities

- Reactive activities are carried out following a specific request from a KOL
- This is the core activity of MSLs

2

Proactive activities

- Proactive activities of MSLs are more restricted and correspond to cooperative projects between KOLs and pharma companies

3

Internal activities

- Internal activities are divided into 3 categories:
 - Personal development
 - Internal interactions
 - Administrative tasks

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"*

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

2

Proactive activities

Medical events organization

- MSLs participate in the organization of medical events such as ad boards, congresses, symposiums, staff meetings, other medical meetings at local or region levels

Clinical studies

- 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

RWE

- More recently, MSLs have also participated in Real World Evidence studies (RWE), especially in implementation and data collection

Comments from experts interviewed

- "MSLs are mostly involved in regional events, whereas headquarters medical team takes the lead for national events"*
- "MSLs are actively involved in medical education events re. improving patient care, treatments, etc."*
- "RWE is a historical activity for us with MSLs setting up and then relaying to the CRA¹ or a CRO²"*
- "MSLs are involved in RWE studies, while for phase I to III clinical studies their contribution is limited to centers identification"*
- "Our MSLs are involved in clinical studies"*

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

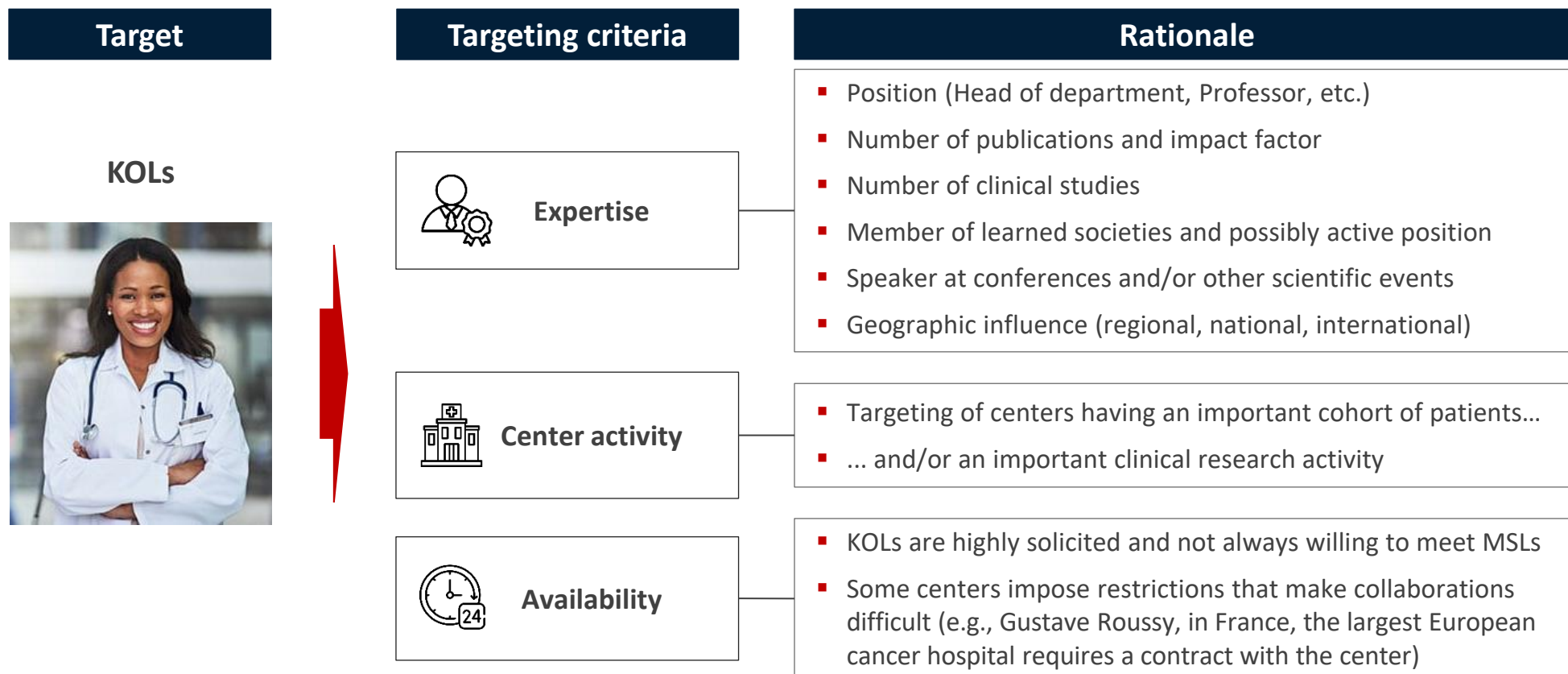
- Administrative tasks represent a significant part of MSLs' daily activity (e.g., planning of interactions with KOLs, filing information in the CRM software)

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)"*

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
- 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"*

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

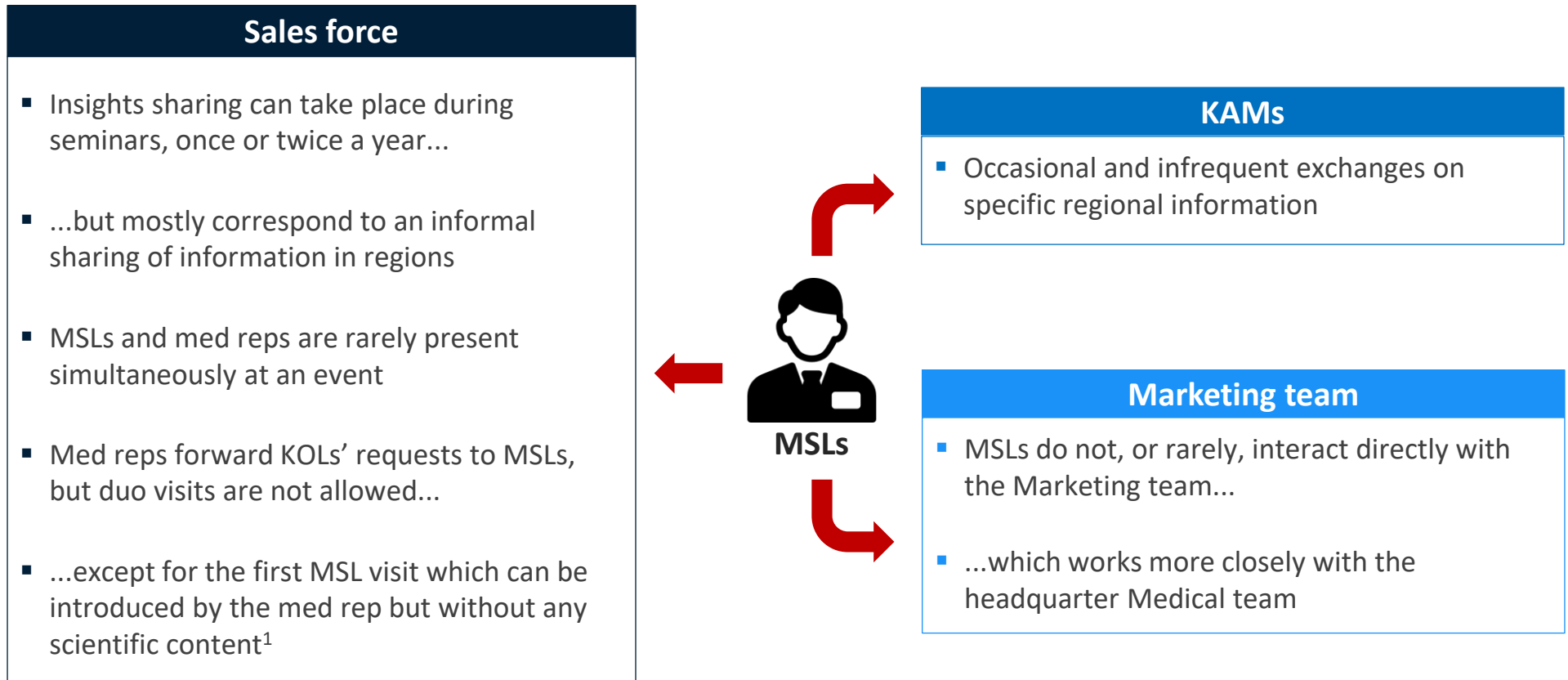
- The involvement level of sales force impacts the activity of MSLs by being a vector of solicitations from KOLs

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



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

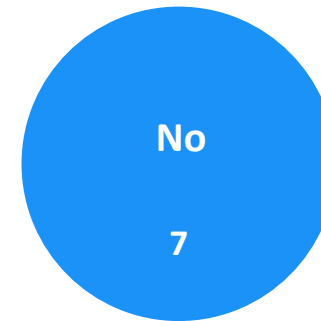
MSLs' action plan crafting

"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

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)

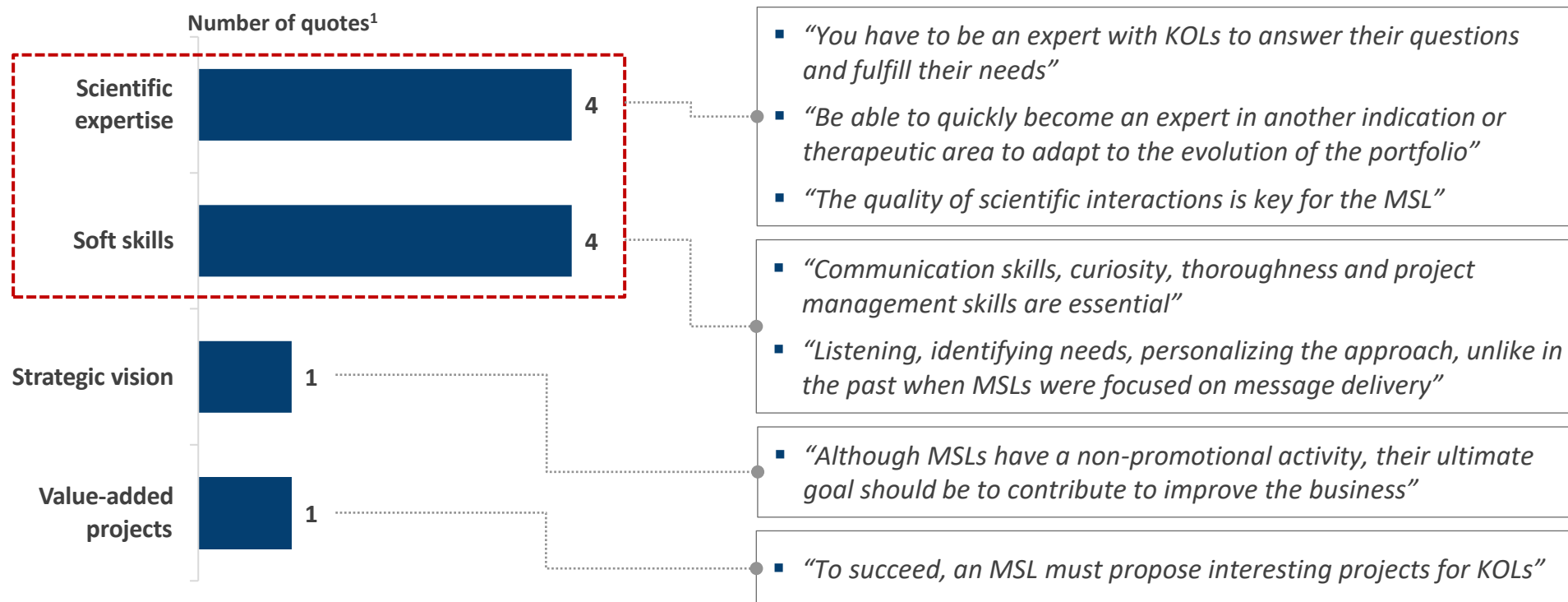
Qualitative indicators

- 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)

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?"



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)

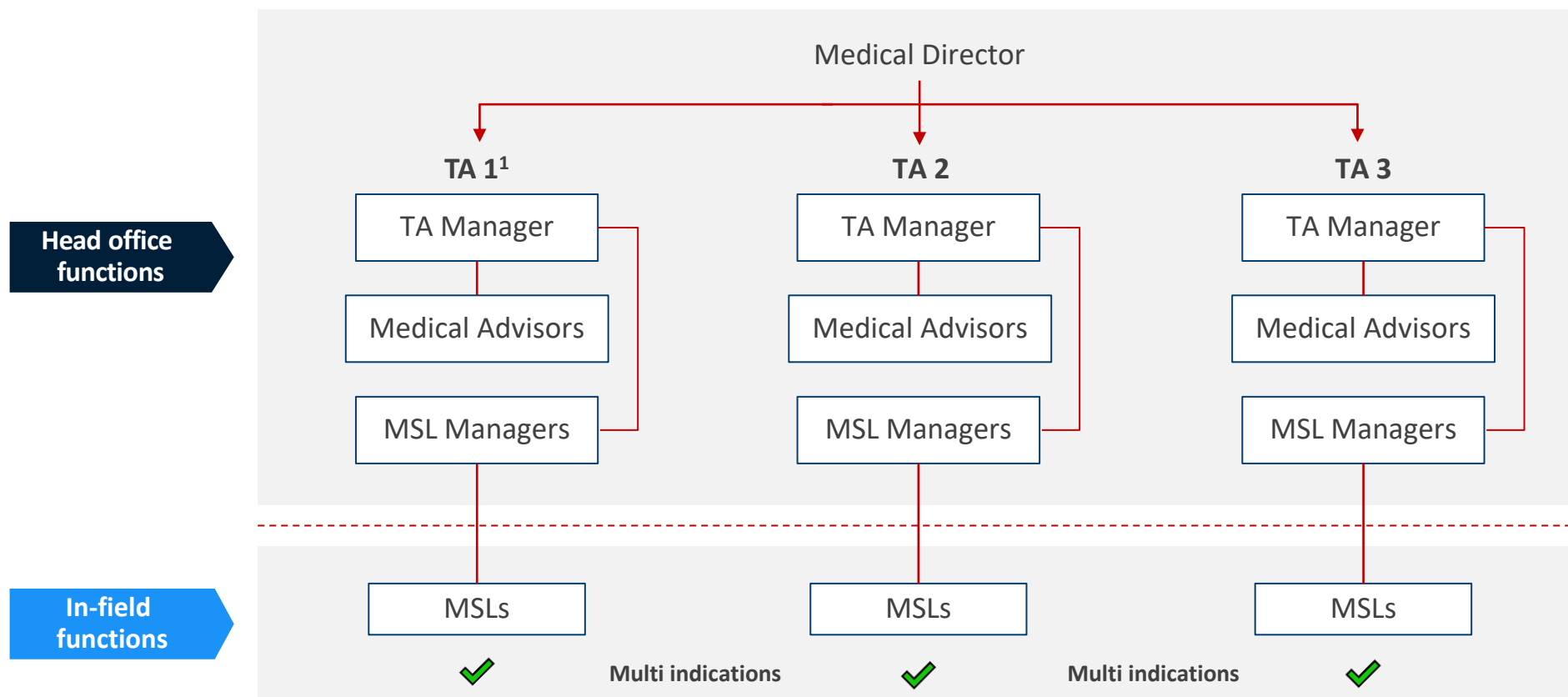
MSLs' activities are quite homogeneous across Europe, although some adaptations may be required to local specificities

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

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



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

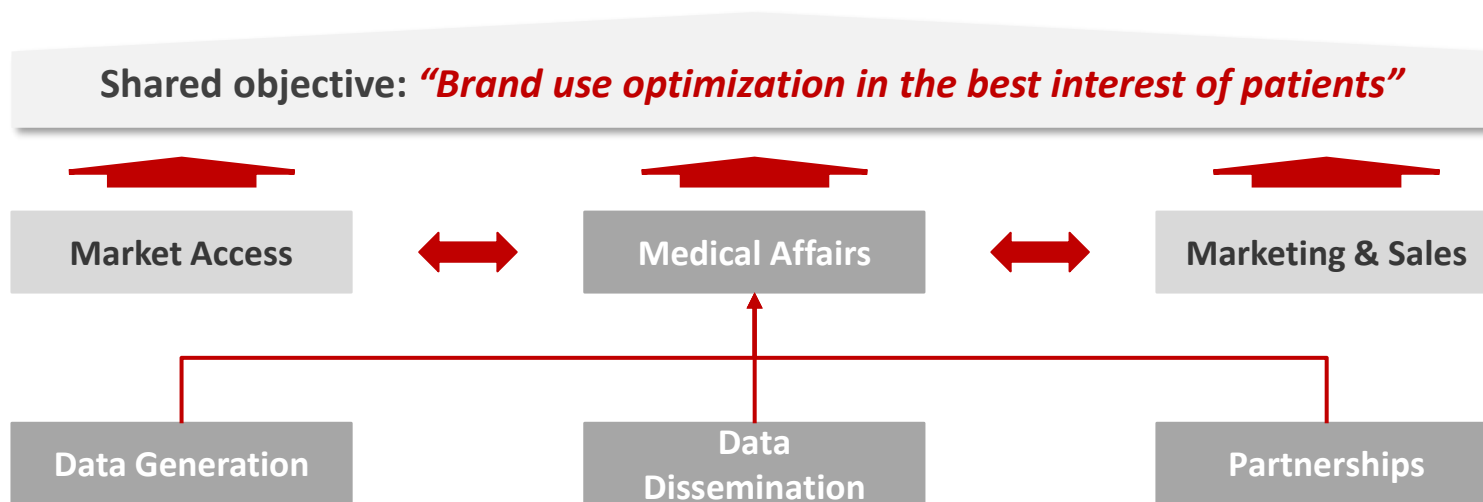
High-Performance Strategic Medical Plans

———— MEDICAL SERIES ————

5 Key Recommendations

Medical Affairs activities should contribute to optimize the use of pharma companies' brands by HCPs in the best interest of patients

Medical Affairs mission



- Medical Affairs play a central role in supporting internal¹ company stakeholders to fulfill the needs of external ones² on medical aspects re.:
 - Disease management
 - Specific indications
 - Brands

- From a brand perspective, it is essential that Medical Affairs, Market Access and Marketing & Sales departments:
 - Share the same objective
 - Craft a common strategy to meet this objective
 - Coordinate their activities
 in their field of expertise, while complying with regulations

The purpose of Strategic Medical Plans is to allocate the right resources to reach the medical objective set, in an effective and efficient way

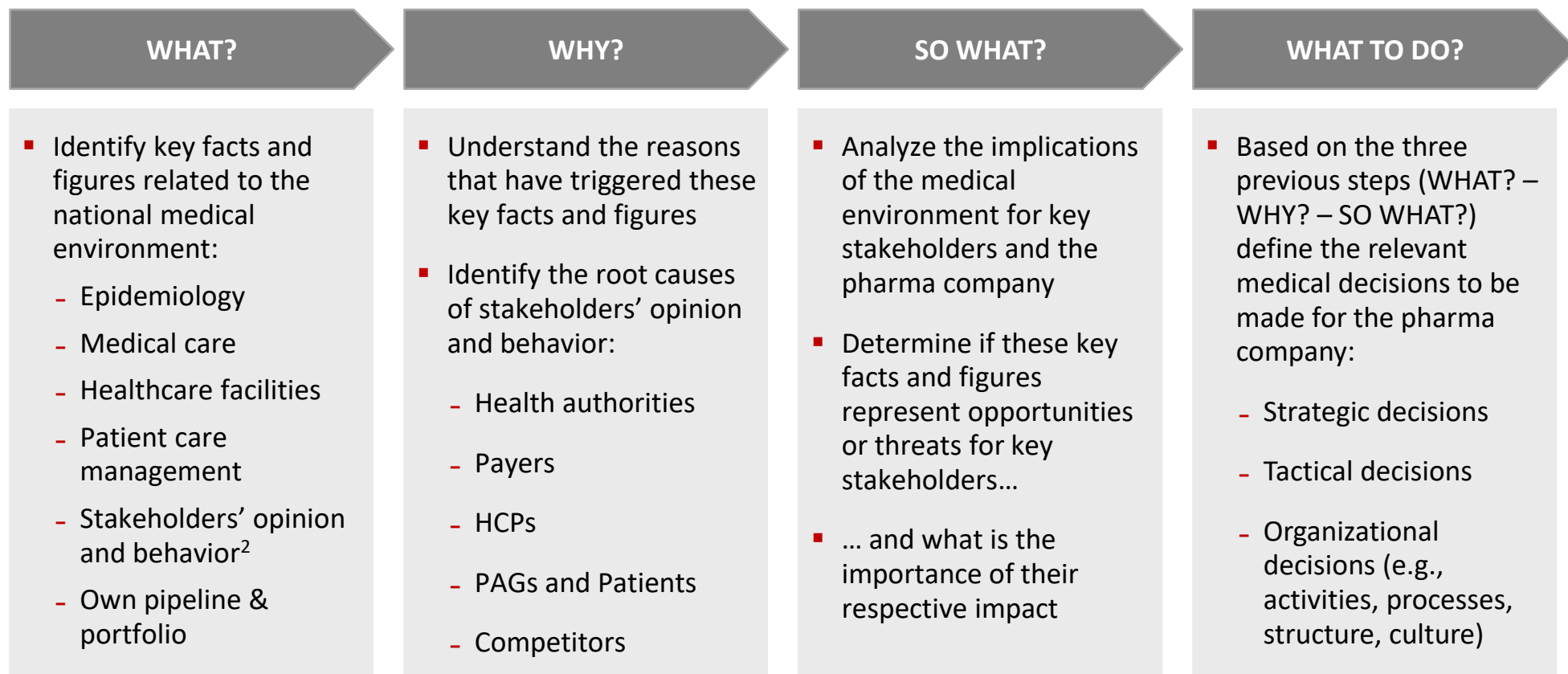
Why draft a Strategic Medical Plan?

- To prioritize medical activities to be carried out, based on:
 - The analysis of the situation
(e.g., disease management, unmet medical needs, therapeutic alternatives, patient journey)
 - The needs of health authorities, payers, HCPs and patients
(e.g., generate RWE data, evaluate the medico-economic value of a product, disseminate scientific and medical data)
 - The objective of the company
(e.g., modify the prescription of a brand, reinforce its proof of efficacy, update medical guidelines, etc.)
- To organize the execution of these medical activities in synergy with other departments of the pharma company
- To monitor the quality of execution and the impact of these activities

PURPOSE 

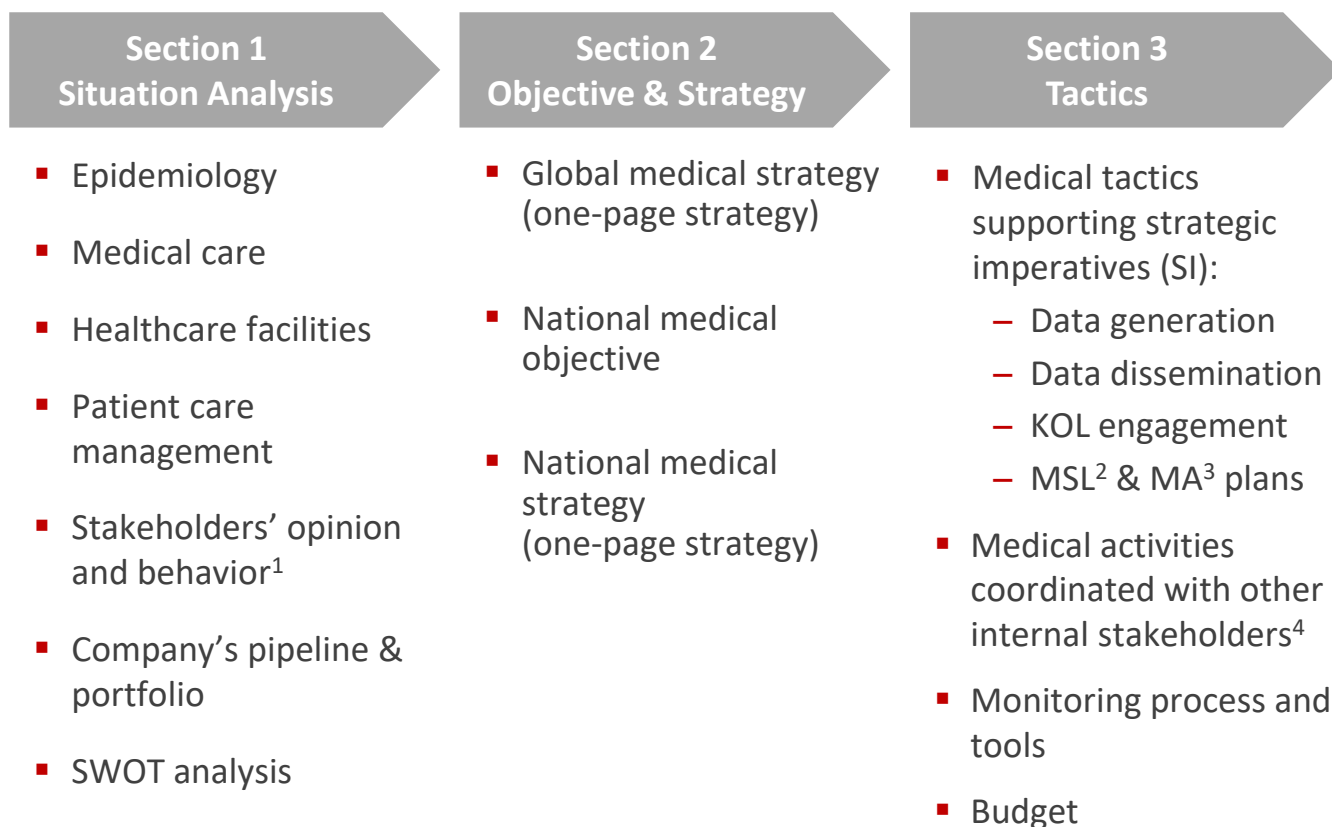
We suggest to adopt the 4 Ws¹ framework to reinforce the relevance and consistency between the national medical situation, medical objective, strategic imperatives and corresponding tactics

How to draft a Strategic Medical Plan?



Conventionally, Strategic Medical Plans are structured in three sections,
on the same model as brand plans or any other business plans

How to structure a Strategic Medical Plan?



High-Performance Strategic Medical Plans require method, rigor and pragmatism

5 key recommendations

Recommendation #1

Analyze – don't just describe the medical situation

Recommendation #2

Carry out a structured and fact-based medical SWOT analysis

Recommendation #3

Craft a medical strategy enabling to meet the set medical objective

Recommendation #4

Select key medical activities to support the crafted medical strategy

Recommendation #5

Integrate indicators to monitor activity execution and corresponding impact

Recommendation #1**Analyze – don't just describe the medical situation**

The situation analysis should focus on identifying and analyzing current and future key medical environment features

What do we observe?

- The situation analysis is most often a situation description
- Knowledge and understanding of the local medical environment are too often inaccurate or incomplete
- The main reasons for these weaknesses come from:
 - Affiliate medical teams considering the strategic medical plans as having little, if any, value for them
 - Insufficient time spent to carry out in-depth analyses to enhance medical environment insights (knowledge and understanding)
 - Lack of reliable data (e.g., epidemiological data)

What do we recommend?

- A robust analysis of the situation requires to identify key medical environment features by gathering precise and reliable data regarding:
 - Epidemiology
 - Medical care
 - Healthcare facilities
 - Patient care management
 - Stakeholders' opinion and behavior
 - Patient care management / patient journey
 - Competitors position and own pipeline and portfolio
- In-depth knowledge and understanding enable to identify opportunities and threats in the environment, and to assess brand strengths and weaknesses

Recommendation #1

Analyze – don't just describe the medical situation

The following chart is an enabling tool to identify and analyze the key medical facts and figures relative to the medical environment, and from which implications for the portfolio can be drawn

Medical Situation Analysis Chart

Illustrative

Key Facts & Figures – WHAT?		Driving Factors – WHY?	Implications – So WHAT?
Epidemiology (Prevalence – Incidence)			
Medical care (Diagnosis – Treatment – Guidelines)			
Healthcare facilities			
Patient care management (Patient journey)			
Stakeholders' opinion & behavior	Health Authorities		
	Customer group A (HCPs ¹)		
	Customer group B (PAGs)		
	Competitors		
Own pipeline & portfolio			

Recommendation #2**Carry out a structured and fact-based medical SWOT analysis**

**The SWOT analysis is a structured summary of the situation analysis
from which strategic imperatives are drawn**

What do we observe?

- The conventional SWOT framework is not well conceived and most often leads to misuses:
 - It is frequent to see a long list of items, not always relevant, and considered to be of equal importance
 - Opportunities are often confused with strengths, and threats with weaknesses
 - It is not rare for an item to be mixed-up with its cause, leading to wrong strategic decisions¹
- The frequent inappropriate use of the SWOT framework has led detractors to rename it

“Silly Way Of Thinking”

What do we recommend?

- Opportunities and threats relative to the national medical environment should be structured by topic (i.e., epidemiology, medical care, healthcare facilities, patient care management, stakeholders’ opinion and behavior (authorities, HCPs, PAGs, patients, competitors))
- Brand strengths and weaknesses should be evaluated vs. alternative options and consider:
 - The product attributes (efficacy, indications, clinical and real-world data, safety profile, convenience)
 - Related services: to authorities, HCPs, patients, PAGs
 - Corporate reputation: portfolio, pipeline, partnerships
- It is essential to estimate the importance of each item according to its relative importance (RI) by using, for instance, a five-point scale

Recommendation #2

Carry out a structured and fact-based medical SWOT analysis

The “Advanced SWOT” helps medical teams carry out a more specific and relevant assessment of the medical environment and of the brand medical position

Advanced SWOT analytical tool

Medical Environment Opportunities	RI ¹	Medical Environment Threats	RI ¹
<ul style="list-style-type: none"> ▪ Epidemiology (prevalence, incidence) ▪ Medical care (diagnosis, treatment, guidelines) ▪ Healthcare facilities (institutions, CoE², networks) ▪ Patient care management (patient journey) ▪ Stakeholders’ opinion and behavior (authorities, HCPs, PAGs, patients, competitors) 		<ul style="list-style-type: none"> ▪ Epidemiology (prevalence, incidence) ▪ Medical care (diagnosis, treatment, guidelines) ▪ Healthcare facilities (institutions, CoE², networks) ▪ Patient care management (patient journey) ▪ Stakeholders’ opinion and behavior (authorities, HCPs, PAGs, patients, competitors) 	
Brand Strengths	RI ¹	Brand Weaknesses	RI ¹
<ul style="list-style-type: none"> ▪ Product attributes: (efficacy, scope of indications, clinical and real-world data, safety, convenience) ▪ Related services: to authorities, HCPs, patients, PAGs ▪ Corporate Reputation: portfolio, pipeline, partnerships 		<ul style="list-style-type: none"> ▪ Product attributes: (efficacy, scope of indications, clinical and real-world data, safety, convenience) ▪ Related services: to authorities, HCPs, patients, PAGs ▪ Corporate Reputation: portfolio, pipeline, partnerships 	

Recommendation #3**Craft a medical strategy enabling to meet the set medical objective**

The medical strategy is too often crafted irrespective of the medical environment and the tactics are not always carefully selected to support the strategic imperatives

What do we observe?

- Too often, strategic imperatives crafted are not driven from the SWOT analysis or...
- ... the link between the SWOT and the strategic imperatives is not clearly established
- In principle, resources and capabilities should be focused to support the strategic imperatives, which is not always the case

What do we recommend?

- The strategic imperatives should be derived from the SWOT analysis
- Strategic imperatives can be a:
 - Medical environment opportunity to seize
 - Medical environment threat to fight again
 - Brand strength to capitalize on, and/or
 - Brand weakness to address
- The preferred strategic imperatives are those the most efficient and effective to achieve the set medical objective for the brand
- It is important to ensure the consistency between the objective – the strategic imperatives – the key tactics

Recommendation #3



Craft a medical strategy enabling to meet the set medical objective

The Medical Strategy Card is a useful tool to align medical objectives, strategic imperatives and corresponding tactics, while ensuring complementarity with other functions¹

The Medical Strategy Card

Illustrative

Medical Objective			
Quantitative & Qualitative objectives			
SI #1	SI #2	SI #3	SI #4
Tactical Objectives	Tactical Objectives	Tactical Objectives	Tactical Objectives

 Complementarity & coordination with other key functions¹ of the pharma company

Recommendation #4**Select key medical activities to support the crafted medical strategy**

**Tactics do not always support strategic imperatives and therefore,
do not significantly contribute to enhance the medical value of the brand portfolio**

What do we observe?

- Key tactics do not always support strategic imperatives...
- ... while they should be their operational expression
- In such a case, the probability to meet the medical objective will be lowered
- Key tactics are too often described as a series of activities for which objectives have not been clearly set and the impact formerly measured
- Being rarely based on the assessment of experience, the process to prioritize these tactics is in general, weak
- When tactics are not well-defined, the quality of their execution is generally poor

What do we recommend?

- If Medical Affairs departments are not supposed to promote brands...
- ... they should however contribute to optimize their use in the best interest of patients...
- ... by contributing to generate and disseminate relevant medical data to health authorities, HCPs and PAGs
- For each tactic, it is important to:
 - Precise the concerned target
 - Set a precise objective
 - Plan the corresponding activities
 - Name a responsible
 - Estimate a budget

Recommendation #4



Select key medical activities to support the crafted medical strategy

Each tactic should be carefully selected to best support the strategic imperatives and carefully planned to ensure a high-quality of execution

Table of tactical objectives related to strategic imperatives

Illustrative

Strategic Imperative

Medical Department

Tactic	Target	Objective	Timing	Responsible	Budget

Sources: Smart Pharma Consulting analyses

Recommendation #5**Integrate indicators to monitor activity execution and impact**

It is rare to see Strategic Medical Plans with integrated monitoring tools and process, which therefore prevents from measuring the efficacy and efficiency of the selected tactics

What do we observe?

- Rare are the companies which integrate, in their strategic medical plans, indicators to monitor:
 - The quality of execution (Key Execution Indicators) and/or
 - The impact (Key Performance Indicators) of their tactics
- Without these indicators and the implementation of a monitoring process, it is impossible to evaluate the efficacy and efficiency of the tactics planned in the medical plan
- Thus, a strategic medical planning without monitoring tools can be viewed as a window-dressing exercise

What do we recommend?

- All plans should include monitoring tools and a monitoring process related to each selected tactic
- We recommend to use:
 - Key Execution Indicators (KEIs) which measure the quality of execution of tactics
 - Key Performance Indicators (KPIs) which measure the outcomes of tactics
- By measuring carefully, the quality of execution and the impact of tactics, it is possible to adjust the strategic medical plans (during the year or from the previous year) to make them more efficient and effective

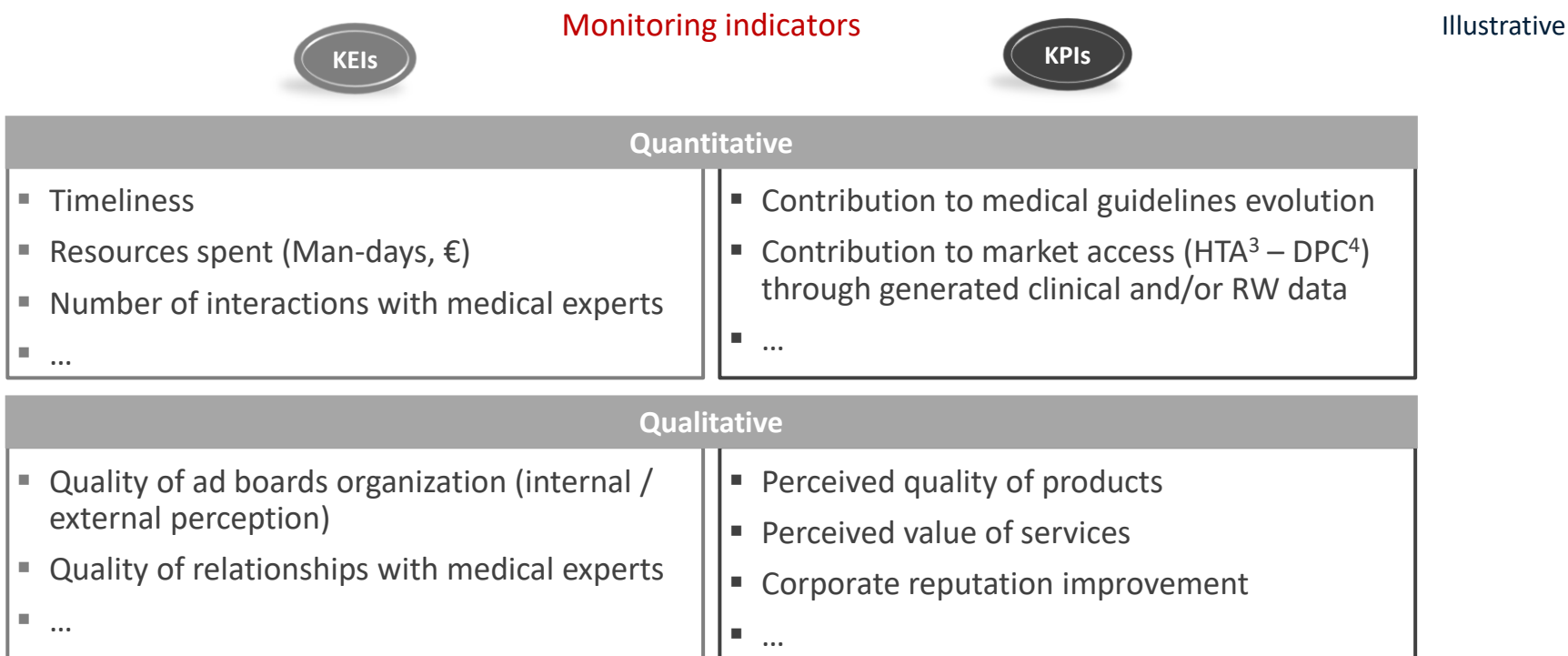
“If you can’t measure it, you can’t manage it!” – Peter Drucker

Recommendation #5



Integrate indicators to monitor activity execution and impact

KEIs¹ and KPIs² are both essential; the first type of indicators measuring the quality of execution and the second the degree of objective achievement



“KEIs check that you are on the right track and KPIs check that you arrive at destination”

Recommendation #5



Integrate indicators to monitor activity execution and impact

This proposed ID Card includes, on one page, a planning section and a monitoring section for each key tactic

ID Card

Illustrative

<ul style="list-style-type: none"> ▪ Strategic imperatives: precise the SI this tactic is supposed to support ▪ Tactical objective: define the specific objective of this tactic ▪ Description: describe briefly the tactic 			<ul style="list-style-type: none"> ▪ Stakeholder type: internal, external (e.g., HCPs, payers, PAGS) ▪ Number of stakeholders: 		Importance L–M–H*	
Planning	Actions			Timing	Owner	FTE / OpEx
What are the key actions to realize this tactic?	1.					•
Monitoring	Quantitative / qualitative metrics	Indicator objective	Indicator achievement		Key implications / Comments	
Key Execution Indicators (Quality of implementation)	•	•	•		•	
Key Performance Indicators (Impact of the action)	•	•	•		•	

Strategic Medical Plans are essential to ensure the optimal use of drugs, knowing the increasing importance of medical evidence to drive opinion and behavior of external stakeholders¹

Key takeaways

- **D**esign Strategic Medical Plans to allocate the right resources to reach the medical objective...
- ... and not just as a formality to be reported at corporate or management committee level
- **A**dopt the 4Ws² (What? – Why? – so What? – What to do?) approach to improve the relevance, the consistency and the robustness of the content
- **A**pply the “Advanced SWOT” for a better analysis of the medical environment, the competitive landscape and the company’s product position, while identifying and prioritizing opportunities, threats, strengths and weaknesses
- **S**eek preference rather than satisfaction of external stakeholders by improving their perception of the product attributes, the quality of the proposed services and the corporate reputation
- **M**ake the best use of the “Medical Strategy Card” to formalize clearly and precisely the medical objective, the strategic imperatives and the corresponding key tactics
- **D**efine Key Execution Indicators and Key Performance Indicators to monitor respectively the quality of execution and the impact of the medical tactics



Smart Pharma
CONSULTING

Medical Affairs Best Practices...

———— MEDICAL SERIES ————

... in a Changing Environment

The purpose of this position paper is to analyze strategic, tactical and organizational best practices of Medical Affairs departments in a changing environment

Introduction

CONTEXT

- Over the past decade, Medical Affairs have moved from a support function providing medical information...
- ... to a strategic function collecting insights to direct R&D to better fulfill unmet needs and...
- ... disseminating scientific and medical data to take the best advantage of innovations

OBJECTIVE

- Provide information about the evolving mission and organization of Medical Affairs departments
- Share thoughts re. Medical Affairs strategic planning and implementation
- Make recommendations likely to improve the contribution of Medical Affairs to value creation for patients, HCPs and Pharma companies

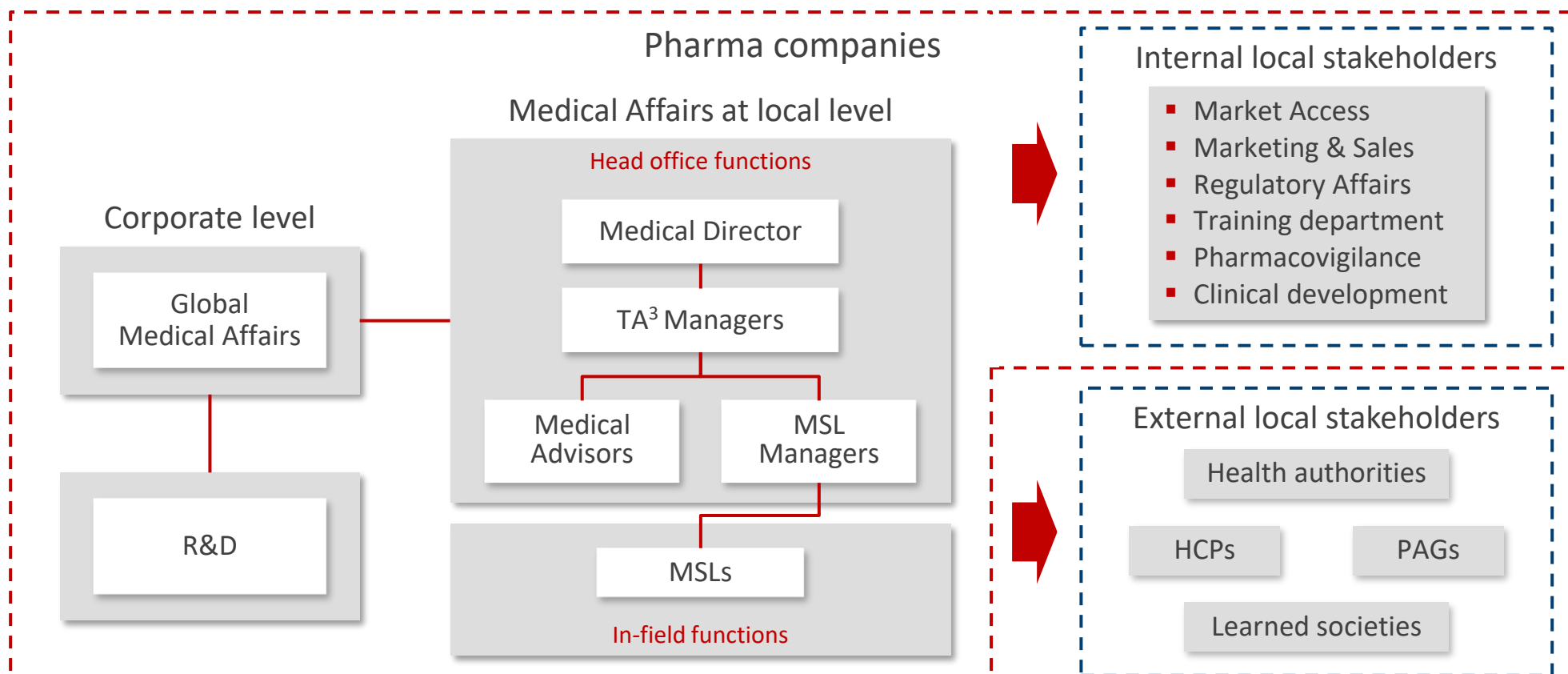
METHOD

- The content of the position paper is based on:
 - Desk research carried out in May 2023
 - Smart Pharma Consulting experience and previous publications related to medical topics
 - Selected interviews with senior executives from Pharma companies' Medical Affairs department

Medical Affairs are at the crossroads of pharma companies, interacting internally with all operational functions; and externally with health authorities, HCPs¹, PAGs² and learned societies

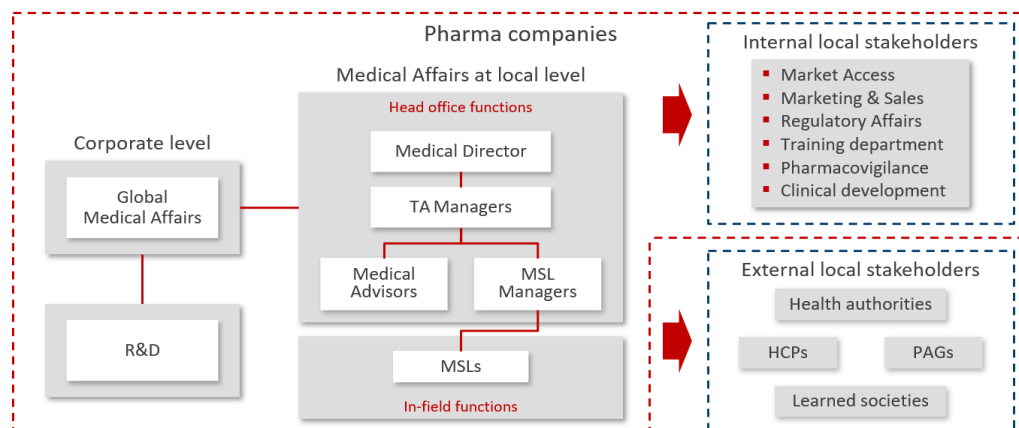
Medical Affairs positioning

Illustrative



Medical Affairs guarantee a two-way communication to align R&D programs with medical needs and to favor the optimal use of marketed brands by generating supportive evidence

Medical Affairs mission (1/2)



Insights gathering

Gathering of insights re. medical needs from which they will craft a medical strategy to direct and contribute to prioritize the pharma company R&D programs

Data generation & dissemination

Generation and dissemination of medical and scientific data to help HCPs optimize disease management with the company's drugs by supporting their proper usage

Medical education

Knowledge sharing and education of internal and external stakeholders throughout products lifecycle:

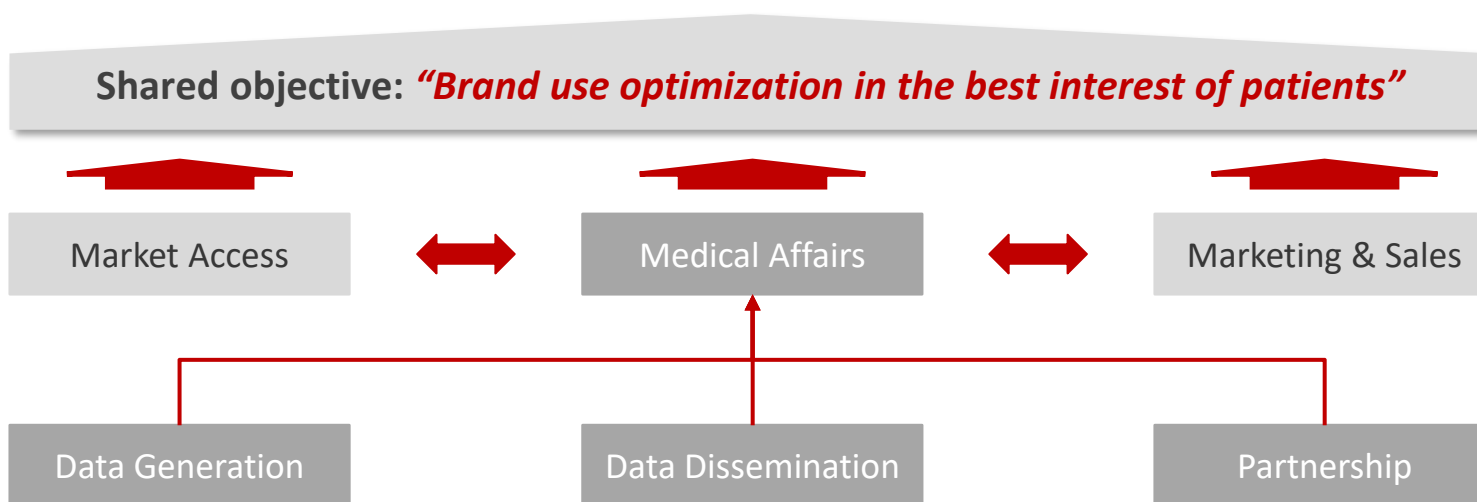
- Early-development: to raise KOLs interest
- Pre-launch: to build awareness and position the product
- Launch: to educate on clinical evidence and product use
- Post launch: to provide CME (Continuing Medical Education)

Scientific platform development

Development of a living document¹, regularly updated, to ensure that disease state and drug information are consistently and optimally communicated

Medical Affairs activities should contribute to optimize the use of pharma companies' brands by HCPs in the best interest of patients

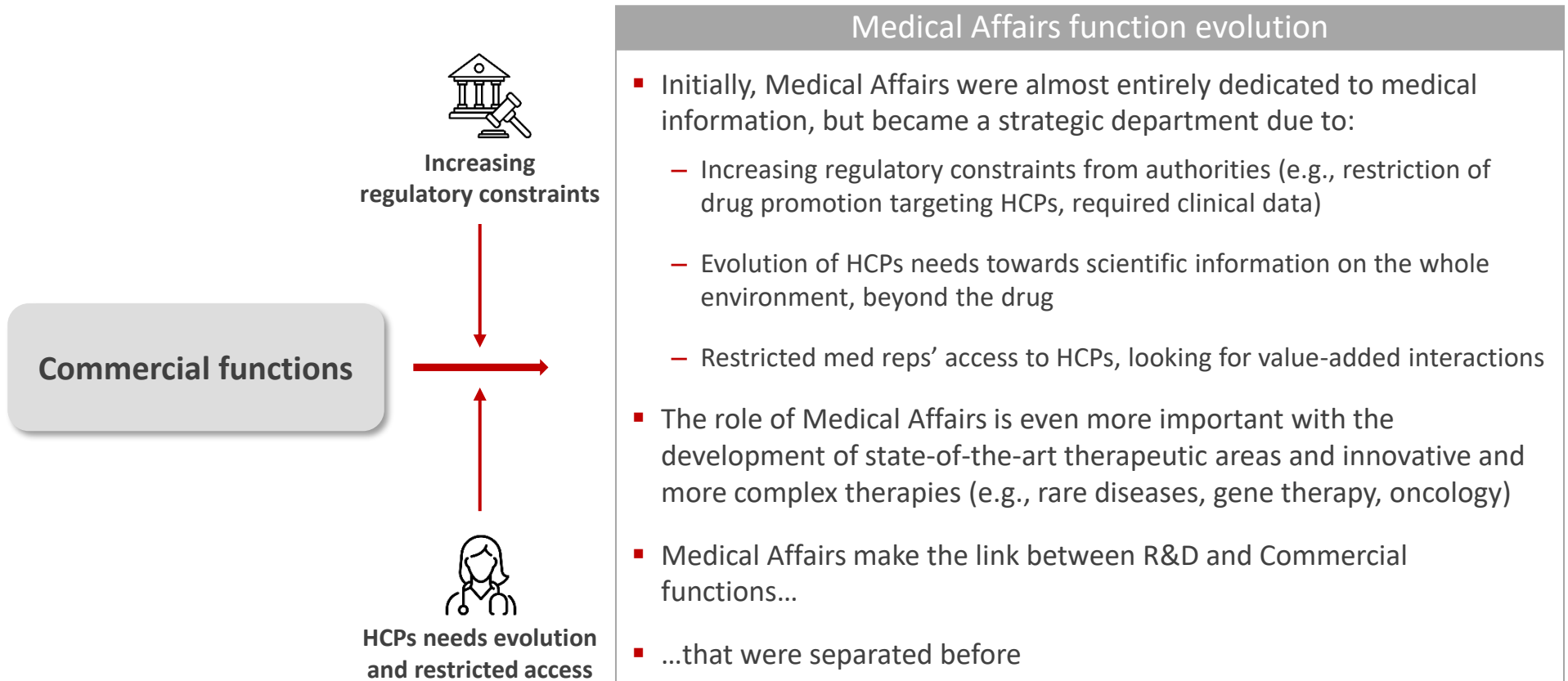
Medical Affairs mission (2/2)



- Medical Affairs play a central role in supporting internal¹ company stakeholders to fulfill the needs of external ones² on medical aspects re.:
 - Disease management
 - Specific indications
 - Brands
- From a brand perspective, it is essential that Medical Affairs, Market Access and Marketing & Sales departments:
 - Share the same objective
 - Craft a common strategy to meet this objective
 - Coordinate their activities
 in their field of expertise, while complying with regulations

The role of Medical Affairs has evolved into an independent and pillar function mainly due to the increasing pressure from authorities, and evolving expectations and practices of HCPs

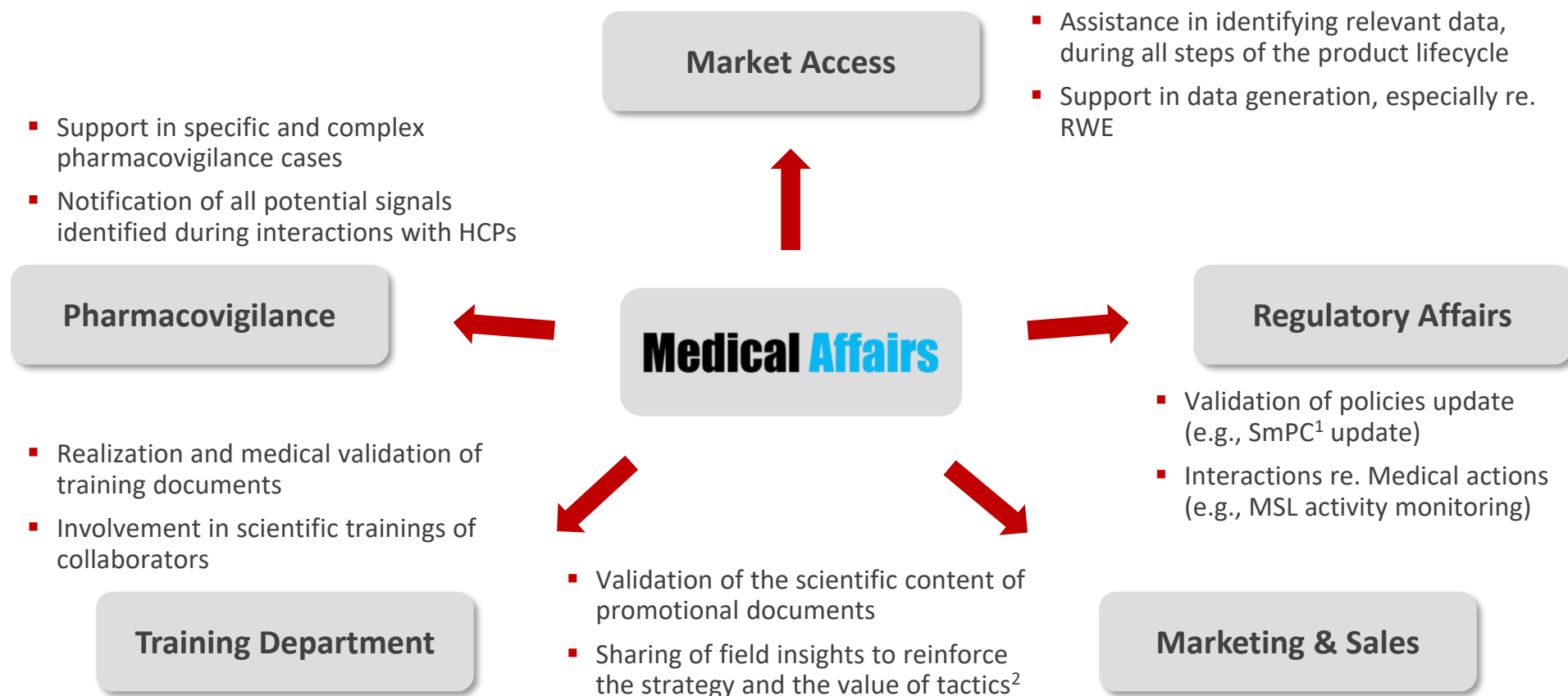
Shift of Medical Affairs interactions with other affiliate departments



Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – The role of Medical Affairs in moving from R&D to Commercialization (2013) – Smart Pharma Consulting analyses

Medical Affairs have a cross-functional role and act as a true scientific platform and partner, for all key internal departments

Interactions with internal local stakeholders

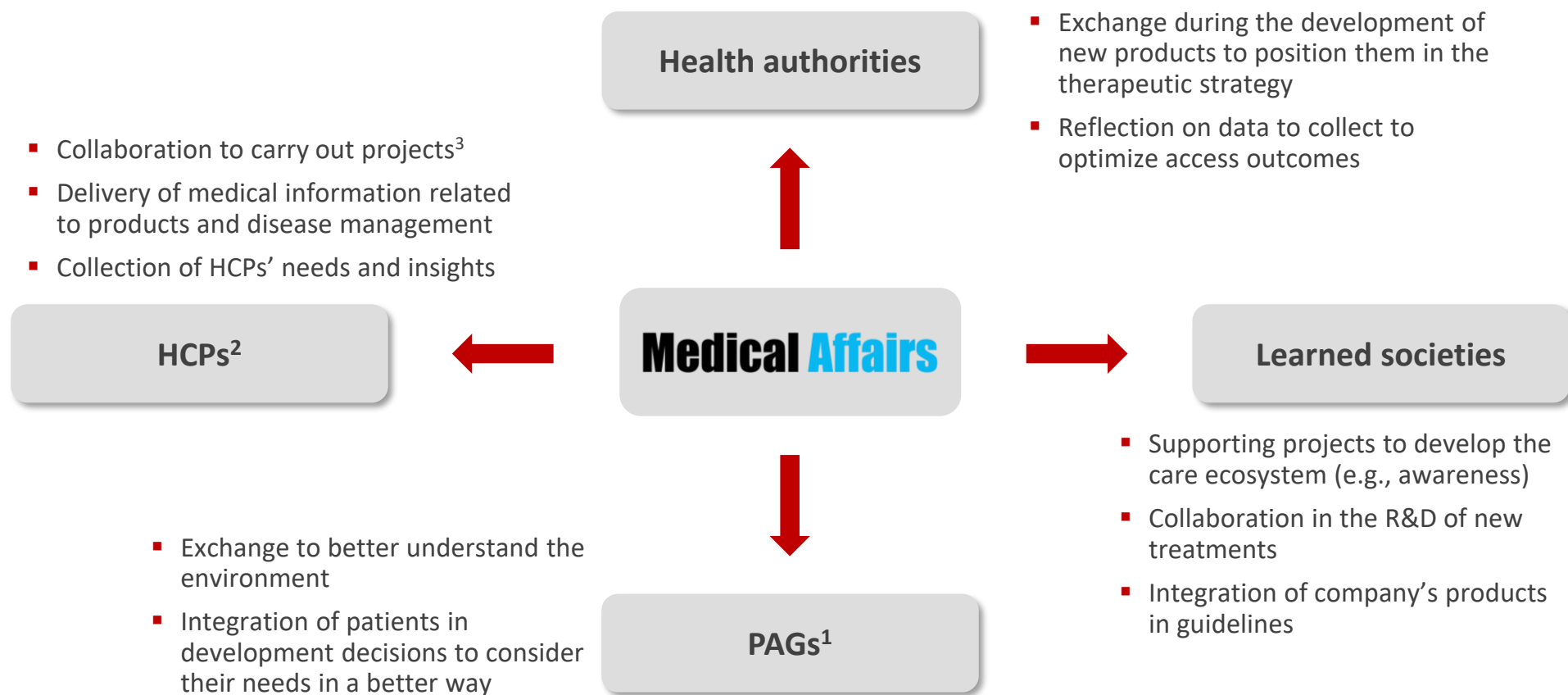


Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – Complete guide on pharmaceutical medical affairs, Viseven (2022) – Smart Pharma Consulting analyses

¹ Summary of Products Characteristics – ² Especially while developing brand plans

Medical Affairs have an essential role to play towards key external stakeholders, whether in product and disease knowledge collection, management, and delivery

Interactions with external local stakeholders



Sources: *The role of medical affairs in positive and appropriate engagement with PAGs* (Openhealth group 2022) – “Medical Affairs: its role and added value within pharmaceutical industry”, C. Picard (2021) – Smart Pharma Consulting analyses

¹ Patient Advocacy Groups – ² Especially KOLs –
³ E.g., Investigator-initiated study, speakers at congress, advisory board

Medical Advisors play a key role within Medical Affairs by ensuring the downward alignment of the global medical strategy at national level and providing local insights to Global Medical Affairs

Medical Advisor role

Mission

- The Medical Advisor is the scientific and medical expert of a pathology, its environment and related treatments
- He ensures the accuracy and the relevance of the scientific and medical data that are collected and disseminated

Activities with internal stakeholders

- Ensure a two-way communication w/ Global Medical Affairs
- Develop a national medical strategy formalized in a plan
- Propose scientific and medical data to be used for marketing authorization and/or value dossiers
- Identify non-interventional studies to fulfill a need
- Validate the scientific content of promotional materials
- Develop training documents and train collaborators
- Provide expert opinion re. pharmacovigilance cases
- Validate the update of SmPCs¹ made by Regulatory Affairs
- Support MSLs (i.e., training, content, strategy sharing)

Activities with external stakeholders

HCPs

- Support HCPs to carry out research projects²
- Interact during congresses, symposia and other meetings³

Health authorities

- Select data to position scientifically new drugs in the therapeutic strategy in the context of market access

Learned societies

- Collaborate on projects to improve patient screening, diagnosis, therapeutic choices, therapeutic adherence, etc.

Patient Advocacy Groups (PAGs)

- Gather PAGs needs to define projects to fulfil patient needs

Sources: "Medical Affairs: its role and added value within pharmaceutical industry", C. Picard (2021) – Smart Pharma Consulting analyses

¹ Summary of Products Characteristics – ² Such as collaborative studies or Investigator-Initiated Studies –

³ HCPs can also be selected by Medical Advisors to participate to advisory boards, to give lectures, etc.

MSLs are the field team of Medical Affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications

Medical Science Liaison (MSL) role

Mission

- The Medical Science Liaison (MSL) is field-based in a designated territory where he focuses on building non-promotional relationships with KOLs and other HCPs
- He is allowed to discuss off-label indications re. drugs on HCPs' demand

Activities with internal stakeholders

Global Medical Affairs

- Translate the global medical strategy at its territory level
- Coordinate the execution of research projects by KOLs¹
- Gather medical insights from the field²

Marketing & Sales

- Develop an action plan complementing the med reps' one
- Answer questions and train on scientific environment
- Co-organize local scientific events³

KAMs⁴ & KIMs⁵

- Provide medical data to support hospital listing process
- Provide medico-economic data re. company's drugs

Activities with external stakeholders

HCPs

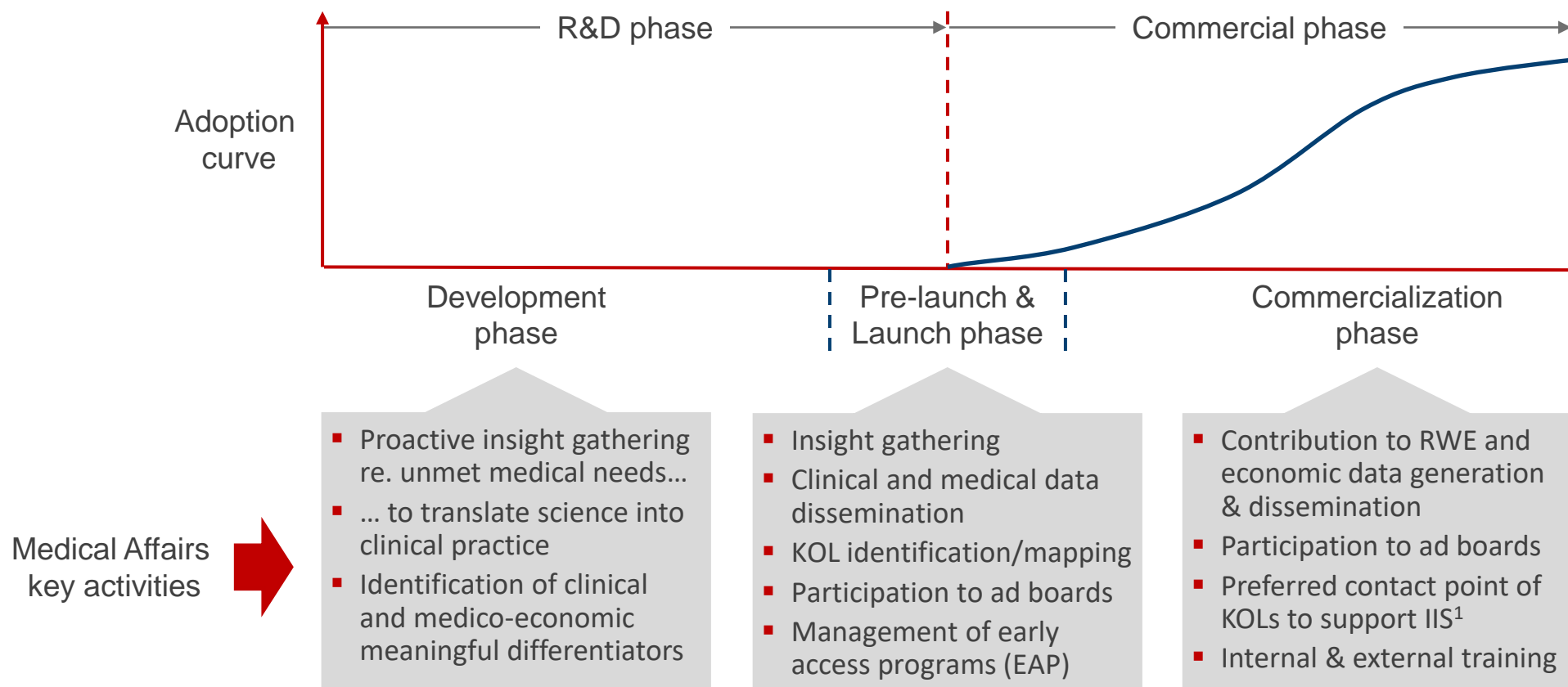
- Map and target KOLs to raise their interest for new drugs
- Identify high potential centers and investigators for company-sponsored clinical studies
- Support studies implementation jointly with CRA⁶
- Collect insights re. medical needs, drug use and competition
- Contribute to medical education of HCPs for better drug use
- Respond to HCPs requests re. clinical development, RWE studies, Investigator-Initiated Studies (IIS)
- Interact with HCPs during congresses, symposia and other meetings, such as advisory boards

Sources: "Medical Affairs: its role and added value within pharmaceutical industry, C. Picard (2021) – "The changing role of the modern MSL", Pharmaceutical Market Europe, October 2015 – Interviews with 5 MSLs – Smart Pharma Consulting analysis – Smart Pharma Consulting analyses

¹ Collaborative studies or Investigator-Initiated Studies – ² E.g., KOLs needs, frequent medical questions / objections – ³ Such as staff meetings in hospital departments, medical meetings, webinars – ⁴ Key Account Managers – ⁵ Key Institution Managers who interact with regional health authorities and payers – ⁶ Clinical Research Associates

Medical Affairs play an essential role to ensure that clinical development will fulfill patient unmet needs and that health authorities, payers and HCPs will make the best use of marketed drugs

Medical Affairs activities along the drug lifecycle



The use of digital technology in clinical trials facilitates patient recruitment and retention, reduces associated costs and generates real-world evidence

Medical Affairs digitalization: Clinical data generation



sanofi

Real-world evidence generation

- **Digital tools** represent an opportunity to generate **real-world evidence** and thus strengthen patient's role to assess drugs value and to design innovative products
- Their development has been facilitated by **rapid advances in technology**¹
- The generation of these data offers a better understanding of **real-world care pathway** with the help of **new indicators** such as:
 - **PROMs (Patient-Reported Outcomes Measures)**
 - **PREMs (Patient-Reported Experience Measures)...**
- ...enabling to **evaluate the quality of care** as perceived by patients

Case study: VERKKO trial application

- A **Phase IV trial** has been launched, **fully digitally** using a **connected blood glucose meter**, by Sanofi in collaboration with Mendor and eClinicalHealth
- 60 patients **recruited via Facebook** with an **81% conversion rate** (recruitment/application), which is better than typical recruitment results
- The digitalization of the study resulted in a:
 - High **patient satisfaction**
 - **Reduced coordination time** by 2/3
 - **Patient-centered** study design

Sources: eClinicalHealth Announces Successful Results for an Entirely Remote Online Clinical Trial (Businesswire 2016) – From recruiting to data collection, the impact of connected digital health in clinical trials (Nadir Ammout 2016) – Smart Pharma Consulting analyses

¹ Smartphones, tablets, electronic medical records, big data analysis through AI, etc.

Digital tools and channels offer a wider choice of innovative ways to deploy medical communication strategy and have changed the profile of KOLs

Medical Affairs digitalization: Medical communication

Digital channels	Content personalization	KOL / DOL
<ul style="list-style-type: none"> ■ Use of innovative formats to communicate with HCPs (e.g., chatbots, podcasts, webinars) is increasing ■ Digitalization of MSL activities and interactions with KOLs has become increasingly important ■ Post-Covid-19, 66% of KOLs surveyed by the MSL Society indicated that they preferred to use digital tools over face-to-face visits with MSLs ■ Thus, more and more MSLs and medical advisors adopt an omnichannel approach with KOLs 	<ul style="list-style-type: none"> ■ As for medical reps, AI-based tools provide a better understanding of HCPs' needs (e.g., habits, learning preferences)... ■ ...and advanced analysis of interactions allows to propose the most engaging and impactful content for HCPs ■ Digital tools are particularly useful to disseminate specific data to KOLs because they facilitate the identification, collection, storage and structure of scientific and medical information 	<ul style="list-style-type: none"> ■ The emergence of digital channels has changed the landscape of medical influencers: <ul style="list-style-type: none"> — DOLs (Digital Opinion Leaders) who have an influential role in sharing medical information on social networks, coexist with... — KOLs, knowing that less than 30% of the latter have a social media presence ■ Ideally, companies will identify experts that combine the strengths of traditional and digital thought leaders and develop relationships with the most relevant of them

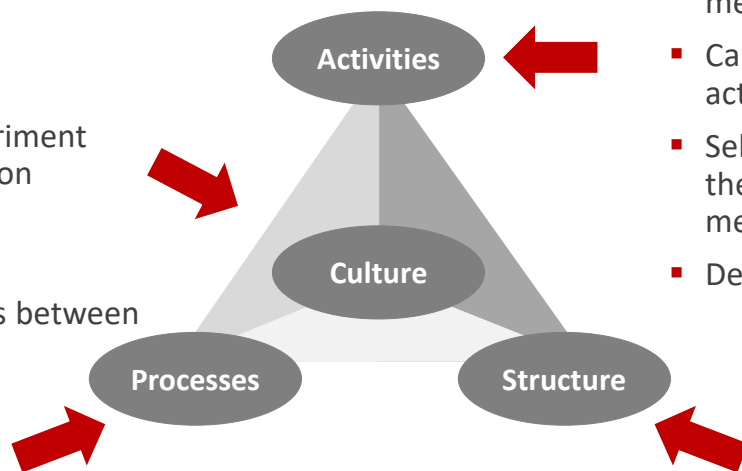
Sources: Transforming Medical Affairs: Tapping the alchemy of storytellers and digital start-ups (McKinsey 2019) – Medical Affairs Digitization (PharmExec.com 2021) – Digital Medical affairs with a human touch – To maximize KOL impact, Medical Affairs needs a digital strategy too (PharmaSpectra resources 2021) – How to digitalize MSL teams for increased efficiency (Pharmafield) – Medical affairs: Key imperatives for engaging and educating physicians in a digital world (McKinsey 2018) – Smart Pharma Consulting analyses

The Medical Affairs organization should be designed and adjusted to best support the implementation of the medical strategy crafted by the pharma company

Key organizational dimensions to be leveraged

- Develop a culture of superior stakeholder satisfaction
- Develop a powerful vision so that collaborators feel connected¹
- Install a participative culture²
- Engrain a culture of excellence
- Encourage pro-activity, agility and experiment to find new solutions to excel in execution

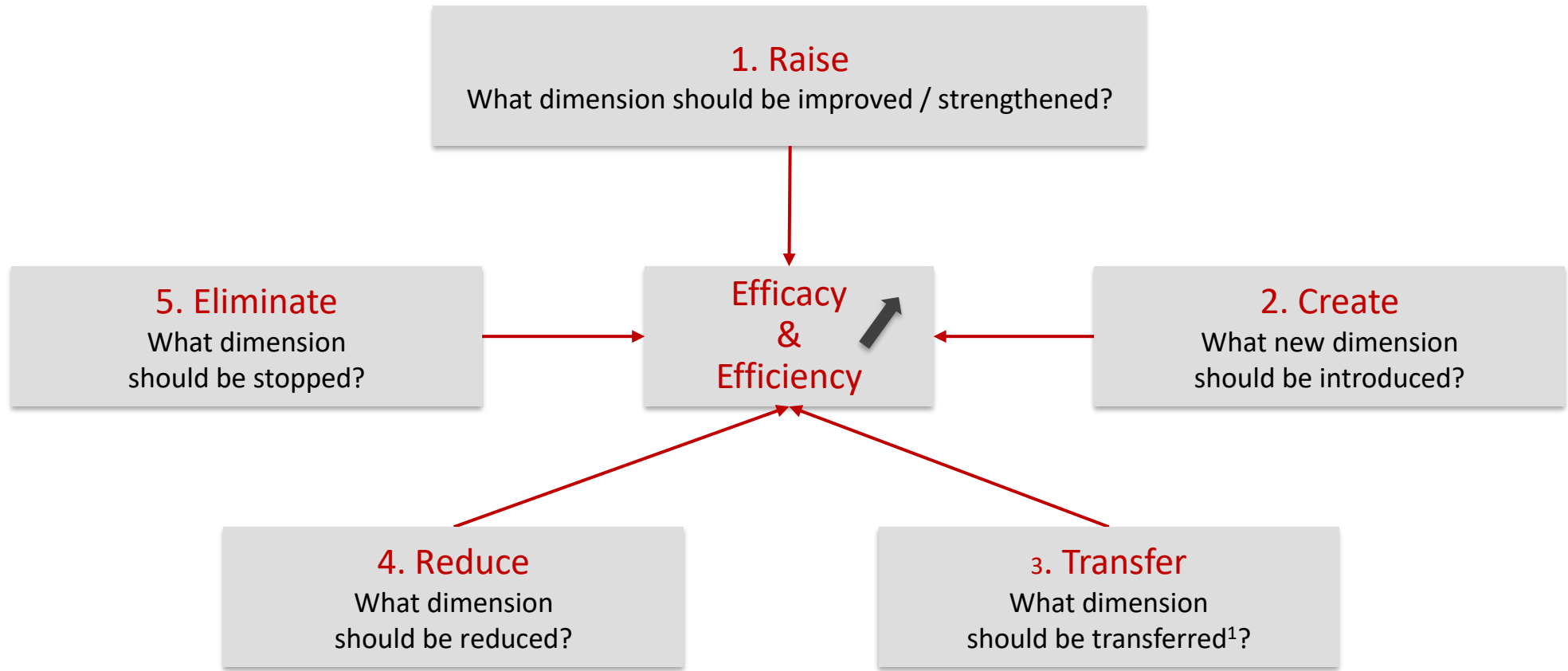
- Facilitate cross-functional collaborations between Medical Affairs and other departments
- Develop tools to:
 - Align objective, strategy and tactics
 - Measure the quality of execution and the impact of activities
 - Reinforce the cohesion of teams
 - Learn from experience
- Streamline processes and set up standards of excellence



- Provide direction and resources for achieving medical strategic objectives
- Focus on activities that best support the medical strategy
- Carefully plan the execution of key medical activities
- Select a limited number of metrics to monitor the quality of execution and the impact of medical activities
- Develop the skills of collaborators
- Design an adaptative structure
- Set up a flat and lean organizational chart
- Simplify structures by eliminating needless complexity
- Delineate lines of command and decision rights

When applied to Medical Affairs departments, the five following actions can help improve their organizational efficacy and efficiency

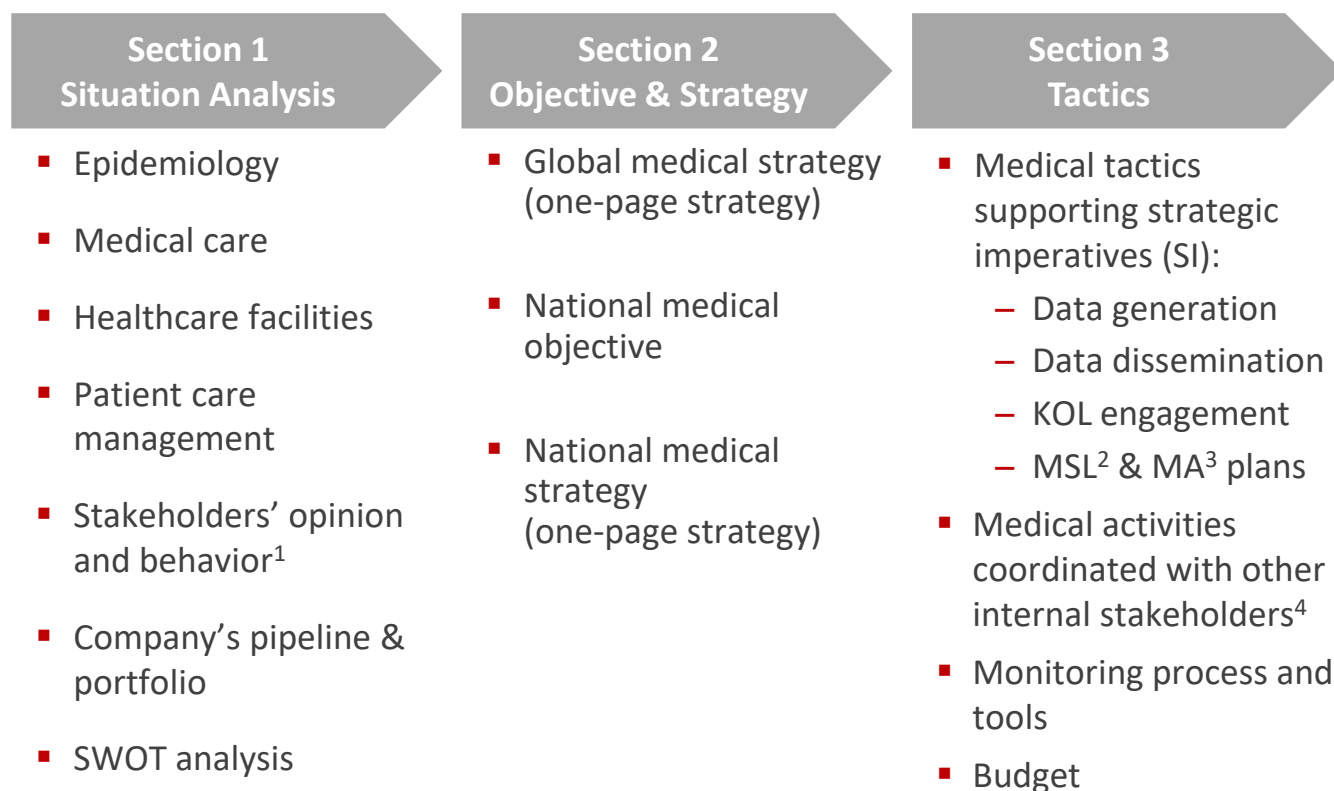
How to leverage key organizational dimensions?



The purpose of Strategic Medical Plan is to allocate the right medical resources to reach the medical objective set, in an effective and efficient way

Strategic medical plan – Structure

Conventionally, strategic medical plans are structured in three sections



High-Performance Strategic Medical Plans require method, rigor and pragmatism

Strategic medical plan – Recommendations

Recommendation #1

Analyze – don't just describe the medical situation

Recommendation #2

Carry out a structured and fact-based Medical SWOT analysis

Recommendation #3

Craft a medical strategy enabling to meet the set medical objective

Recommendation #4

Select key medical activities to support the crafted medical strategy

Recommendation #5

Integrate indicators to monitor activity execution and corresponding impact

Medical Affairs will evolve in their activities with the development of digital tools but also, in their role which is becoming increasingly central and essential within the pharma industry

What is the future of Medical Affairs?

Insights Management

- Use of conventional and digital scientific data sources (e.g., publications, social listening, connected devices) and...
- ...capitalization on digital tools (e.g., algorithms, AI) to generate and analyze HCPs and patient insights that are valuable to direct pharma companies' R&D programs, and deliver relevant medical information

Scientific Evidence Generation

- New digital tools allow to generate RWE data...
- ...which are more and more requested by health authorities and valuable for pharma companies
- Science, safety and transparency are the key drivers of Medical Affairs and a clear governance strategy for new tools must be established



Medical Affairs Transformation

- Medical Affairs are becoming a “Pillar function” oriented towards patients' life improvement as a whole and not only focusing on drugs
- Therefore, several new roles are emerging to fulfill this function (e.g., patient officers)
- In addition, technologies are expanding beyond-the-pill to improve patient care (e.g., DTx¹)

Stakeholders Engagement

- Medical Affairs are at the crossroads of stakeholders (e.g., HCPs, PAGs², health authorities)
- Thus, they must determine best value-added strategies to engage stakeholders and develop sustainable relationships
- Patient-centric initiatives are increasing, with patients engaged as soon as product development



Best-in-class Medical Science Liaisons

————— BEST-IN-CLASS SERIES —————

How to boost MSL's
Competence & Performance

This position paper proposes strategic and operational methods, tools and advice to boost Medical Science Liaisons (MSLs) competence and performance

Context & Objective

- **Medical Science Liaisons (MSLs) play a pivotal role to maintain a close relationship with KOLs¹ who are instrumental in:**
 - Developing new products through their collaboration in pre-clinical and / or clinical trials
 - Raising the awareness and the preference – indirectly or directly – for their products in the mind of HCPs² but also of health authorities, PAGs³, individual patients, etc.
- **The increasing role of Medical Science Liaisons (MSLs) results from:**
 - New molecular entities becoming more and more complex...
 - ... and mainly prescribed by specialists, less and less inclined to be informed by medical reps
- **In this position paper, Smart Pharma Consulting proposes:**
 - **Methods, tools and advice to boost MSLs competence and performance**
 - **KOL Partnership Model to recruit and manage KOLs in a more efficient and effective way**

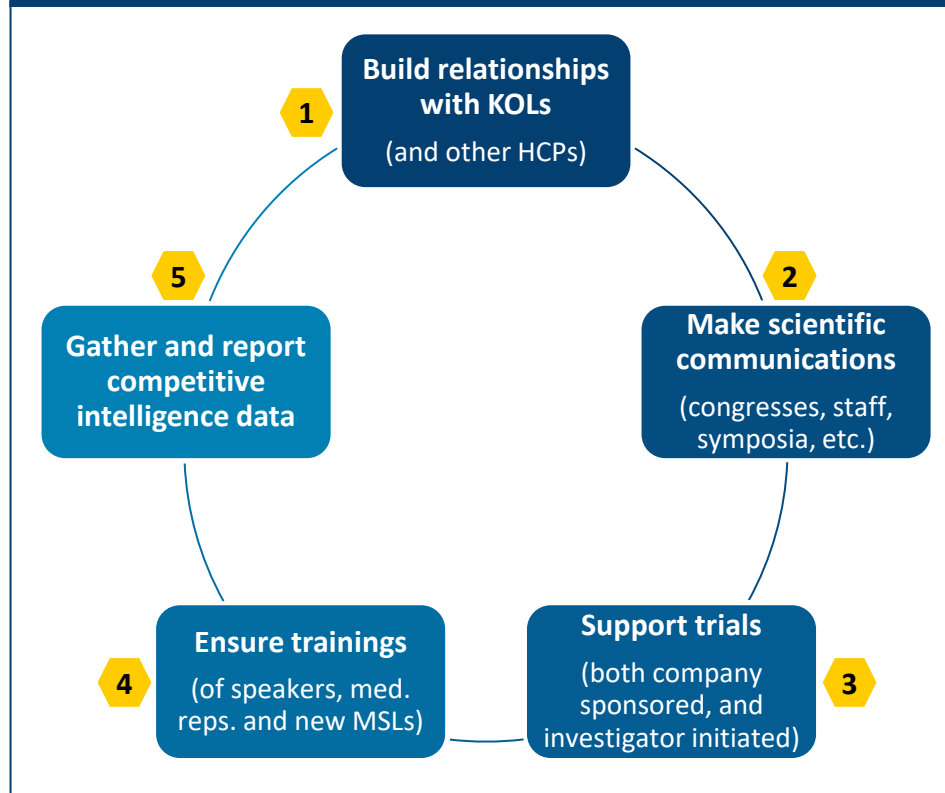
MSLs are the field team of medical affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications

Overview: MSLs

MSLs: Medical Science Liaisons¹

- MSLs are one of pharma companies' field teams dedicated to enhance the full exchange of **scientific information** with physicians, especially with KOLs
- MSLs have a more robust scientific background than medical representatives, such as: **MSc, MD, Pharm. D, PhD degrees** (90% of them have a doctorate degree)
- MSLs were first established by **Upjohn Pharmaceuticals** (now Pfizer) in **1967** with the objective **to build a strong relationship with KOLs**
- The central activity of MSLs is to develop long-term, peer-to-peer **relationships with KOLs**
- MSLs are in most cases affiliated to the **medical affairs department** (whereas med reps. are affiliated to the sales / marketing department)

Core activities² of MSLs



Sources: MSL Society – “An insight into the emerging role of regional medical advisor in the pharmaceutical industry”, Perspectives in Clinical Research, 2013 – Smart Pharma Consulting analysis

¹ Other names than MSLs can be used by pharmaceutical companies such as: Medical Liaisons, Regional Medical Managers, Regional Scientific Managers, Scientific Affairs Managers, Medical Information Scientists, Clinical Liaisons – ² Excluding administrative time

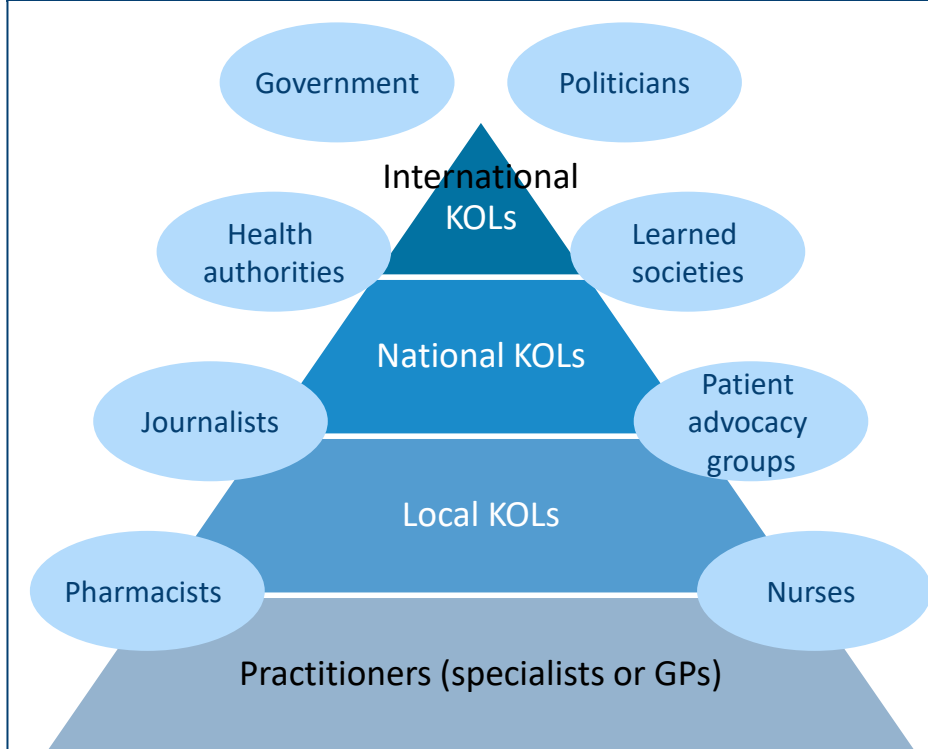
KOLs have the potential to influence their peers, but also other stakeholders in a specific area, at international, national and local levels

Overview: KOLs

KOL: Key Opinion Leader

- The acronym KOL is generally used to qualify physicians who have a **recognized expertise in a specific field** (e.g., oncology, endocrinology, epidemiology, biostatistics, etc.)...
- ... and who can **influence the opinion** and **the medical practice** (e.g., treatment scheme, prescribing habits, preference for a given product, etc.) of their peers (specialists or GPs)
- KOLs may also contribute to **modify medical guidelines** when they are members of learned societies or when they advise health authorities
- KOLs' influence can be at international, national or local levels
- Other stakeholders may also be considered as KOLs (e.g., members of governments, of health authorities, of learned societies, of patient advocacy groups, journalists, pharmacists, nurses, etc.)

Pyramid of influence & types of influencers



The relationships between pharmaceutical companies¹ and healthcare professionals are increasingly regulated, and potential conflicts of interest must be disclosed

Regulatory framework² regarding KOLs & pharmaceutical companies' partnerships



European regulations - Directive 2001/83/CE (Article 94)

- Prohibition of bonuses, benefits (in cash or in kind) from pharmaceutical companies to prescribers
- Hospitality at a reasonable level



France

- **Prohibition of benefits** (in cash or in kind), in any form whatsoever, directly or indirectly, for medical professionals
- Obligation to **disclose potential conflicts of interest** between health professionals or health facilities with pharmaceutical companies
- Measures put in place in the DMOS law **extended to students in healthcare** and patient advocacy groups



UK

- **Interdiction to supply, offer or promise gift, pecuniary advantage or benefit** to HCPs in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- During meetings organized by pharma companies, **provision of inexpensive items only** (pens, etc.) that **must not bear the name of any medicine** or any information about it



Germany

- No influence of HCPs in a **dishonest** manner and therefore **no** advantages **granted** or **promised**
- **Open** and **transparent** cooperation
- Existence of a code for the collaboration (FSA) of the pharmaceutical industry with physicians, pharmacists and other healthcare professionals to **avoid conflicts of interest**



Italy

- **Prohibition** of **any kind of economic incentives** designed to compensate healthcare professionals for time taken from normal professional activities in order to participate in congressional events
- Participation in conferences related to the role performed by the industries in the field of research, development and scientific data and inspired by **ethical, scientific** and **cost-effective criteria**



Spain

- **Prohibition** of **direct or indirect offering** or provision of any type of incentive, prize or gift (in cash or in kind) to HCPs
- **Previous communication to authorities of all events** of a scientific or promotional nature, organized or sponsored by pharma companies
- No **organization** or **sponsor** of events that take place **outside of Spain** (unless it makes more sense from a logistical standpoint)

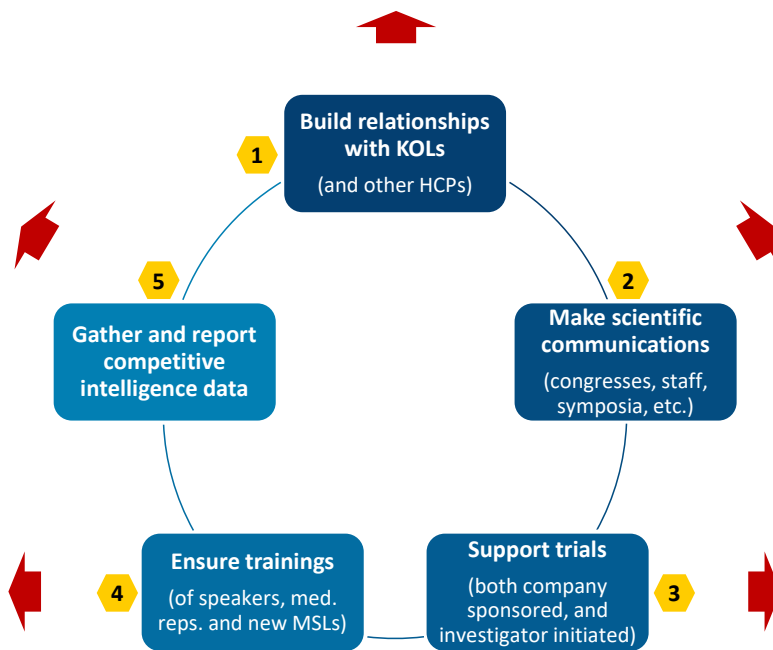
MSLs are often asked to cover a large scope of activities in collaboration with both internal and external stakeholders

MSLs' detailed core activities

- Identification, selection and collaboration with KOLs: setting-up of boards, organization and participation in scientific information meetings, development of continuous medical education (CME) projects, patients or physicians' associations funding, etc.
- Management of Investigator Initiated Studies (IIS)¹: requests processing and follow-up
- Invitations to congresses / symposia, etc.

- Presence in congresses and attendance to competitors' presentations
- Desk research: on competitors, on therapeutic areas, on medico-economic studies
- Critical review of scientific papers

- Training and certifications of med. reps.
- Training of other functions, such as marketing
- Training of speakers communicating on companies' products / therapeutic areas, etc.
- Writing of supports for FAQ&O²



- Answers to HCPs' medical questions
- Participation in scientific information meetings (staffs, face to face, etc.) for on- and off-label indications, re. therapeutic areas and products in the pipeline
- Presentation of studies in congresses / symposia

- Identification of needs and demands of KOLs for IIS
- Identification of high potential centers and investigators for company-sponsored clinical trials
- Support for studies carried out and followed-up jointly with CRAs (Clinical Research Associates)

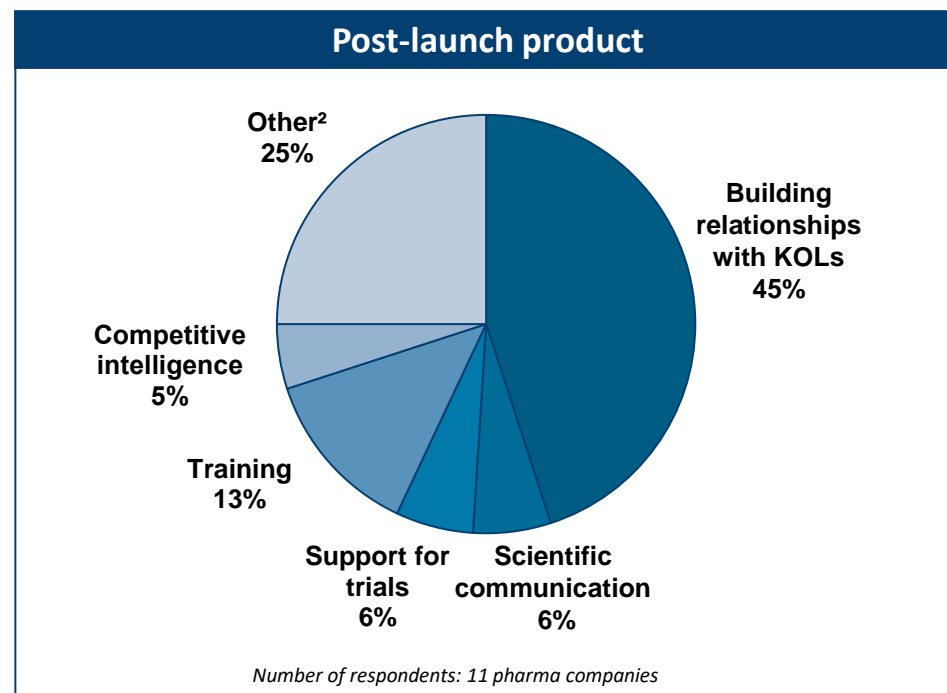
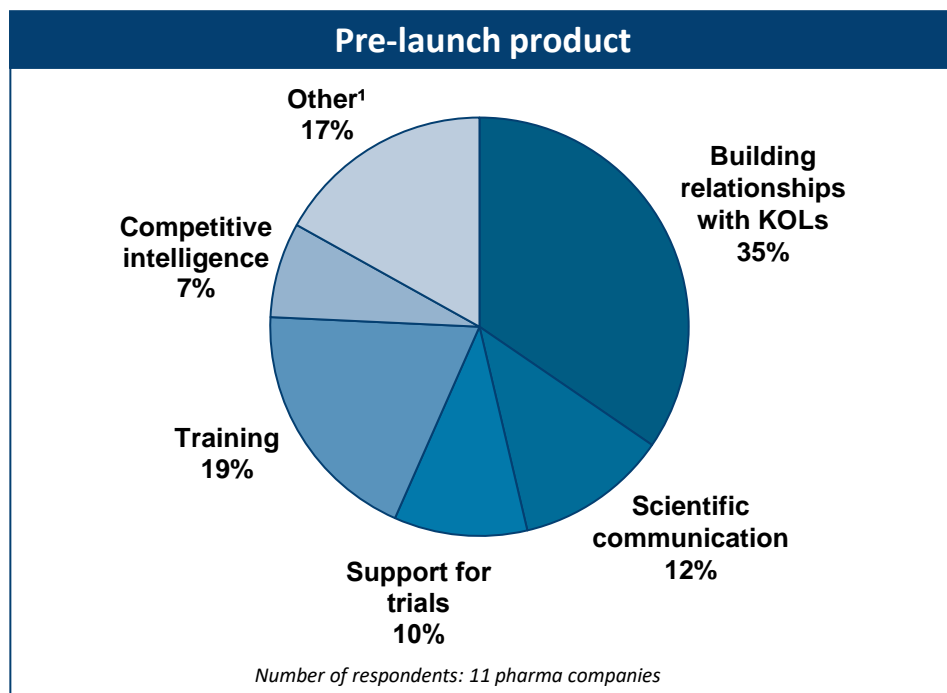
Sources: "An insight into the emerging role of regional medical advisor in the pharmaceutical industry", Perspectives in Clinical Research, 2013 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

¹ Also called: Investigator-Initiated Trials or IIT – ² Frequently Asked Questions & Objections

Building relationships with KOLs and training HCPs or colleagues account together for ~55% to 60% of MSLs' activity in both pre- and post-launch settings

MSLs' time allocation per core activities

MSLs share the same core activities from one company to another, but there could be important variabilities in planning and duties

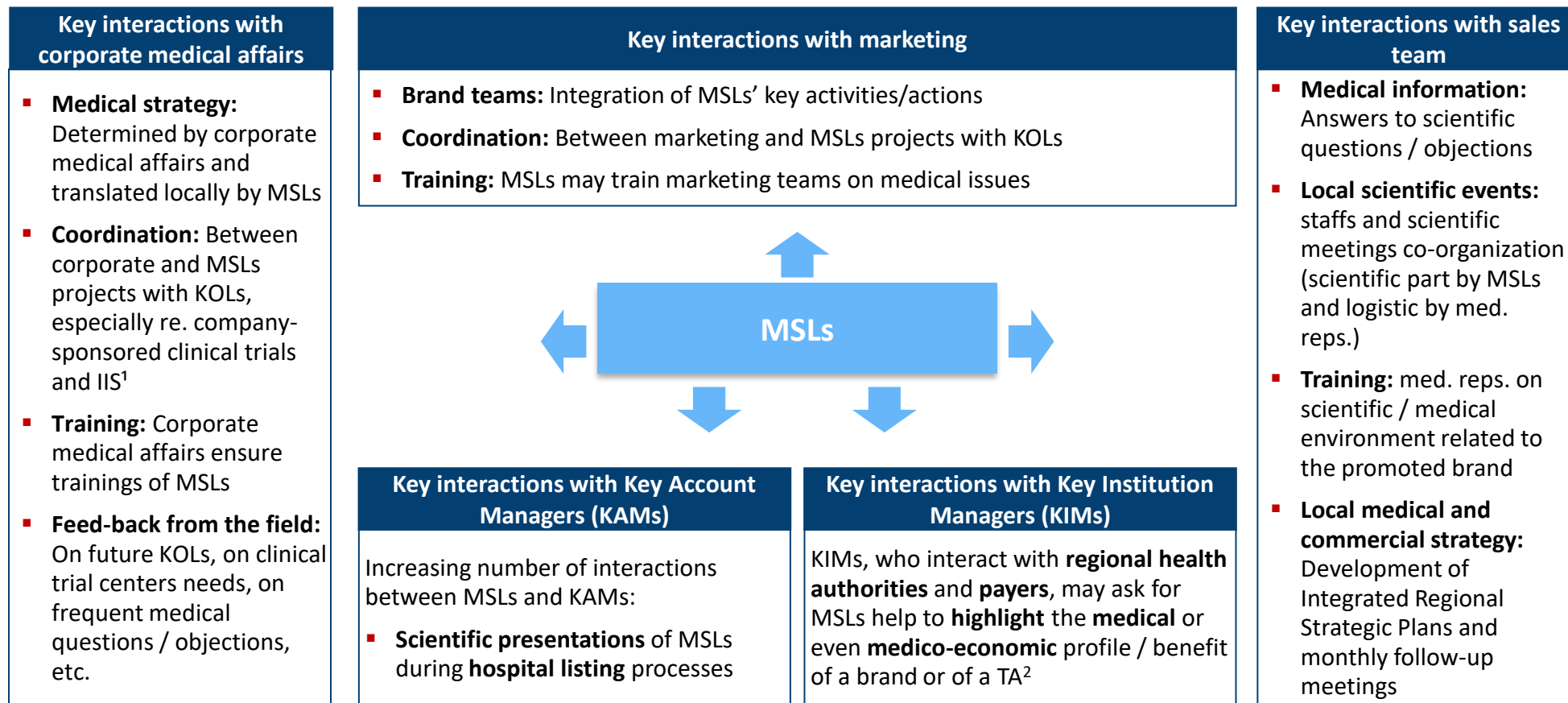


Sources: "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis

¹ Including pre-launch transversal activities with marketing or medical teams, etc. –
² Including support to other field forces, participation in internal advisory boards, etc.

MSLs must support KIMs¹ who facilitate regional market access, KAMs² who ensure listing of products at hospital level and marketing and sales reps who promote them

The transversal role of MSLs



Sources: "The changing role of the modern MSL", Pharmaceutical Market Europe, October 2015
 –Interviews with 5 MSLs – Smart Pharma Consulting analysis

¹ Key Institution Managers – ² Key Account Managers – ³ Investigator Initiated Studies – ⁴ Therapeutic Area

MSLs teams face recurrent issues that can be addressed if pharma companies implement the relevant actions

Six main issues facing MSLs teams

	Key issue	What to do?
1	Distinction from sales / marketing	<ul style="list-style-type: none"> Information campaigns to be carried out to inform stakeholders of the specific role of MSLs Information should be provided through calls
2	Disconnection with corporate initiatives	<ul style="list-style-type: none"> The coordination should be improved by implementing standard communication processes and rules
3	Distraction from core activities	<ul style="list-style-type: none"> MSLs' responsibilities and objectives should be clearly defined and internally communicated through information campaigns
4	Extensive geographical zones	<ul style="list-style-type: none"> Alternative communication technologies such as web conferencing, e-mailing, teleconferences, etc., should be considered
5	Complex regulatory environment	<ul style="list-style-type: none"> Pharma companies should focus on MSLs' compliance with local regulations... ... which should be carefully monitored
6	Trend towards specialization	<ul style="list-style-type: none"> Pharma companies should keep on investing on their MSLs' scientific training

Sources: "Implementing a MSL team", Publicis Touchpoint – "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis

MSLs' most important challenge is certainly to create highly valued interactions and trusted collaborative relationships with KOLs to support companies and products

MSLs' challenges – Required skills – Expected outputs

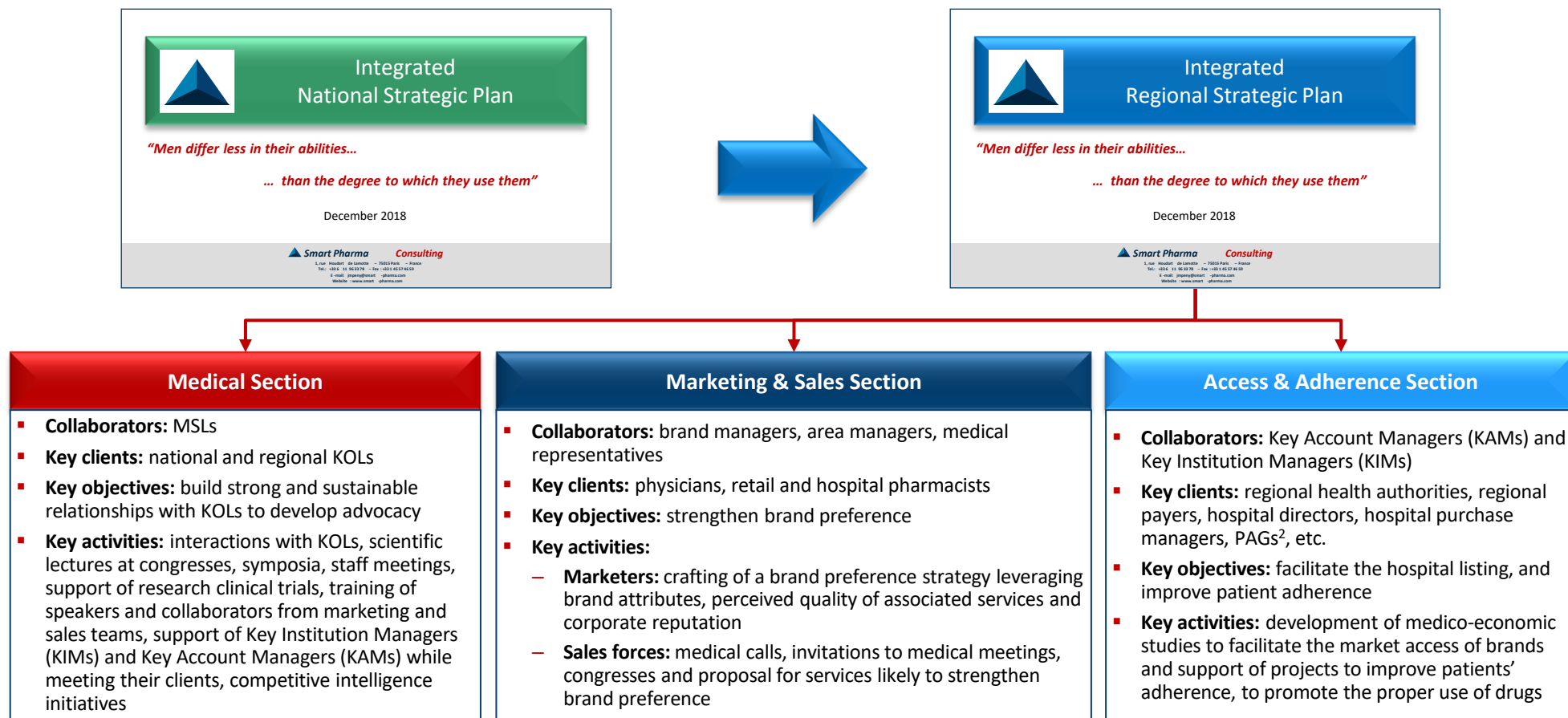
MSLs' challenges

- Keeping up with the **latest scientific information**
- Building strong and sustainable **relationships with KOLs**
- Managing **multiple and diversified tasks**
- Complying with **national regulations** and **internal code of conducts**
- Ensuring effective **coordination with collaborators**

Required skills	Expected outputs
<ul style="list-style-type: none"> ▪ Excellent scientific knowledge and understanding to carry out peer-to-peer discussions during interactions with KOLs 	<ul style="list-style-type: none"> ▪ Ability to inform, challenge and / or convince KOLs based on robust and updated scientific evidence
<ul style="list-style-type: none"> ▪ Strong communication skills to properly position: <ul style="list-style-type: none"> – The company's therapeutic expertise – A given product at pre- or post-launch stage 	<ul style="list-style-type: none"> ▪ Convince KOLs to carry out research or clinical studies ▪ Convince KOLs to support the company's products
<ul style="list-style-type: none"> ▪ Ability to manage projects with KOLs (e.g., while supporting investigators-initiated studies or company-sponsored clinical trials) 	<ul style="list-style-type: none"> ▪ Identification of clinical research opportunities with KOLs ▪ Effective implementation of clinical research trials
<ul style="list-style-type: none"> ▪ Ability to train / teach and / or develop support documents for companies' collaborators and / or HCPs 	<ul style="list-style-type: none"> ▪ Improvement of participants' knowledge, understanding of the disease area and of the benefits of the company's products
<ul style="list-style-type: none"> ▪ Capture and share insight gathered through interactions between KOLs' and all customer-facing teams 	<ul style="list-style-type: none"> ▪ Profiling and selecting the relevant KOLs to partner with ▪ Fulfilling of KOLs needs related to MSL activities
<ul style="list-style-type: none"> ▪ Cooperate and coordinate activities with other customer-facing collaborators and corporate teams interacting with KOLs 	<ul style="list-style-type: none"> ▪ MSLs being the preferential contact of KOLs, they will ensure consistent interactions and address potential issues
<ul style="list-style-type: none"> ▪ Comply with national regulations and ethical considerations regarding disseminated information (e.g., off-label) 	<ul style="list-style-type: none"> ▪ Prevent the company to be sued and to be fined
<ul style="list-style-type: none"> ▪ Ability to manage time, set priorities and adjust unforeseen changes inherent to MSLs' job 	<ul style="list-style-type: none"> ▪ Timely and proper execution of multiple tasks under the responsibility of MSLs

MSLs' activities should be integrated in a Regional Strategic Plan to ensure synergies with marketing, sales, market access and patient adherence departments' activities¹

Integrated Regional Strategic Plan – Principle



MSLs' activities should be defined in an Integrated Regional Strategic Plan in coordination with marketing, sales, market access and adherence departments

Integrated Regional Strategic Plan – Structure of the Medical Section



Structure

- **Situation analysis**
 - KOLs mapping (level of influence – advocacy behavior)
 - Activity review (quantitative and qualitative analysis):
 - KOLs' partnership (calls, preparation of staff meetings, invitation to congresses, support of IIS¹ and / or of the company-sponsored clinical trials, etc.)
 - Participation in congresses
 - Training of speakers, of marketing and sales collaborators
 - Support to Key Institution Managers (KIMs) in charge of regional market access and patient adherence programs
 - Support to Key Account Managers (KAMs) in charge of product listing at hospital (or purchasing platform) levels in highlighting medical benefits
 - Competitive intelligence data gathering and analysis
 - Measurement and assessment of activities' impact
 - MSL Advanced SWOT analysis²
- **Ambition & strategic priorities**
 - Ambition setting
 - Strategic priorities to fulfill the ambition set (MSL Strategy Card)²
 - Key activities to support strategic priorities:
 - Shared activities with other departments (e.g., marketing, sales, KAMs, KIMs)
 - Non-shared activities
 - Monitoring of the quality of execution and impact of activities

The Advanced SWOT is a useful tool to help MSLs analyze and evaluate regional medical opportunities and threats as well as their own competitive position

Integrated Regional Strategic Plan – Specific tools of the Medical Section (1/4)

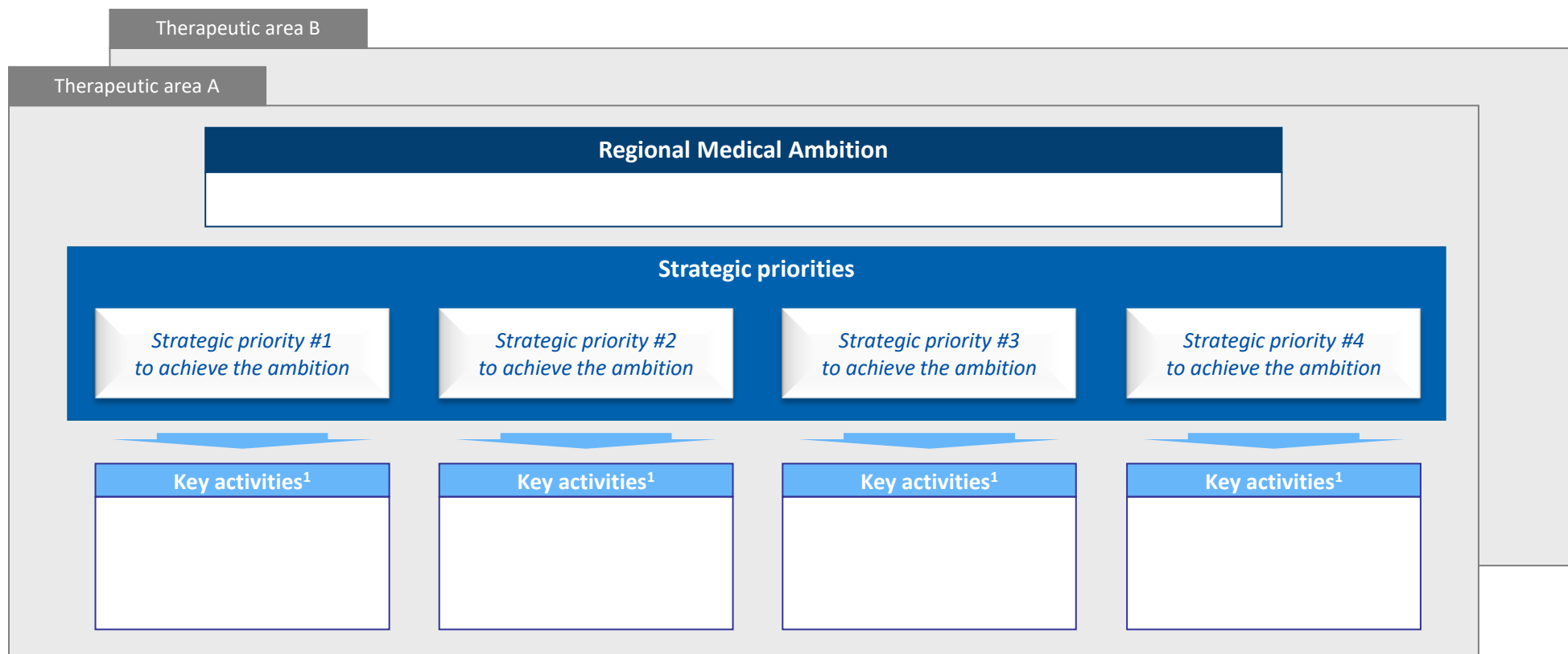
MSL Advanced SWOT

Opportunities	Relative importance ¹	Threats	Relative importance ¹
<p>What regional changes are likely to favor the medical environment?</p> <ol style="list-style-type: none"> National & regional regulations relating to MSLs' activities (e.g., off-label communication, invitation process to congresses, grants, etc.) KOLs' opinion & position re. the company and its products, KOL's level of influence Scientific events: regional congresses, other meetings 		<p>What regional changes are likely to disfavor the medical environment?</p> <ol style="list-style-type: none"> National & regional regulations relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.) KOLs' opinion & position re. the company and its products, KOL's level of influence Scientific events: regional congresses, other meetings 	
Strengths	Relative importance ¹	Weaknesses	Relative importance ¹
<p>What are the absolute or relative advantages of the company's medical activity at regional level vs. competition?</p> <ol style="list-style-type: none"> Relationships with KOLs: quality and sustainability Scientific communications: congresses, staff meetings, symposia, etc. Support to trials: company-sponsored trials and IIS² Training of speakers, med. reps, new MSLs, etc. Competitive intelligence: data gathering and analysis 		<p>What are the absolute or relative disadvantages of the company's medical activity at regional level vs competition?</p> <ol style="list-style-type: none"> Relationships with KOLs: quality and sustainability Scientific communications: congresses, staff meetings, symposia, etc. Support to trials: company-sponsored trials and IIS² Training of speakers, med. reps, new MSLs, etc. Competitive intelligence: data gathering and analysis 	

The MSL Strategy Card will help design a “one-page strategy” including his ambition, the strategic priorities to meet it and the corresponding medical activities

Integrated Regional Strategic Plan – Specific tools of the Medical Section (2/4)

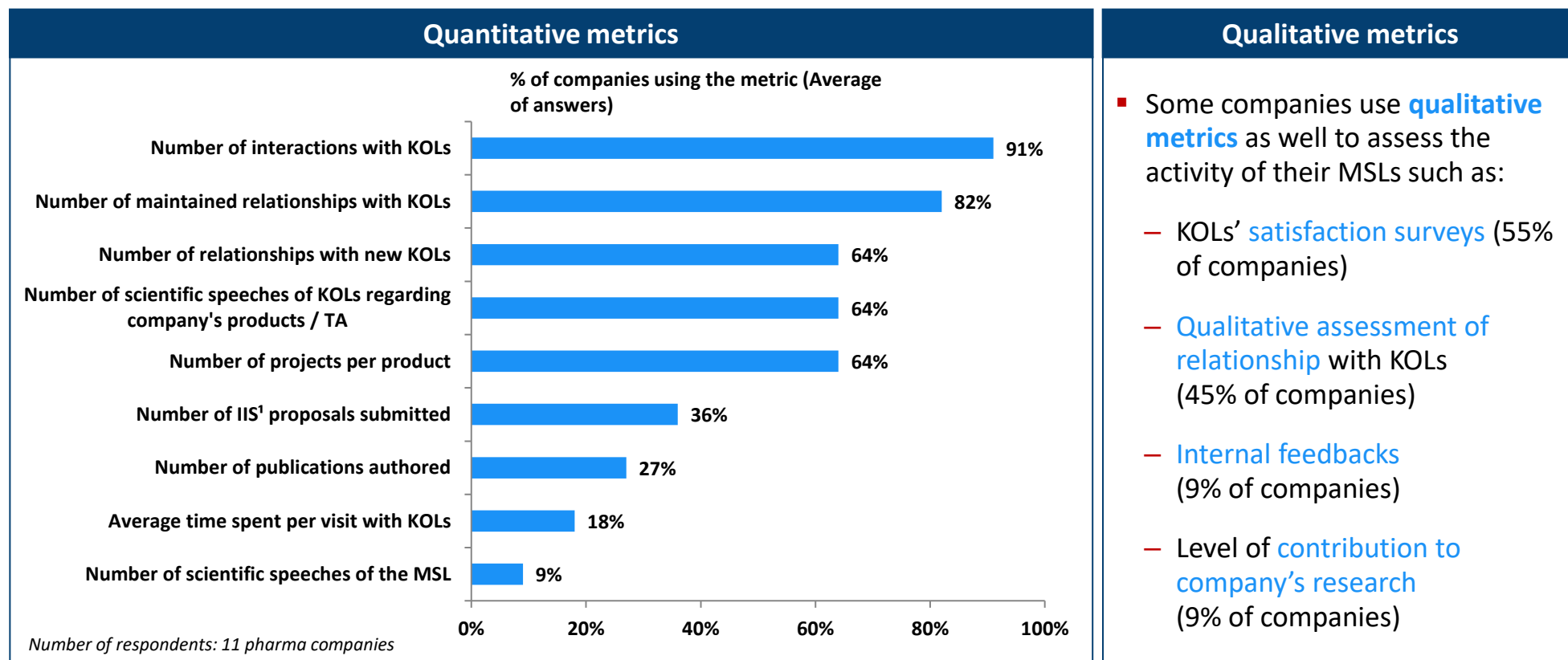
MSL Strategy Card



The assessment of MSLs' activity often includes quantitative criteria based on their relationships with KOLs since they are not allowed to be incentivized on sales

Integrated Regional Strategic Plan – Specific tools of the Medical Section (3/4)

Performance metrics to assess MSLs' activity – Current practice in Europe



Qualifying MSLs' activity is a challenge, however, several qualitative and quantitative metrics can be considered for pharma companies to ensure a proper monitoring

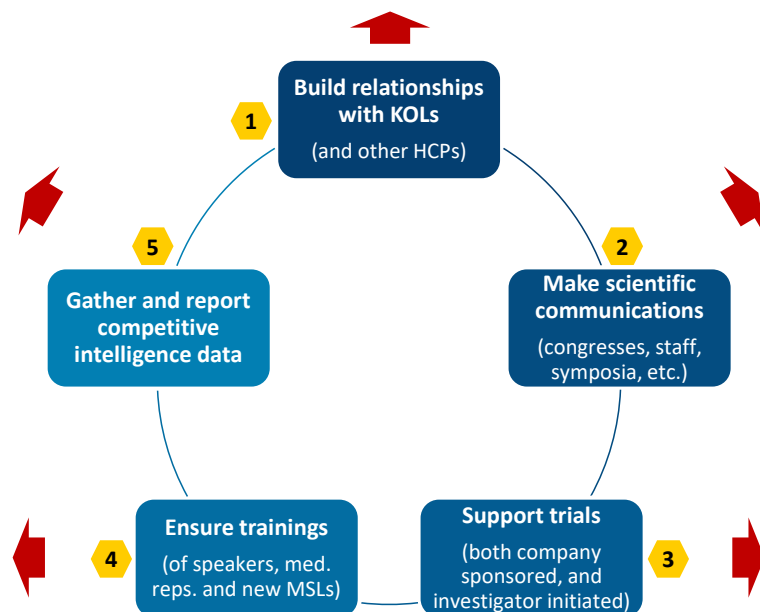
Integrated Regional Strategic Plan – Specific tools of the Medical Section (4/4)

Recommendations of metrics to monitor MSLs' activities

- Number of partnerships initiated with KOLs
- Number of contacts and / or time spent with KOLs in face-to-face meetings, teleconferences, staff meetings, etc.
- Qualitative assessment of KOLs partnership management

- Number of competitive reports
- Number of congresses reviews
- Quality of information gathered

- Number of people trained
- Qualitative feedbacks of trained people



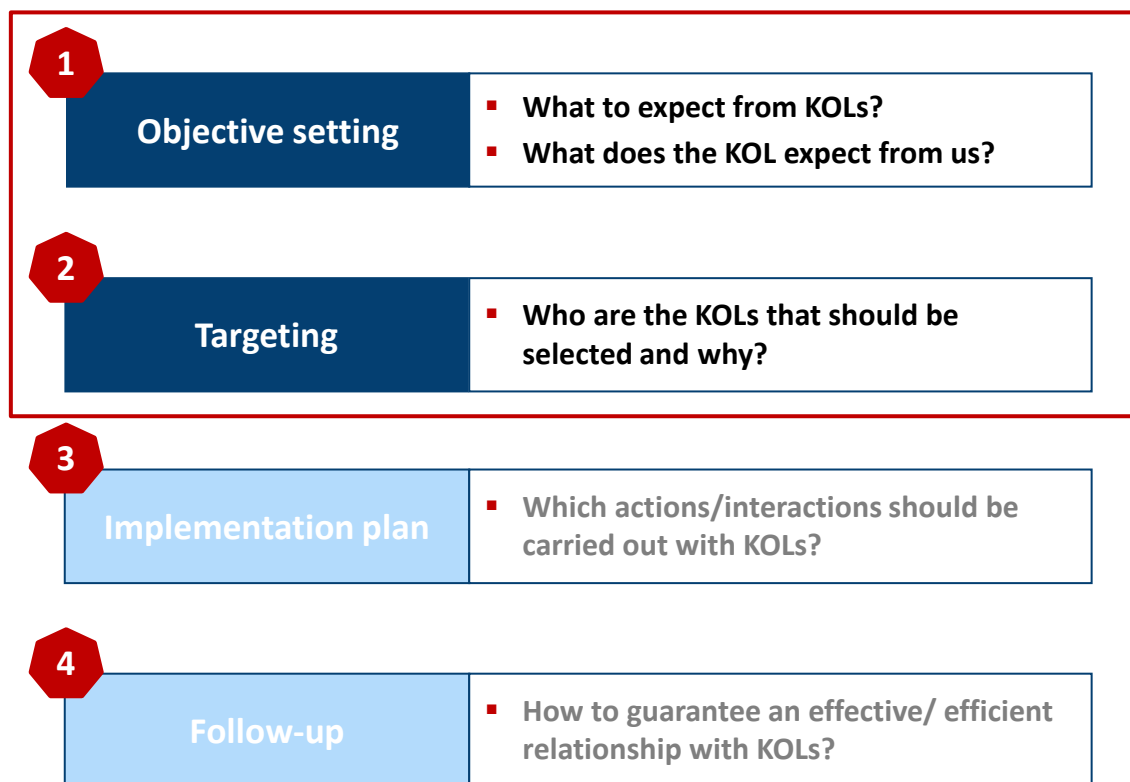
- Number of speeches delivered
- Number of articles authored
- Number of attendees
- Qualitative feedbacks of attendees

- Number of IIS¹ and / or company-sponsored clinical trials submitted / completed
- Number of investigators or patients included in company sponsored-clinical trials

An effective collaboration with KOLs requires to follow a rigorous recruitment process that should be based on the gathering of accurate information

Recruitment & Management process of KOLs

The 4 key steps



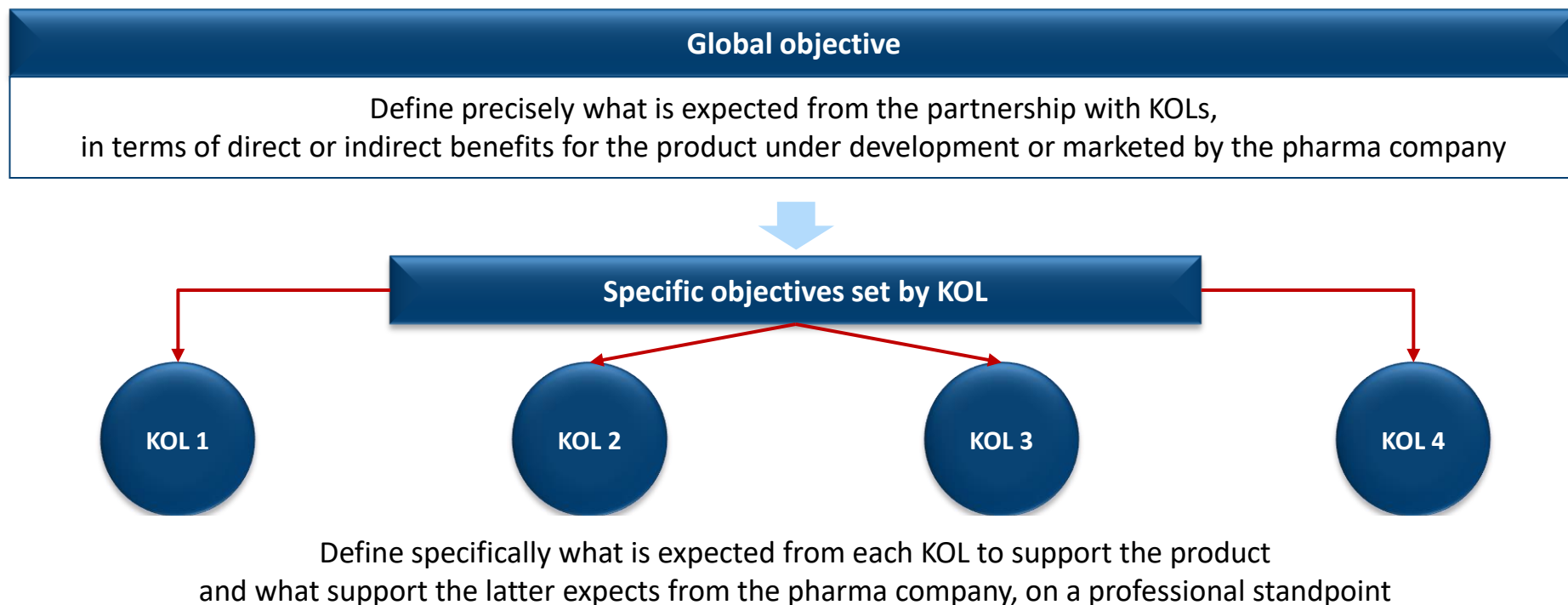
- Relationships with KOLs should be defined according to the set objectives
- Then, the prospective KOLs should be profiled and targeted
- Once KOLs have been selected, their interactions with the pharma company and the activities they are expected to implement should be defined and formalized in an implementation plan
- The implementation of the plan should be carefully monitored with the help of KPIs (Key Performance Indicators) and of KEIs (Key Execution Indicators)

Before defining the activities to be carried out by KOLs, specific objectives, consistent with a global objective, must be set for each of them

Objective setting

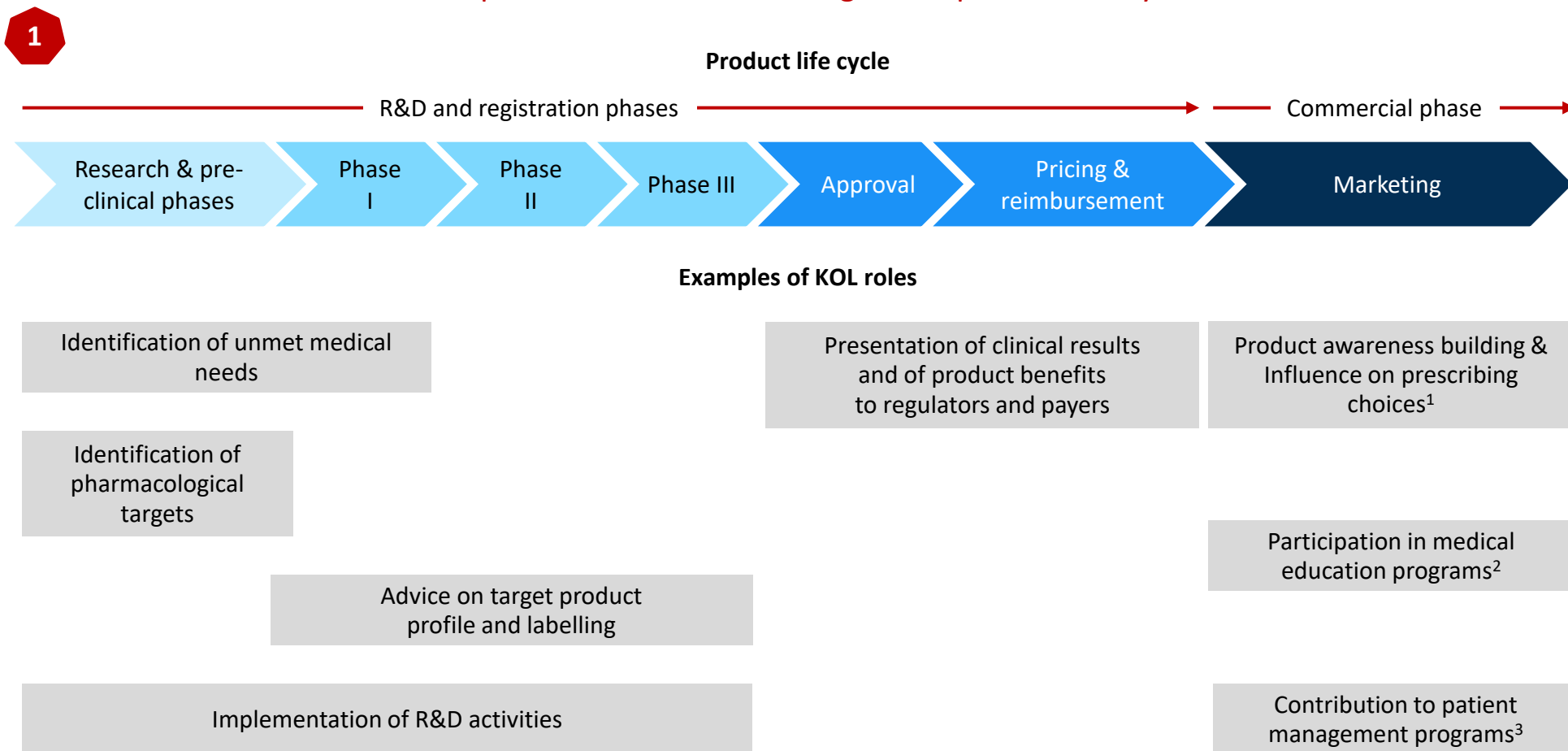
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Partnerships with KOLs should be part of a global strategy, including also market access, medico-marketing and sales initiatives



The objective of the KOL partnership and the corresponding activities will depend on where the product is positioned on its life cycle

Examples of KOL roles according to the product life cycle



The targeting phase should enable to identify the KOLs with whom a partnership should be beneficial and to understand their networks of influence

KOLs targeting – Methodology (1/2)

2

Key questions

What to do?

Selection criteria

- What are the relevant selection criteria to be used considering the final objective?

- Review of relevant criteria (e.g., level of influence, scope of influence, scientific/media awareness, membership of a network, etc.)
- Selection of a limited number of relevant criteria

KOLs profiling

- What information should be collected?
- How to collect and analyze this information?

- Internal / external databases review to qualify KOLs
- Assessment of the number of publications, quotes, lectures during conferences and congresses, etc.

KOLs segmentation

- What is the degree of interest and the likely support of the KOL for the product?

- Mapping of preselected KOLs on a matrix according to the most relevant criteria
- Identification of KOLs' networks

KOLs selection

- Who are the KOLs that should be selected to partner with?
- For which kind of partnership?

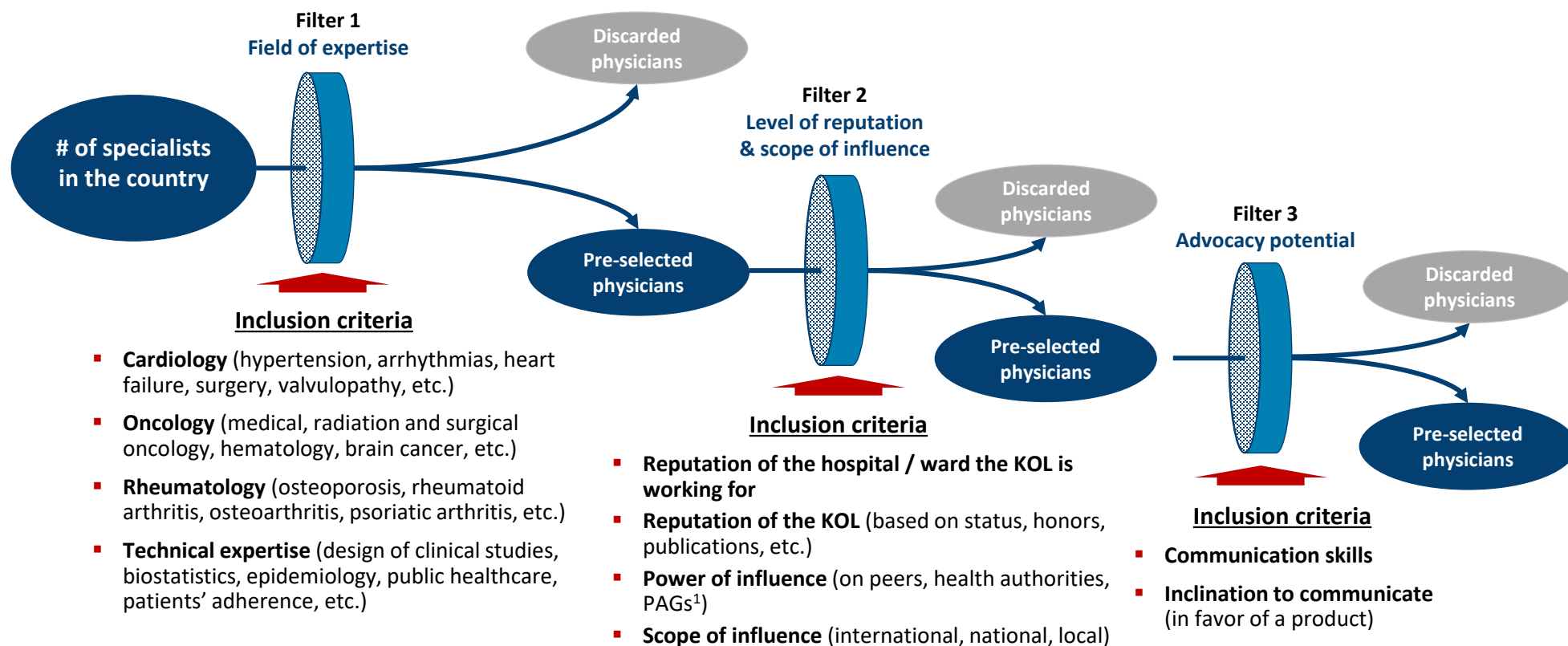
- Selection of KOLs
- Preliminary definition of the type of partnerships to be carried out with the targeted KOLs

Relevant selection criteria and gathering of accurate and reliable information about the KOL profile are of utmost importance to optimize the value of the partnership

KOLs targeting – Methodology (2/2)

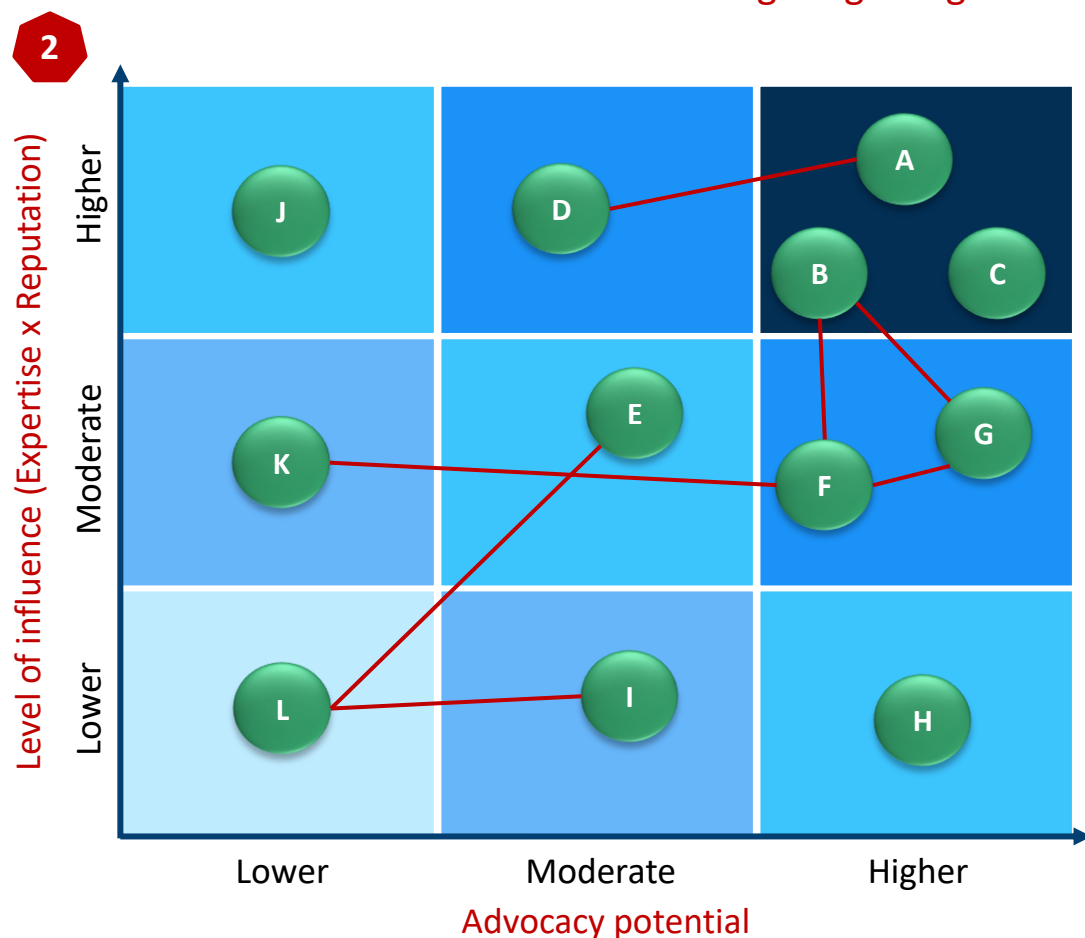
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Screening process (illustrative)



The proposed matrix is a useful tool to prioritize the candidate KOLs to partner with and to pre-define the type of partnerships that could be considered with them

KOL targeting – Segmentation & selection



- The proposed matrix facilitates the **final selection** (targeting) of pre-selected KOLs based on their **level of influence** and their inclination to support the development and/or the use of the pharma company product
- The matrix helps to define the kind of **partnerships** to be set with the KOLs
- The prioritization of the targeted KOLs, should also consider:
 - The **life cycle** of the product
 - The **networks** of influence of the KOLs

Qualification of KOLs should be documented with reliable data collected through desk research and field research (e.g., interviews of peers and of prospective KOLs)

How to qualify KOLs?

2

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> ▪ Status (e.g., head of medical department, professor, age, public vs. private practice, place(s) of practice) 	<ul style="list-style-type: none"> ▪ Internet, direct search 	<ul style="list-style-type: none"> ▪ Being head of hospital and professor is a plus
<ul style="list-style-type: none"> ▪ Field of expertise/interest in a therapeutic area, in a technique, etc. 	<ul style="list-style-type: none"> ▪ Probing by MSL¹, medical reps and other collaborators of the pharma company 	<ul style="list-style-type: none"> ▪ KOLs should express their field of interest over the long term and their expectations from a partnership with the pharma company
<ul style="list-style-type: none"> ▪ Level of reputation & scope of influence 	<ul style="list-style-type: none"> ▪ Field research (e.g., peers, pharmacists' interviews, etc.) 	<ul style="list-style-type: none"> ▪ Internal or national level is preferable in general to local level (but it depends on the objective)
<ul style="list-style-type: none"> ▪ Communication skills 	<ul style="list-style-type: none"> ▪ Analysis of past performances ▪ Interviews of peers 	<ul style="list-style-type: none"> ▪ Verbal communication (e.g., lectures, courses) ▪ Written communication (e.g., articles, websites)
<ul style="list-style-type: none"> ▪ Type & level of communication <ul style="list-style-type: none"> – # articles published (impact factor², peer-/ non peer reviewed journals, position as an author...) – # of trainings p.a. (CME³) – Teaching activity at university – Presence on the Internet – # of lectures (congresses, round tables) – # of quotes by journalists in current year 	<ul style="list-style-type: none"> ▪ Review of scientific articles published (PubMed/Medline, Google scholar, Expertscape) ▪ Probing by collaborators of the pharma company and peers' interviews to evaluate trainings, teaching activities and lectures ▪ Google searching for presence and quotes on the Internet 	<ul style="list-style-type: none"> ▪ The higher the impact factor is, the better ▪ Each KOL should be ideally positioned as 1st or last author in articles ▪ The higher the number of trainings, teaching seminars and lectures, the better ▪ Perceived quality of articles, training, teaching and lectures should be assessed
<ul style="list-style-type: none"> ▪ Membership in learned societies <ul style="list-style-type: none"> – Title / position / activities 	<ul style="list-style-type: none"> ▪ On the website of the learned societies or by calling them 	<ul style="list-style-type: none"> ▪ Being a member of the management board is a plus
<ul style="list-style-type: none"> ▪ Inclination to partner with a pharma company and to support its products 	<ul style="list-style-type: none"> ▪ Probing by collaborators of the pharma company 	<ul style="list-style-type: none"> ▪ They should clearly express their interest in the product and the company... ▪ ... and in the types of partnerships they are looking for

To convince KOLs to partner, it is important to consider their expectations and to highlight the benefits, they will draw from it, in terms of professional development

How to convince KOLs to partner?

2

What do they want?

- Qualify a KOL to **design a partnership that will fulfill his professional expectations** (*simultaneously with that of the pharmaceutical company*):
 - Is the KOL yet a partner of the pharmaceutical company?
 - What has qualitatively and quantitatively his level of involvement been?
 - What has his feed-back from previous collaborations been?
 - What is his mid- to long-term professional ambition?
 - What does he expect from pharmaceutical companies in general, and specifically?
 - Is he looking for a long-term partnership?
 - Is he more inclined to enter a “win-win” partnership or a “fee-for-service” transaction?

What should be proposed?

- Based on the knowledge and understanding of the KOL’s professional expectations...
- ... propose ideas – to be discussed – of activities to be carried out through the partnership
- **Emphasize the benefits the KOL will draw** in terms of **personal awareness** and **competence development** through the partnership:
 - Increasing awareness and fame through publication of articles, interviews in media, presentations during congresses, lectures during medical meetings, etc.
 - Increasing reputation and extending influence by participating to scientific works (e.g., clinical trials)
 - Professional development through the access to recent information, to high education programs¹, by working in new research/medical areas, etc.
 - Funding of Investigator Initiated Studies (IIS)

The KOL ID card is a practical tool which contains in one single page the most important information required to qualify and then recruit pre-selected KOLs

Tool to facilitate the recruitment process: KOL ID card

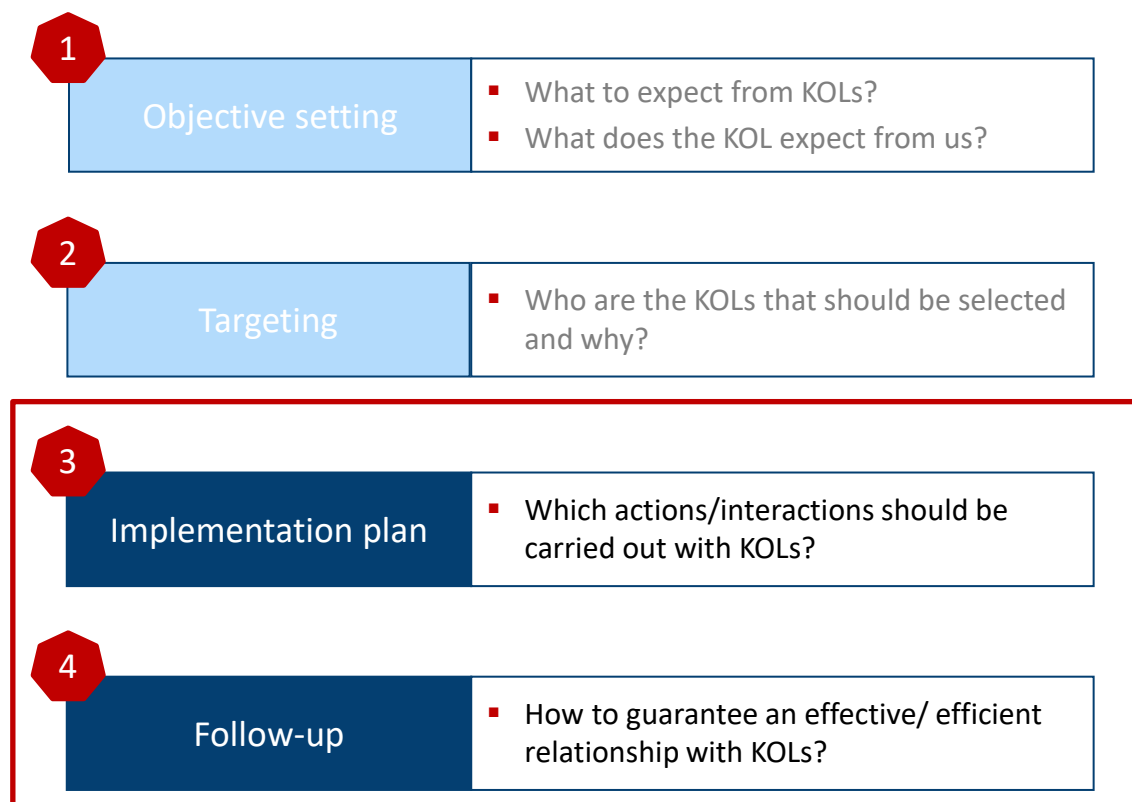
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KOL name	(First name – surname)	Medical status	MD – head of medical department – professor of medicine, etc.	Location	Address & City
Specialty	(Oncology – cardiology, etc.)	Medical setting	Private hospital – public hospital – teaching hospital – private office	Country	
Specific objectives for the pharma company		•			
Specific benefits for the KOL		•			
Items		Assessment¹	Facts / Rationale	Source	
KOL Profile	Field of expertise/interest in the therapeutic area	International - National - Local	•		
	Level of reputation	Low -Medium-High	•		
	Scope of influence	Low -Medium-High	•		
	Advocacy potential	Low -Medium-High	•		
Recommendations		Priority¹	Rationale		
Medical department		Low -Medium-High	•		
Final decision					
Selection: YES - NO		Rationale:			

An effective collaboration with KOLs requires to follow a rigorous recruitment process that should be based on the gathering of accurate information

Recruitment & Management process of KOLs

The 4 key steps



Recruitment

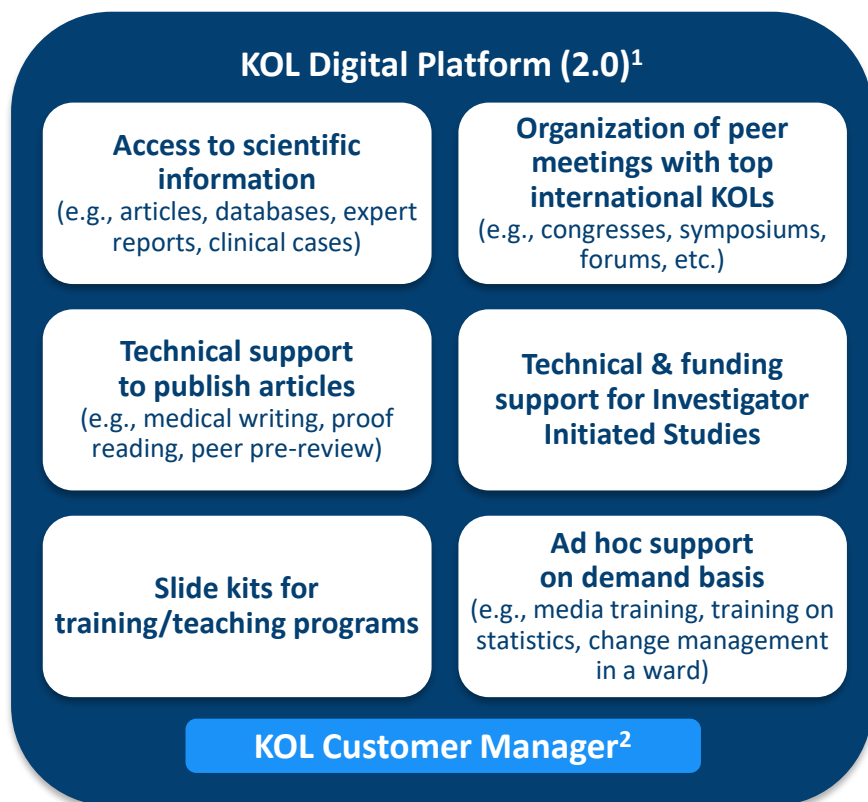
Management

- Relationships with KOLs should be defined according to the set objectives
- Then, the prospective KOLs should be profiled and targeted
- Once KOLs have been selected, their interactions with the pharma company and the activities they are expected to implement should be defined and formalized in an implementation plan
- The implementation of the plan should be carefully monitored with the help of KPIs (Key Performance Indicators) and of KEIs (Key Execution Indicators)

Pharma companies should balance what they expect from KOLs in terms of activities and what they give them in terms of services to ensure a win-win partnership

Services proposed to & activities carried out by KOLs

3

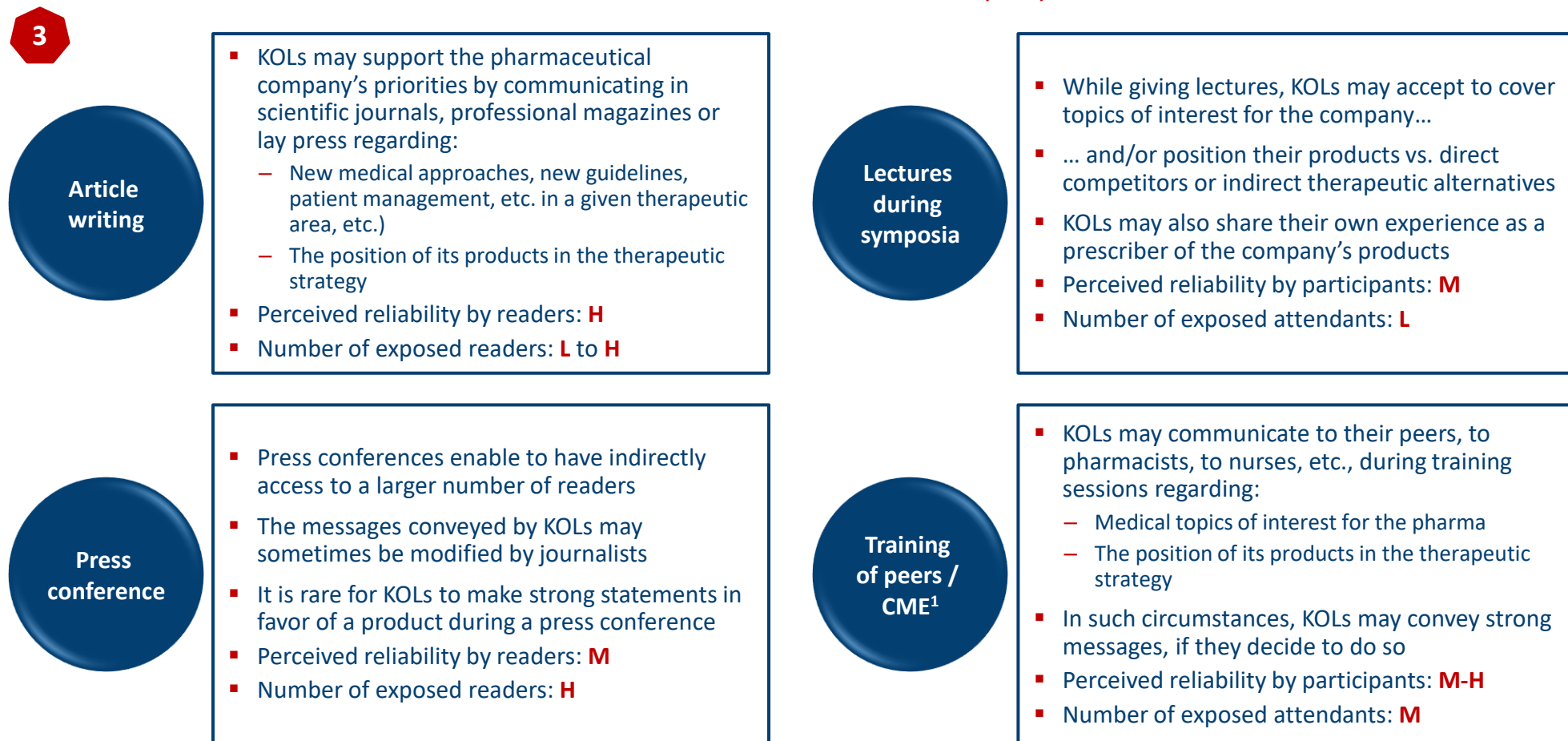


Activities carried out by KOLs (Illustrative)



If KOLs share the objective of the pharma company and accept to communicate, the following means can influence medical practices and help better position products

Potential value of KOL activities (1/2)



H: Higher – **M:** Medium – **L:** Lower

KOLs can be of great value through direct collaboration (by training, informing, giving advice, etc.) with medical, marketing and sales teams of the pharma company

Potential value of KOL activities (2/2)

3

Participation to internal meetings

- KOLs may play an effective role during internal meetings by:
 - Informing / training medico-marketing-sales teams about scientific trends and position of competitors
 - Role playing with sales reps (e.g. selling forums)
 - Being invited as a “guest star” to show collaborators the ability of the pharma company to partner with top medical leaders

Promo material review

- KOLs may collaborate with the marketing team by contributing to the creation of promotional materials
- Thus, they can create value by:
 - Suggesting messages
 - Developing a scientific rationale to support messages/claims of the products
 - Assessing and editing the content of promotional materials (visual aid, booklet...)

Advisory board member

- Advisory board meetings with KOLs should be preferred to individual meetings with KOLs when the objective is to:
 - Generate innovative ideas or concepts (brainstorming sessions)
 - Estimate key market trends (including stakeholders’ opinions and behaviors)
 - Obtain a consensual opinion regarding market environment, products development, marketing strategy, etc.

Participation to scientific studies

- KOLs, especially if they are supposed to sign or co-sign the corresponding publication, may be very helpful to:
 - Participate to the design of the study
 - Carry out the study (either about a given pathology only or a pathology & its treatments involving the pharmaceutical company product)
- Involvement of KOLs in medical/clinical studies will depend on their field of interest

To build a useful and effective “KOL Partnership Plan”, it is recommended to follow the 5-step process proposed here-below

KOL Partnership Plan (K2P) – How?

3



- Step 1: Design of templates that can be shared with the KOLs and the pharmaceutical company’s collaborators (i.e., from market access, medical, marketing departments)
- Step 2: Filling up of the templates by the KOL Customer Manager assigned by the pharmaceutical company to the KOL (e.g., MSL) in coordination with the Medical Director and possibly with the Marketing Director¹
- Step 3: Review and adjustment of the content of the K2P by the MSL with the KOL:
 - Objectives
 - Services proposed by the pharmaceutical company
 - Activities to be carried out by the KOL
 - Fees to be paid at a fair market value (if any)
 - Monitoring process of each service/activity
- Step 4: Follow up of the K2P:
 - Prepare the planned services/activities
 - Analyze the quality of execution of these services/activities
 - Reconsider – if not relevant anymore – planned services/activities
- Step 5: Assessment of the partnership:
 - Twice a year by the KOL Customer Manager and the KOL to measure the level of mutual satisfaction and decide about potential adjustments to be carried out
 - Once a year by a committee including: the Medical Director, the Marketing Director, the KOL Customer Manager, and possibly the General Manager, to evaluate the KOL partnership and decide about potential adjustments

The “KOL Partnership Plan” should include key information extracted from the KOL ID card¹, specify the objectives of the partnership, its scope and duration

KOL Partnership Plan (K2P) – Model: Introduction

3

KOL name	(First name – surname)	Medical status	MD – head of medical department – professor of medicine, etc.	Medical setting	Private clinic – private hospital – public hospital – teaching hospital
Interest/ Expertise	(e.g., Pulmonology, cardiology, etc.)	Reputation/ Influence	Private hospital – public hospital – teaching hospital – private office	Advocacy potential	Address & City & Country
KOL Customer Manager	(First name – surname – position in the company)	Role	(Describe briefly his role vis-a-vis the KOL)	Coordination with...	(Indicates the other collaborators whom to coordinate)
Objectives of the partnership	•				
Specific scope of the partnership²	•	•	•	•	
Duration of the partnership	Starting date			Ending date	
	•			•	

The “KOL Partnership Plan” should also describe the services proposed to the KOL and the activities the latter will carry out, as well as monitoring indicators

KOL Partnership Plan (K2P) – Model: Service/Activity Card¹

3 4

Service or Activity #1		Pharma company objective	KOL objective	Key step description	Timing

Quality of execution Indicators		Expected impact Indicators		Comments
Expected	Achieved	Expected	Achieved	

Key execution and performance indicators are essential to optimize the chance of a proper execution of services/activities and of a win-win partnership

Examples of tool to monitor partnerships with KOLs

4

Pharma company's services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Access to scientific information Organization of peer meetings with top international KOLs Technical support to publish articles Technical & funding support to IIS¹ Slide kits for training/teaching programs Ad hoc support on demand basis 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) Practicality (10-point scale) Implementation² (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of KOLs (10-point scale) Inclination of KOLs to support the pharma company products: <ul style="list-style-type: none"> Number of lectures / trainings / publications Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc. Increased level of KOLs awareness and reputation Increased level of products awareness and reputation
KOLs' activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Lecture during symposia Training of peers 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) Practicality (10-point scale) Implementation² (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of attendees (10-point scale) Inclination of attendees to support & prescribe the product: <ul style="list-style-type: none"> Number of lectures / trainings / publications Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.
<ul style="list-style-type: none"> Article writing Press conference 	<ul style="list-style-type: none"> Acceptance by recognized journals (scientific, medical, or in lay press, etc.) Post on highly regarded websites Number of journalists and quality of articles 	<ul style="list-style-type: none"> Impact factor (for scientific/medical journals) Number of broadcasted issues for lay press Number of views / likes on Internet Contribution of content to support the product
<ul style="list-style-type: none"> Participation in scientific studies 	<ul style="list-style-type: none"> Implementation (number of patients recruited, timing, cost vs. plan) 	<ul style="list-style-type: none"> Publication of an article in a renowned scientific journal Impact of the publication on product reputation

9 Recommendations *to Boost MSLs' Competence & Performance*

1. Clarify MSLs' roles and responsibilities to avoid confusion with medical representatives
2. Maintain a high scientific knowledge and understanding to guarantee high quality interactions and relationships with KOLs
4. MSLs' activities should be consistent with their ambition and their strategic priorities, as defined both at national and regional levels
5. Develop an Integrated Regional Strategic Plan¹ including a Medical section formalizing MSLs' ambition, strategic priorities and key activities, in line with marketing, sales, market access and adherence departments priorities
6. Define quantitative and qualitative metrics to monitor MSLs' activities and identify potential corrective measures to be introduced
7. Optimize MSLs' limited time by prioritizing their efforts and using new communication technologies, whenever relevant
8. Apply the KOL Partnership Model as follows:
 - a. Define clear and precise objectives for each of them
 - b. Build the relationship based on an exchange of services rather than a fee-for-service deal
 - c. Ensure an open and transparent relationship
 - d. Make sure that the services provided to the KOL contribute to fulfill his needs and expectations
 - e. Don't ask KOLs to promote your products, which would affect his reputation and your company's one
 - f. Make the best use of the KOL limited time by organizing useful exchanges
 - g. Assign a KOL Customer Manager (e.g., an MSL) who will be the KOL-preferred contact point and who will ensure alignment and information sharing between all collaborators of your company in contact with him
9. Define internal guidelines and a control process to prevent any compliance issues that could damage the corporate reputation

Smart Pharma Consulting Services – Optimizing the MSLs' performance (Case study)

Problem to be addressed

- The pharma company *MediSearch* has a team of **6 MSLs** specialized in **oncology**
- The Medical Affairs Director of the French subsidiary questions how MSLs could help improve *MediSearch's reputation* and the **perception** of its **products** by **oncologists**

Proposed approach

1. **Kick-off meeting:**
 - Agreement on the **conditions** for **carrying out** the **mission** (adjustment of the approach, definition of the roles & responsibilities of each member of the project group)
 - Precise definition of the **deliverables**
2. **Interviews with 20 KOLs in oncology:**
 - Analysis of the **determinants** of **pharma companies' reputation** and of their **products' image** in oncology
 - Identification of **pharma companies** whose **MSLs** are considered by oncologists as the **"best-in-class"**
3. **Reflection workshop:**
 - Presentation & analysis of the **results of the interviews** conducted with the 20 KOLs
 - Definition of **"best practices"** enabling MSLs to **strengthen MediSearch's corporate reputation** as well as the **image** of its products
4. **Formalization of recommendations:**
 - **Drafting** of a **guide** of **"best practices"** (e.g., management of interactions with KOLs, activity planning, priority management, development of a culture of services, etc.)
 - Proposal for a **strategic and operational plans model** for MSLs, including **quantitative** and **qualitative indicators** for **monitoring** their **activities**
 - Setting up of a **training program** for MSLs



Strategic KOL Engagement Planning

BEST-IN-CLASS SERIES

How to improve
Efficacy & Efficiency?

This position paper proposes guidelines to help pharmaceutical companies partner with KOLs to better support the development and the marketing of their products

Context & Objective

- **KOLs¹ are part of the means used by pharma companies to:**
 - Develop their products through pre-clinical and clinical trials
 - Disseminate information (scientific, medical, therapeutic, etc.) to raise health authorities, payers, HCPs (Health Care Professionals), PAGs (Patient Advocacy Groups), individual patients' awareness to optimize the positioning and the usage of their products
- **This position paper:**
 - Reviews the best practices in terms of KOL engagement
 - Proposes a simple but rigorous approach and...
 - ... a set of practical tools...

... to recruit, engage and manage KOLs

This position paper has been written, assuming that it is not illegal nor reprehensible to collaborate with medical thought leaders to influence other stakeholders' opinion and behavior vis-à-vis a medical practice or a given medicine, provided it is in the best interest of patients

KOLs have the potential to influence their peers, but also other stakeholders in a specific area, at global, international, national and local levels

Working definitions (1/2)

KOL (Key Opinion Leader)

- KOLs are also called: Key Experts, Key Therapeutic Area Experts, Key Scientific Experts, Thought Leaders, Influencers, depending on the companies
- KOLs are **recognized** physicians with an **expertise in a specific field** (e.g., oncology, endocrinology, epidemiology, biostatistics, etc.)...
- ... and can **influence the opinion** and **the medical practice** (e.g., treatment scheme, prescribing habits, preference for a given product, etc.) **of their peers** (specialists or GPs)
- KOLs contribute also to **modify medical guidelines** when they are members of learned societies or when they advise health authorities
- Their influence can be global, international, national or local
- Other stakeholders are also considered as KOLs¹

Pyramid of influence & types of influencers



Strategic KOL Engagement Planning is essential for pharma companies to ensure an effective, efficient and sustainable relationship with KOLs

Working definitions (2/2)

KOL Engagement

- KOL engagement is a **process** in which pharma companies **build** and **maintain constructive** and **sustainable relationships** with KOLs
- KOL engagement is **essential** for **understanding** their **wants** and **needs**; and **may** result in implementing ideas that **benefit** both **KOLs** and **pharma companies**
- Engaging with KOLs **occurs** when pharma companies want to **consider** the **views** and **involvement** of **KOLs** in making and implementing a scientific or medical decision...
- ... **which might** have an indirect **business impact**
- Pharma companies should **initiate open, two-way dialogue, seeking solutions** to issues of mutual interest

Strategic KOL Engagement Planning

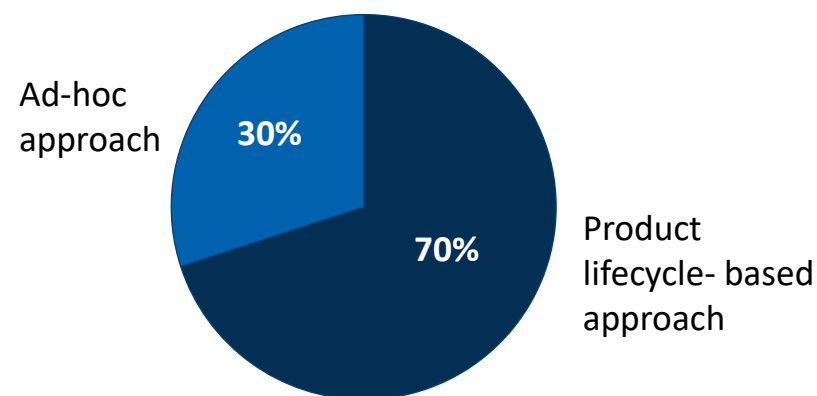
- Considering the **increasing complexity** of the pharmaceutical **environment** and of **pharma companies** organizations¹, it is essential to **plan** and **organize** the **interactions with KOLs**
- Thus, pharma companies should develop Strategic KOL Engagement **Plans** to **ensure** that KOL Engagement **initiatives**:
 - **Support** the Critical Success Factors (**CSF**) to fulfill the corresponding Strategic Imperatives (**SI**) of the related product
 - Are put in a **mid- to long-term perspective** to **build** a **sustainable** win-win **relationship**
 - Are carried out in a **coordinated manner** across the company departments and from headquarter to affiliates to **guarantee** an **optimal efficiency**

More and more pharma companies are adopting an integrated strategic approach of their relationship with KOLs, based on their product position on their life cycle

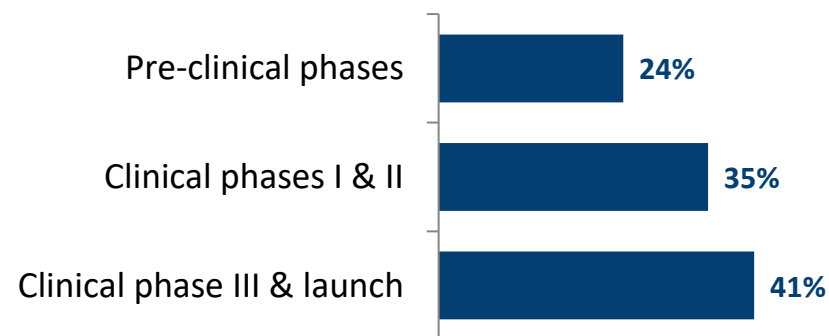
Types of KOL engagement

- According to a study carried out in 2017 by Arx Research, through interviews of 47 executives from medical departments of 34 life science organizations, across 15 countries:
 - 70% of companies indicate that their strategy to engage with KOLs is **based** on the **position** of the product on its **life cycle**, while the remaining 30% adopt an ad-hoc approach
 - 24% of surveyed companies engage with KOLs during pre-clinical phases of the product development and...
 - ... **41%** begin developing **relationships** at **phase III** of their product life cycle, **or after**
- KOLs **exposed** to **early** research and development phases will **better support** the products due to:
 - A better **understanding** of the underlying **science**
 - A better **commitment** and interest in **outcomes**

KOL engagement approach



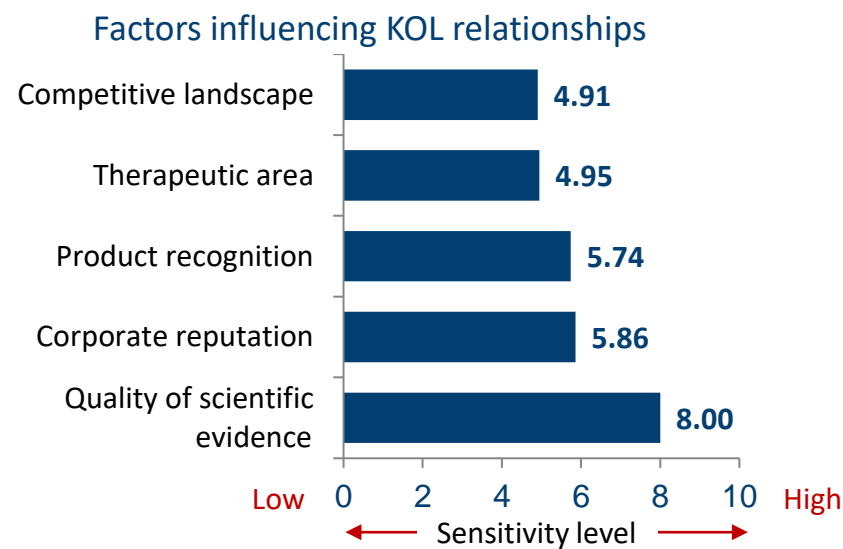
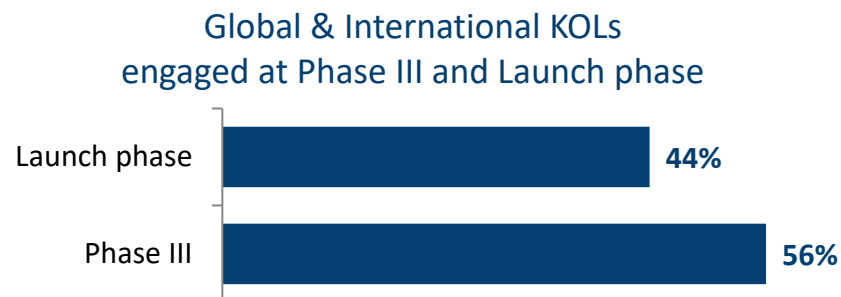
KOL engagement according to product lifecycle



The strength of KOL engagement will strongly depend on the quality of scientific evidence related to the product as well as on corporate and product perception

KOLs engagement & Influencing factors

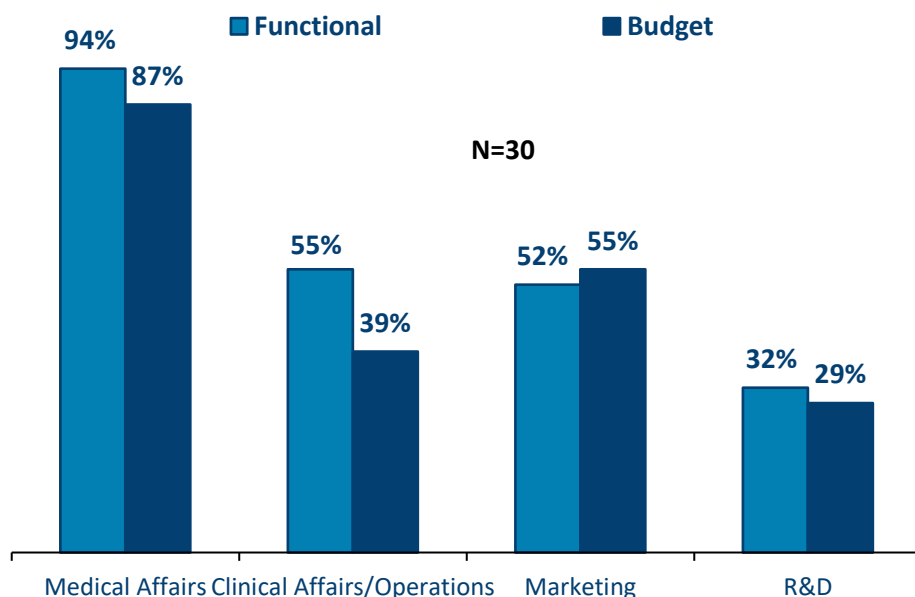
- From preclinical to phase II studies, Global KOLs are engaged to carry out scientific and clinical activities
- At phase III level, Global, International and National KOLs are mainly involved in clinical studies and in disseminating scientific information to physicians' communities
- While preparing the launch of their products or of new indications, pharma companies may engage KOL to support the preparation of the marketing authorization and of the price & reimbursement dossiers
- At launch time, pharma companies usually shift the balance of their focus to national and local KOLs
- The quality of the scientific evidence is critical to establish strong and effective relationships with KOLs
- Corporate reputation and product recognition are also essential to expect a clear commitment from KOLs



The hybrid and centralized management of KOLs are viewed as optimal by interviewees as they enable better coordinated and more consistent interactions

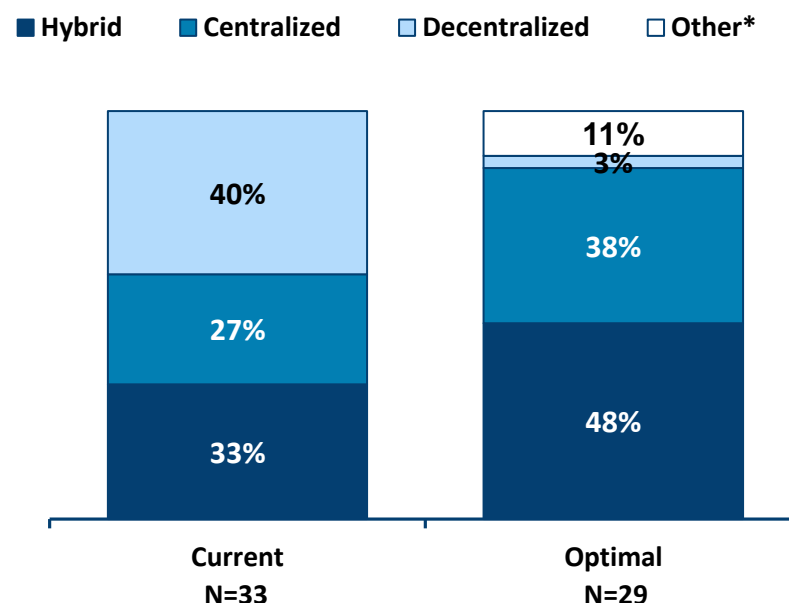
KOLs management by pharma companies

KOL Management responsibility at pharma companies



- Functional and budget responsibility for KOL management are mainly in the hands of **Medical Affairs** departments

KOL Management organization at pharma companies

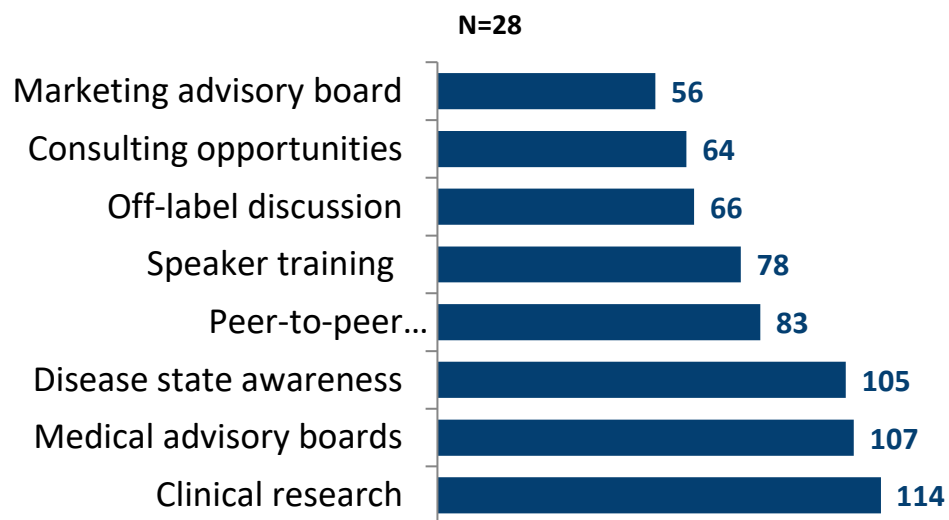


- Decentralized** organizations are **used by 40%** of companies but **recommended by only 3%** of them due to **lack of coordination and consistency**

If KOLs services are mainly focused on clinical research, clinical advisory boards and disease state awareness exchanges; their impact is most often not formally evaluated

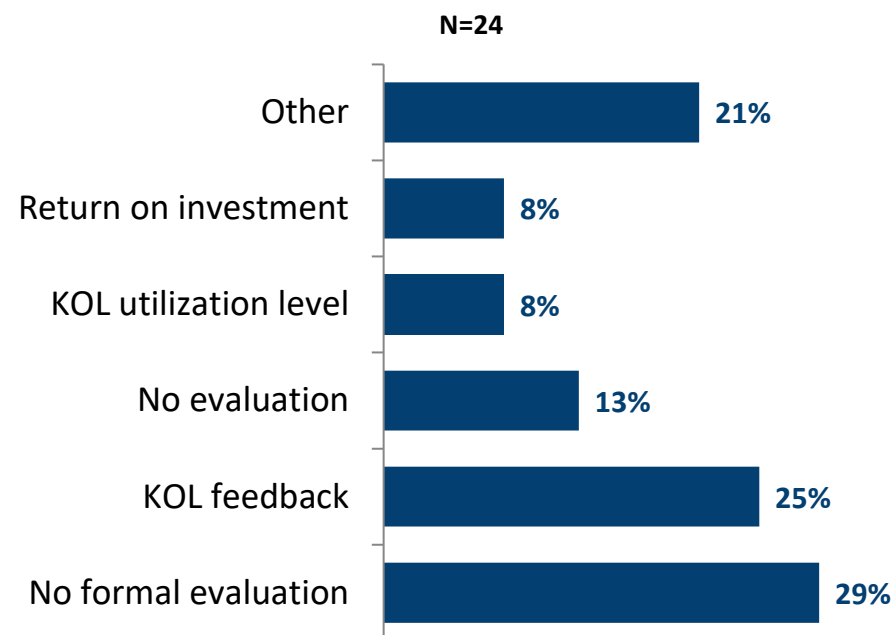
Main KOLs services & assessment

Most important services carried out by KOLs



Note: Score based on the average importance rating (0 to 5) multiplied by the number of respondents per activity

Evaluation of KOL Management & Engagement



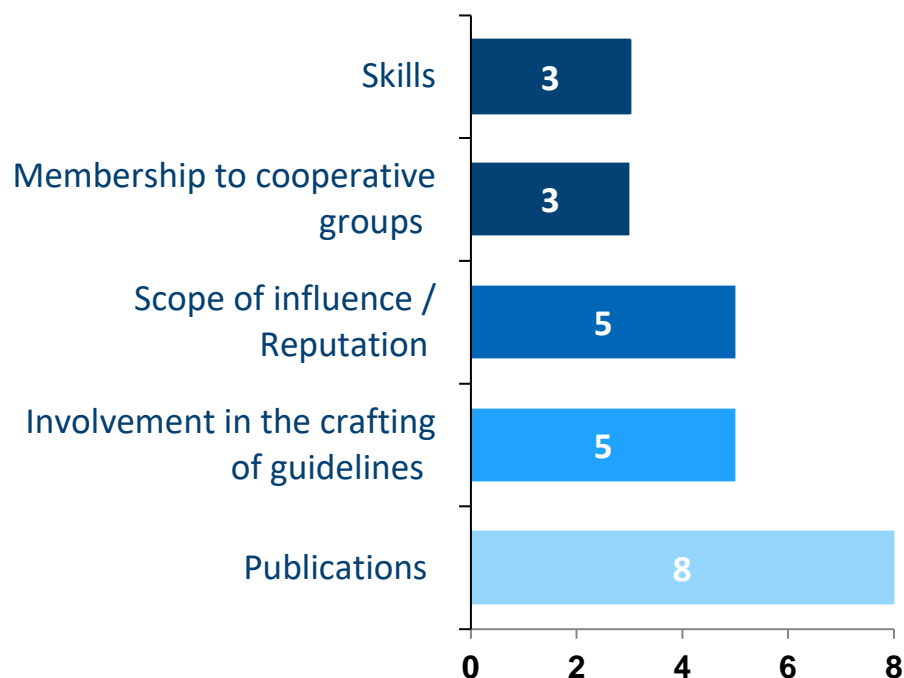
- Clinical research support, participation to medical advisory boards and disease state awareness are viewed as the most important KOLs activities

- There is no formal nor systematic measurement of the impact of KOLs engagement carried out by most of the pharma companies from the panel

Few of the 8 benchmarked pharma companies have put in place a systematic and formalized process to qualify and select Global KOLs

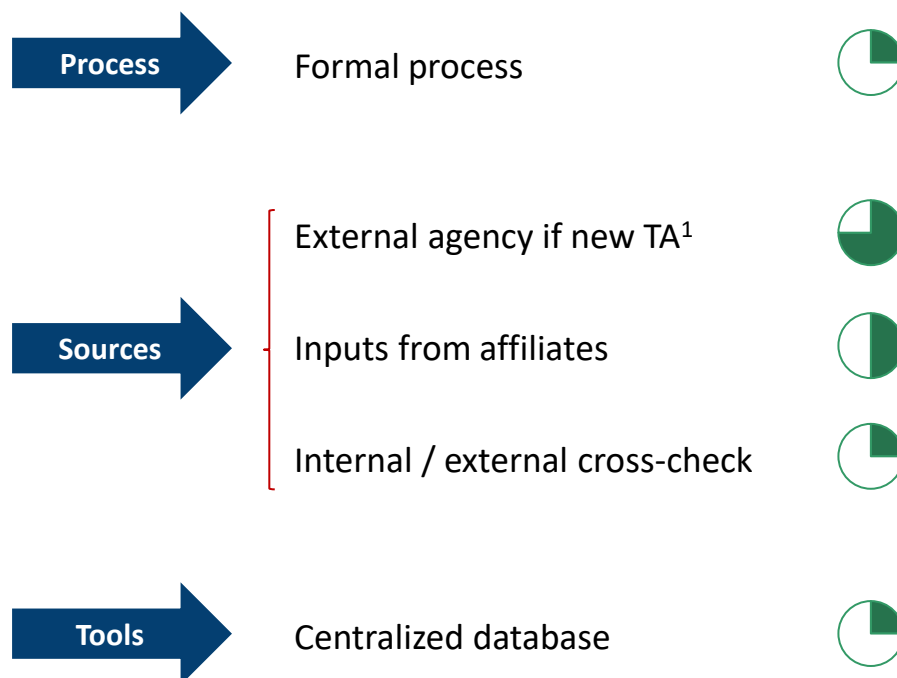
Global KOLs qualification & selection

Main criteria to select Global KOLs



Note: Behavior & personality has been mentioned by one interviewee, as well as KOLs field of interest

Data gathering

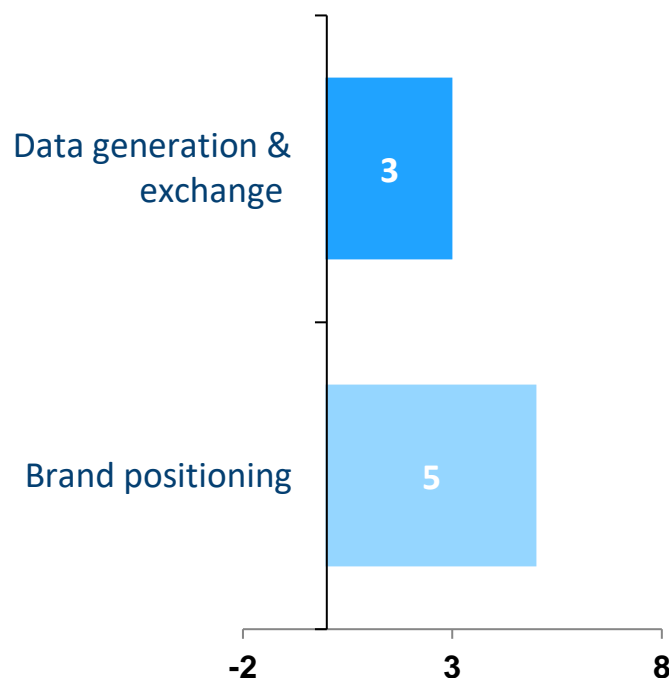


"In case of doubts, Global Medical Affairs may contact local Medical Affairs to get their own opinion regarding a Global KOL"

According to the spontaneous statements of interviewees, Global KOLs are mainly engaged to give advice on brand positioning, produce and exchange scientific data

Main objectives while engaging with Global KOLs

Main objectives¹



“While engaging with a KOL, we make sure he is interested by the project on which we want to involve him”

Objective setting

No formal approach, based on specific KOL expertise and company needs



Objective alignment on product Strategic Imperatives & Critical Success Factors

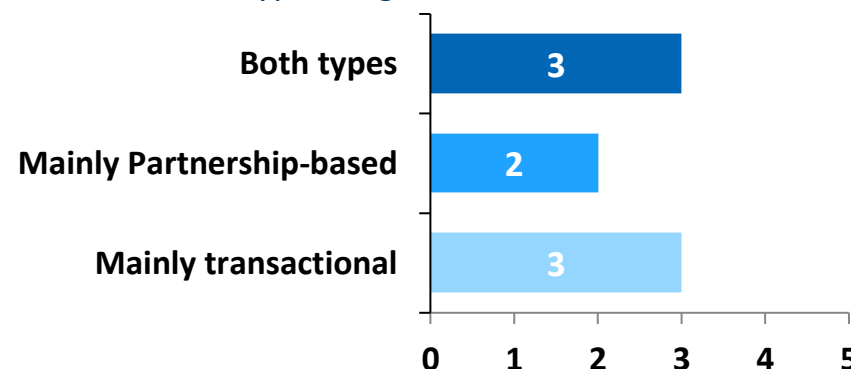
No formal alignment / no global vision



Alignment on Global Strategic Brand Plan / R&D Plan / Global Medical Affairs Plan



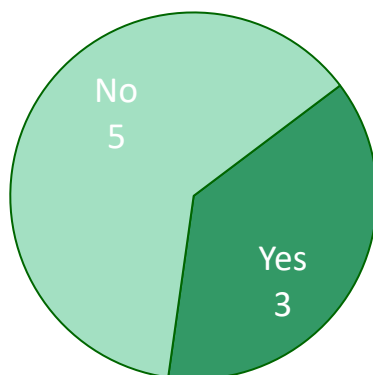
Type of agreements



Global KOL engagement plans are most often not formalized for each KOL and their follow-up over time is far from being systematic

Global KOL engagement planning & execution follow-up

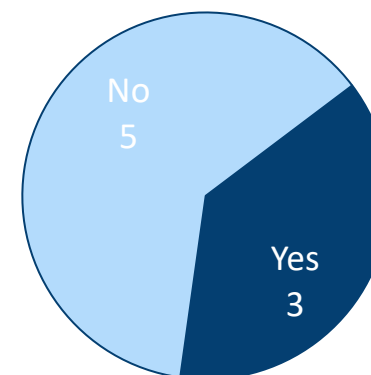
Global KOL engagement plans



"We prepare an engagement plan but by project rather than by KOL. We engage a KOL to carry out a project"

Execution quality follow-up

System to monitor the implementation of Global KOL engagements



"In Europe, it is difficult to evaluate the performance of KOLs. It should be fact-based and not a judgement"

Main difficulties while engaging with Global KOLs

Poor internal alignment and multiple contact points

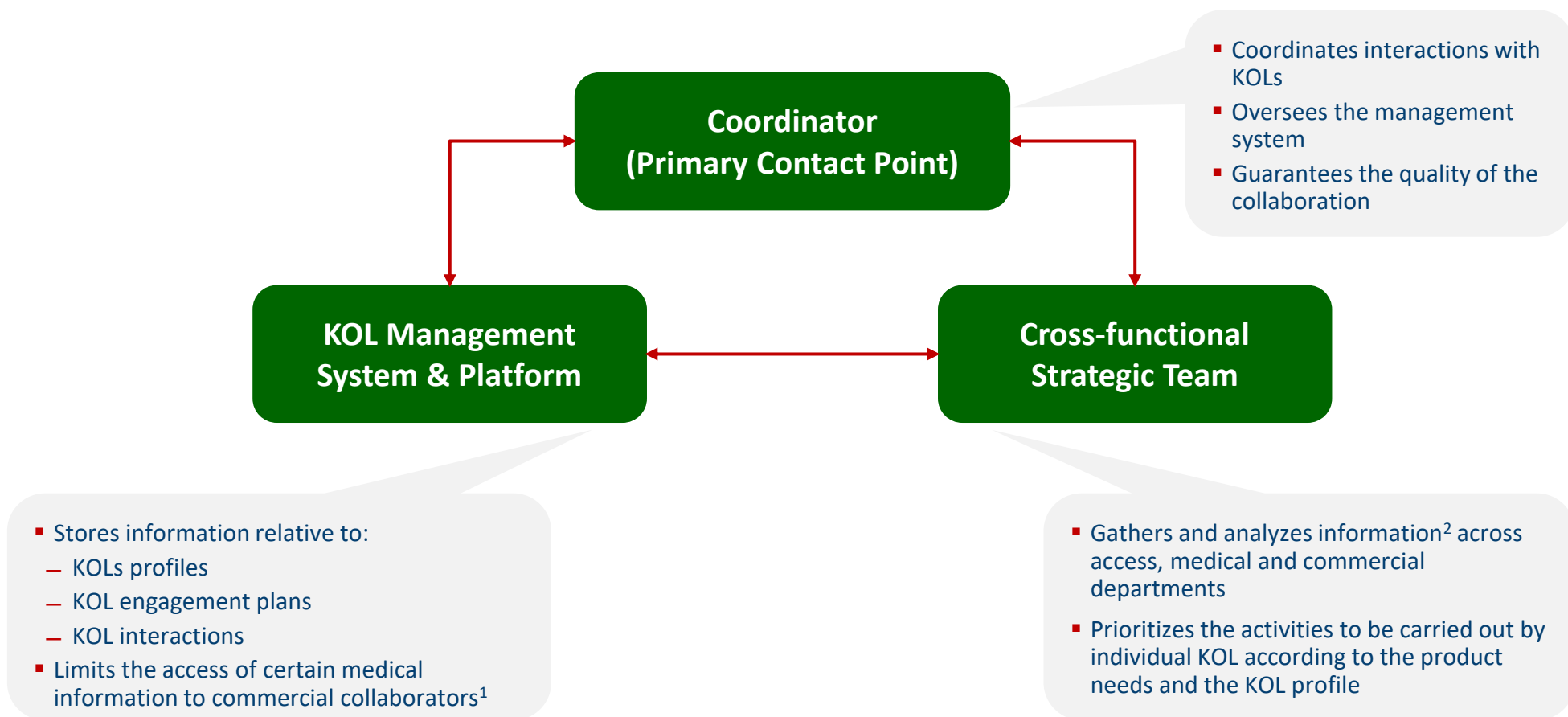


Overbooked and overused KOLs



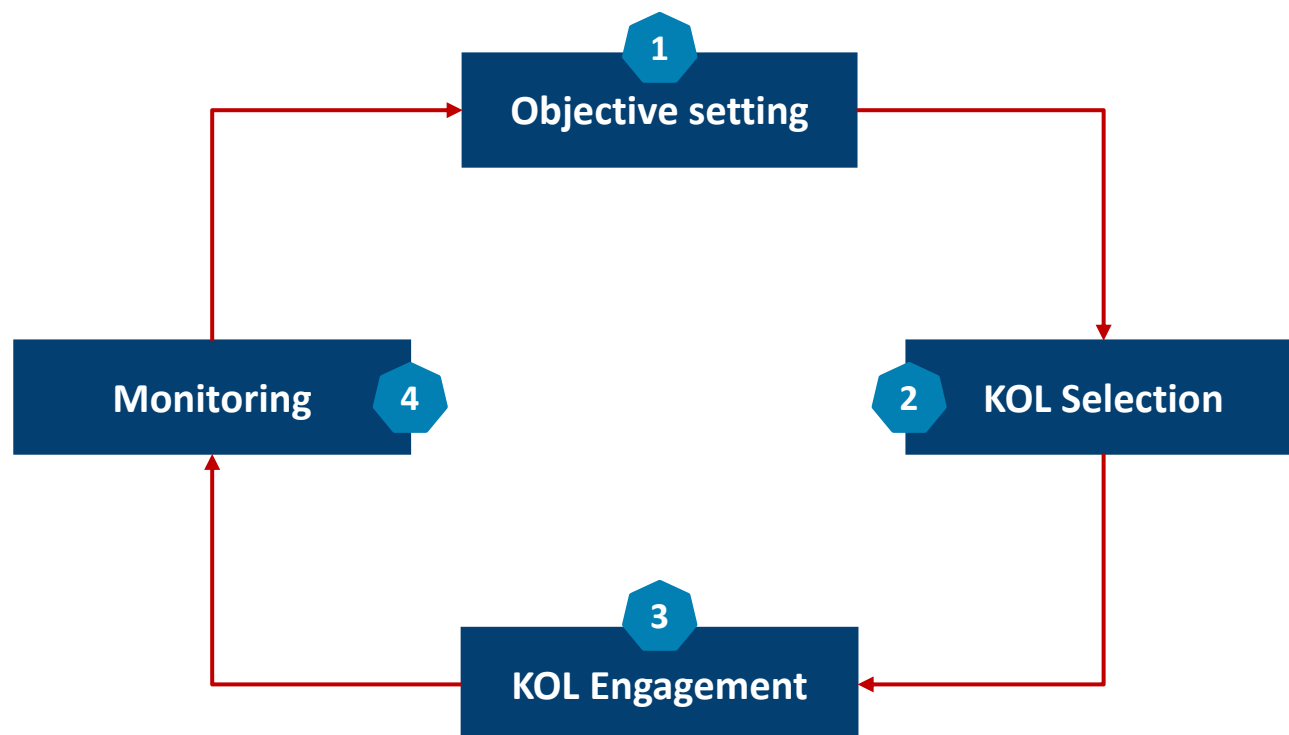
The effective KOL management requires a cross-functional team working in the same direction, in a coordinated manner, with the help of a shared information system

Strategic KOL Management components



The following 4-step approach is proposed to ensure
an effective and efficient Strategic KOL Engagement Planning

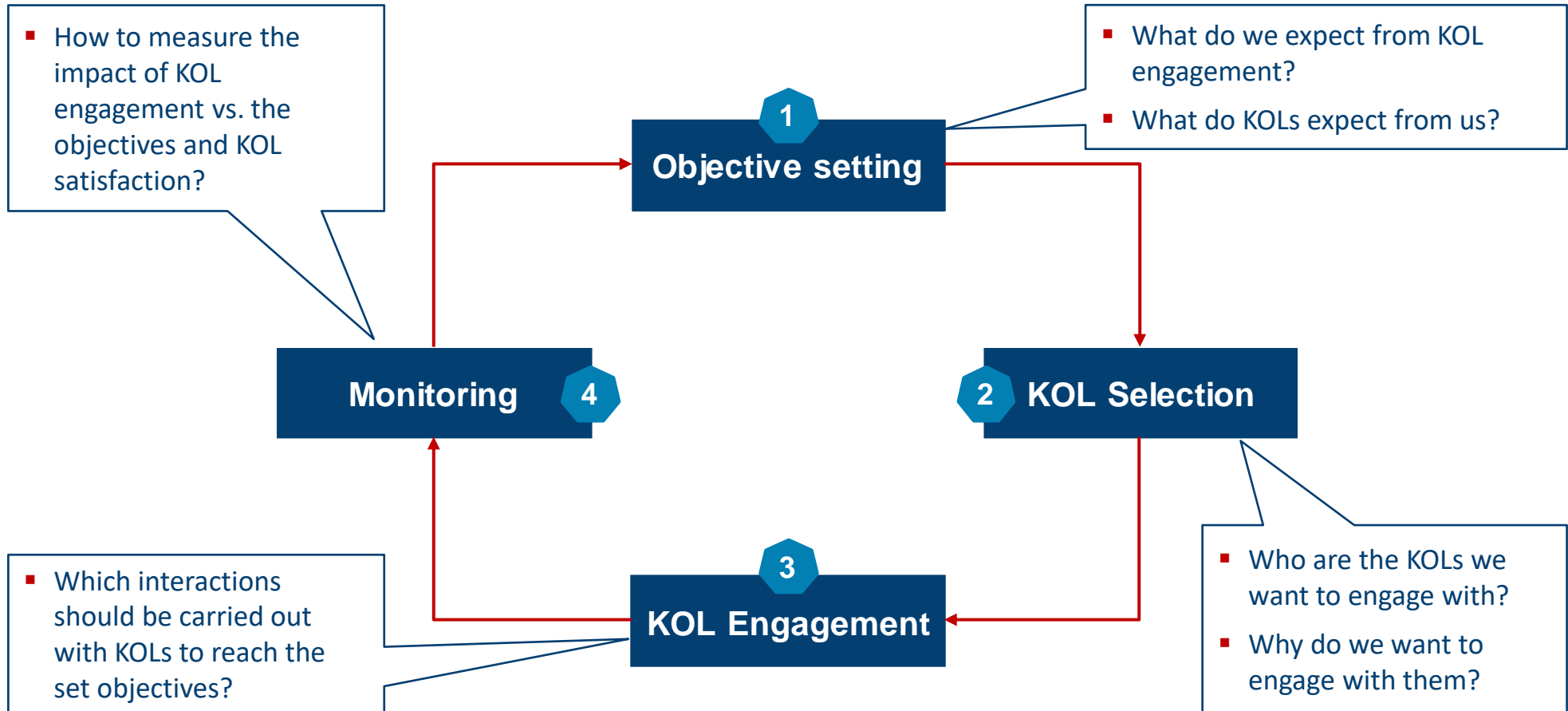
A 4-step approach



- Relationships with KOLs should be defined according to the **set objectives**
- Then, the prospective KOLs should be profiled and targeted
- Once KOLs have been selected, their **interactions** with the pharma company and the **activities** they are expected to carry out should be **defined** and **formalized** in an **engagement plan**
- The **execution** of the plan should be carefully **monitored** with the help of **KPIs** (Key Performance Indicators) and of **KEIs** (Key Execution Indicators)

At each step, the following key questions should be carefully answered to ensure the proper implementation of the proposed Strategic KOL Engagement Planning process

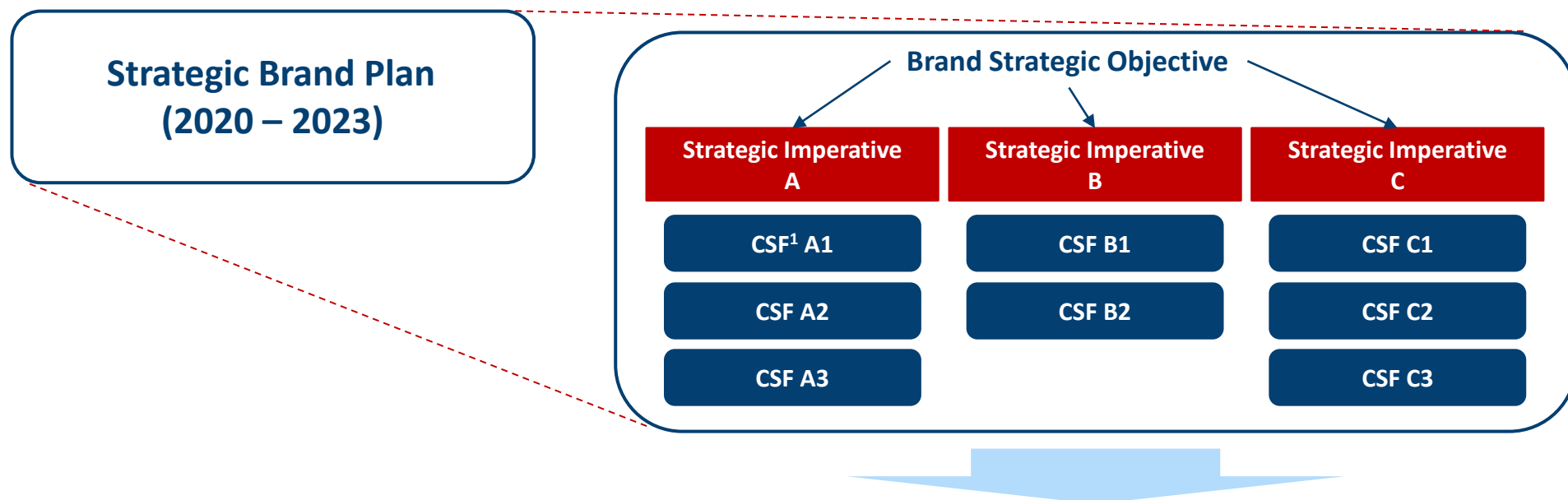
Key questions to be answered by key step



The global objectives set for KOL engagements should contribute – directly or indirectly – to meet the brand strategic objectives, irrespective of its life cycle position

Strategic alignment

1

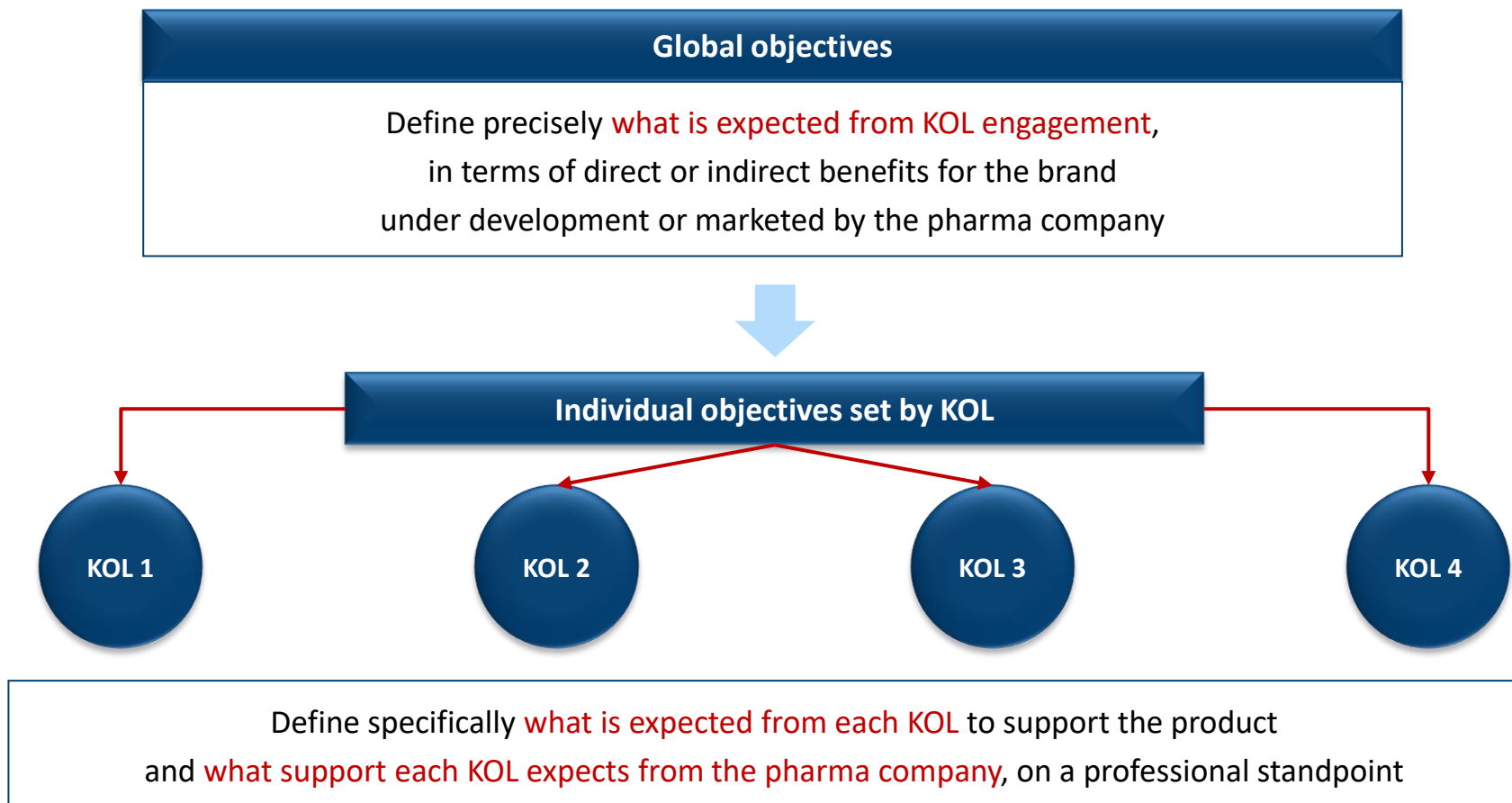


The global objective of KOL engagements must support one or several CSFs and thus, contribute to fulfill the strategic imperatives to reach the Brand Strategic Objective

Before defining the KOL Engagement Plan, specific objectives by KOL, consistent with the Brand Strategic Objective, must be set

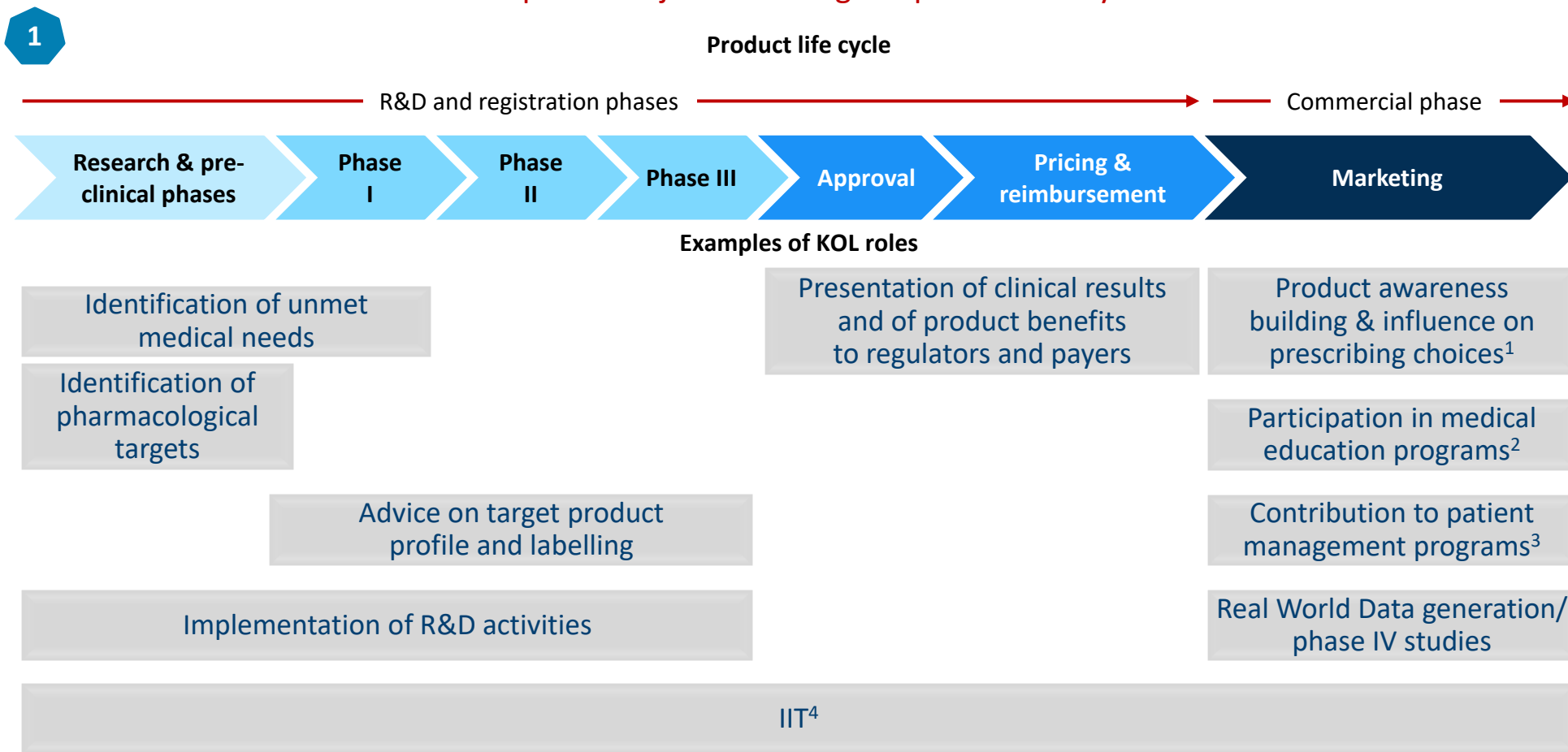
Global vs. individual objective setting

1



The objective of the KOL partnership and the corresponding activities will depend on where the product is positioned on its life cycle

Examples of objectives along the product life cycle



The selection phase consists in a 4-step process leading to a pool of KOLs with whom to engage to benefit (directly or indirectly) the brand

Methodology ¹

2

	Key questions	What to do?
Selection criteria	<ul style="list-style-type: none"> What are the relevant selection criteria to be used considering the final objective? 	<ul style="list-style-type: none"> Review the relevant criteria (e.g., level of influence, scope of influence, scientific/media awareness, membership of a network, presence in Internet, etc.) Select a limited number of relevant criteria
KOLs profiling	<ul style="list-style-type: none"> What information should be collected? How to collect and analyze this information? 	<ul style="list-style-type: none"> Review internal / external databases to qualify KOLs Assess the number of publications, quality of journal, the impact factor, Almetrics¹, quotes, lectures during conferences and congresses, etc.
KOLs segmentation	<ul style="list-style-type: none"> What is the scope of influence and the degree of interest of the KOL for the brand and the related disease(s)? 	<ul style="list-style-type: none"> Map a preselection of KOLs on a matrix according to the most relevant criteria Identify KOLs networks of collaboration and influence (e.g., cooperative groups)
KOLs selection	<ul style="list-style-type: none"> Who are the KOLs that should be engaged? For which kind of engagement? 	<ul style="list-style-type: none"> Select the KOLs Preliminarily define the types of engagement to carry out with the selected KOLs

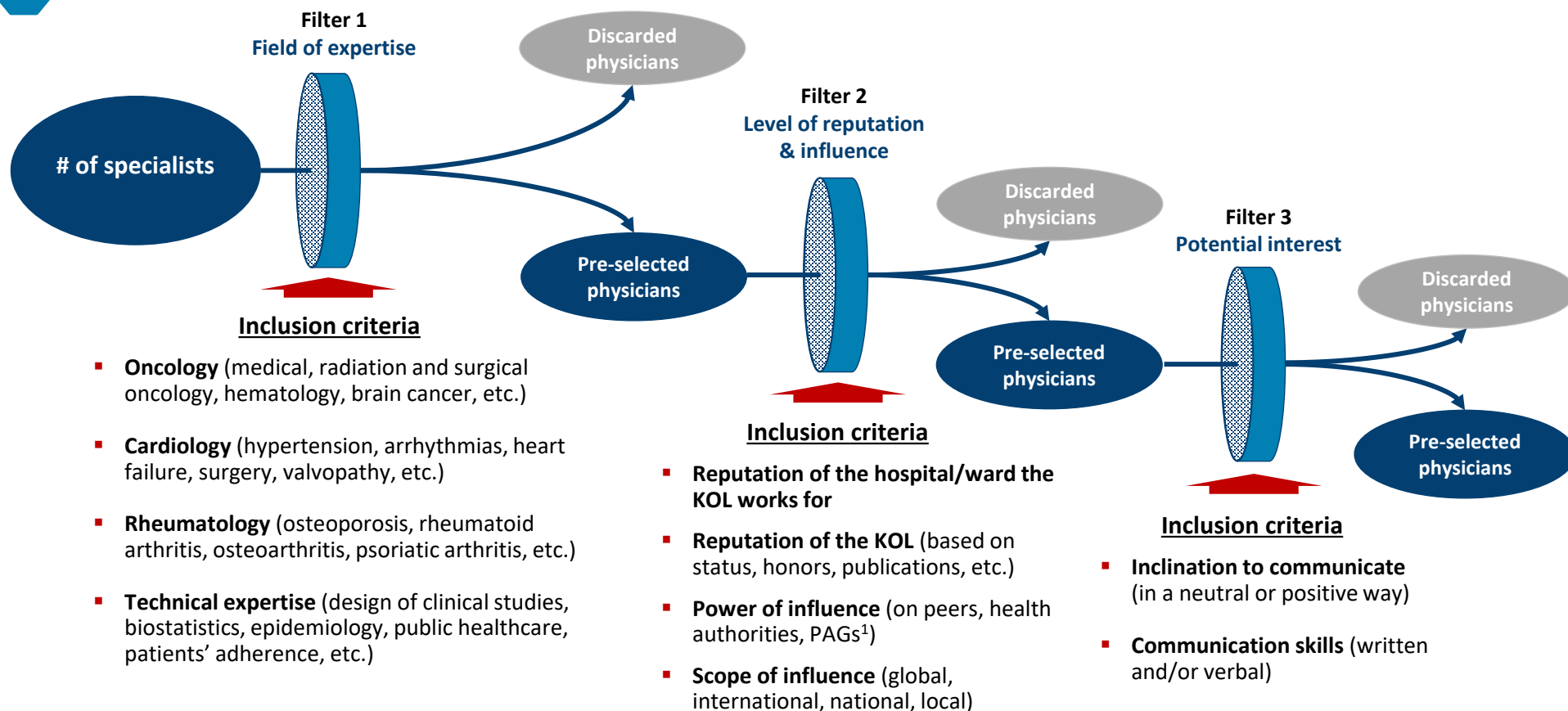
Sources: Smart Pharma Consulting

¹ Collects and collates disparate information on the online activity surrounding scholarly content

Relevant selection criteria and gathering of accurate and reliable information about the KOLs profiles are of utmost importance to optimize the value of their engagement

Screening process (illustrative)

2



Qualification of KOLs should be documented with reliable and real-time data collected through desk research and field research (e.g., interviews of peers, pre-identified KOLs)

How to qualify KOLs? (1/2)

2

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> ▪ Education (e.g., university – hospital) ▪ Medical activity/position (e.g., specialty, medical department, status in the medical department) ▪ Teaching activity/position (e.g., topics taught, professor, lecturer) ▪ Field of expertise and interest (e.g., specific disease, pharmacological route, mode of action, medical technique) ▪ Membership in learned societies (titles / positions / activities) and/or in more or less structured networks 	<ul style="list-style-type: none"> ▪ Internet search, direct search ▪ Field research (e.g., peers, hospital pharmacists' interviews, etc.) ▪ Probing by collaborators from the medical department (e.g., MSLs¹) and collaborators from other departments of the pharma companies (data could be stored and shared on a platform) ▪ KOL Management vendors (e.g., Truven; KOL, LLC; OpenQ; Veeva Systems) 	<ul style="list-style-type: none"> ▪ Being head of hospital and professor is a plus ▪ Reputation of the hospital/teaching hospital or of the private institution where the KOL works should be considered ▪ Global or International scopes of influence are preferable, in general, to national or local levels (but it depends on the objective) ▪ Being a member of the management board of a learned society is a plus in terms of potential level of influence

Qualification of KOLs should be documented with reliable and real-time data collected through desk research and field research (e.g., interviews of peers, pre-identified KOLs)

How to qualify KOLs? (2/2)

2

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> ▪ Communication activities <ul style="list-style-type: none"> – # articles published (impact factor¹, Almetrics², peer-/non peer reviewed journals, principal investigator (PI), etc.) – # of training/teaching activities p.a. (CME³) – # of lectures (congresses, symposiums, round tables) – Presence on the Internet – # of quotes by journalists in current year 	<ul style="list-style-type: none"> ▪ Review of published scientific articles (PubMed/Medline, Google scholar, Expertscape, Cochrane Library) ▪ Evaluation of training/teaching activities and lectures by interviewing peers and collaborators of pharma companies ▪ Google searching for presence and quotes on the Internet 	<ul style="list-style-type: none"> ▪ The higher the impact factor is, the better ▪ KOLs should be ideally positioned as 1st or last author in articles ▪ A high number of training/teaching seminars and lectures is a plus ▪ The perceived quality of articles, training, teaching and lectures should be assessed
<ul style="list-style-type: none"> ▪ Partnership activities <ul style="list-style-type: none"> – Types of activities (e.g., lectures, clinical investigations, advisory boards) – With the company and its competitors – Potential level of interest (inclination to support the development/the proper use of a brand) 	<ul style="list-style-type: none"> ▪ Review of past performances with the company or its competitors (e.g., probing by collaborators of the company) ▪ Interviews of peers 	<ul style="list-style-type: none"> ▪ Verbal (e.g., lectures, courses) and written communication (e.g., articles, websites) ▪ KOLs should express their field of interest over the long term and their expectations from an engagement with the pharma company

The following table shows a proposed approach to evaluate and rank candidate KOLs to set up a list of Top Global KOLs, that should be continuously updated

Scoring of candidate KOLs

2

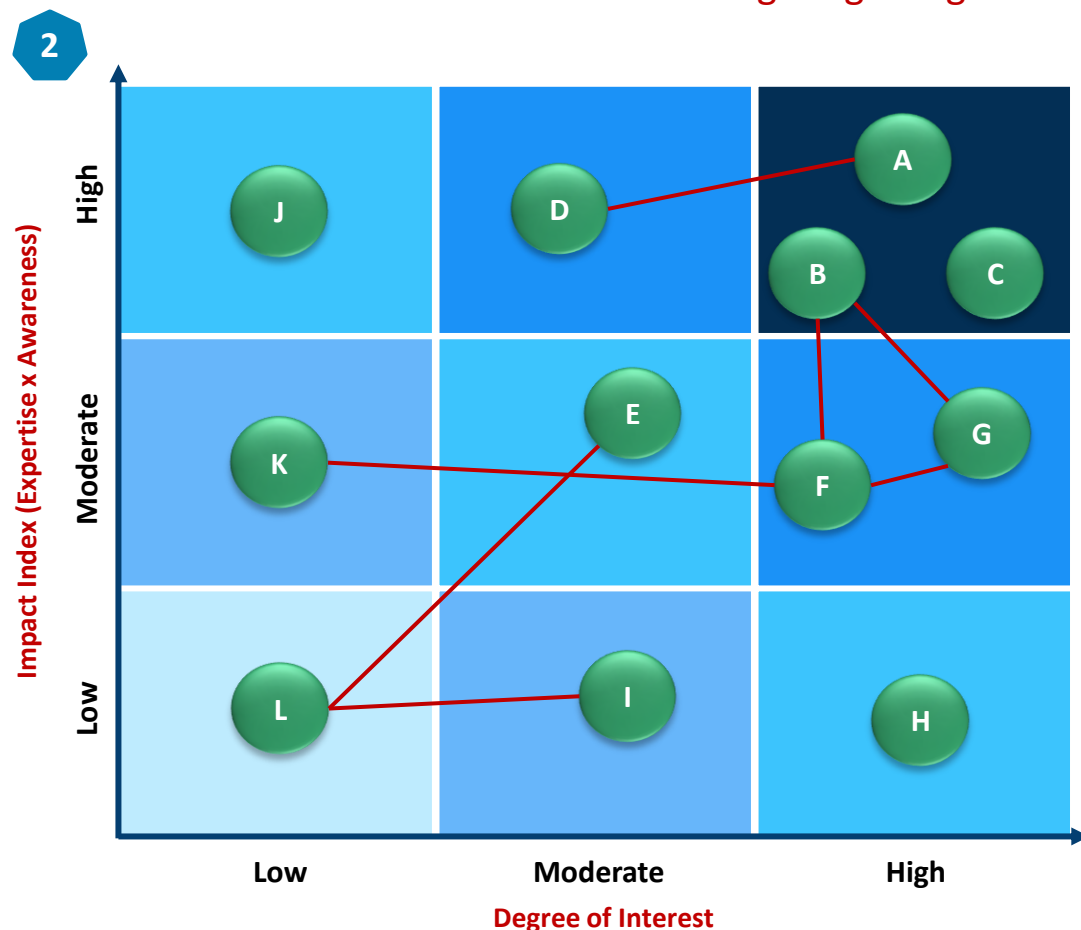
Illustrative

Profiling parameters		Prof. A	Prof. B	Prof. C	Dr. D
EXPERTISE	Pharmacological expertise	8	0	6	0
	Academic research	5	9	0	0
	Clinical research	5	0	9	5
	Clinical practice	0	0	6	9
	Scientific advisory board	8	8	7	6
	Sub-total score (A) ¹	5.2	3.4	5.6	4.0
AWARENESS	Publication record	8	5	4	3
	Speaker record	3	4	8	7
	Communicate skills	6	6	5	7
	Density of the network	5	7	7	3
	Sub-total score (B) ¹	5.5	5.5	6.0	5.0
Impact Index ² score (A x B) ¹		14.3	9.4	16.8	10.0
KOL degree of interest		Moderate	High	Moderate	Low
Ranking		2	3	1	4

- The candidate KOLs can be ranked according to their **field of expertise**, their associated level of recognition in these fields, and their **level of awareness**
- The **KOL degree of interest** for the product should also be considered
- The assessment could be done on a **10-point scale** based on data coming from **external providers**, a panel of peers who will score each expert, combined with **the internal insights** available at the pharma companies' level, etc.
- This approach will **help make a first cut** of the Top Global KOLs that should be continuously reevaluated

The proposed matrix is a useful tool to prioritize the KOLs with whom to engage and to pre-define the types of collaboration to carry out with them

KOL targeting – Segmentation & selection



- The proposed matrix facilitates the **final selection** (targeting) of pre-selected KOLs based on their:
 - **Impact index** (combining their degree of expertise and awareness¹)
 - **Potential interest**
- The **impact index** reflects the KOLs **ability to influence** other stakeholders (i.e., HCPs, policy makers, payers, patients, PAGs)
- The **degree of interest** reflects the KOLs **willingness to support**:
 - The **development** of the company **brand**
 - The proper **use of the brand**, once marketed
- The **network**² of KOLs should also **be considered**

Priority 1
 Priority 2
 Priority 3
 Not a Priority

— Networks of influence / collaborations amongst KOLs

To convince KOLs to partner, it is important to consider their expectations and to highlight the benefits, they will draw from it in terms of professional development

How to convince KOLs to partner?

2

What do KOLs want through engagements?

- The selection of KOLs should consider the **benefits they can offer** to the pharma companies and the **benefits** the pharma **companies** can **offer to them**
- *For so doing, the following questions should be addressed:*
 - Is the KOL **yet a partner** of the pharma company?
 - What has been qualitatively and quantitatively **his level of involvement?**
 - What has been **his feed-back** (level of satisfaction) from previous collaborations?
 - What is his mid- to long-term professional **ambition?**
 - What does **he expect from collaborations** with pharma companies?
 - Is he looking for a long-term partnership or a “fee-for-service” transaction?

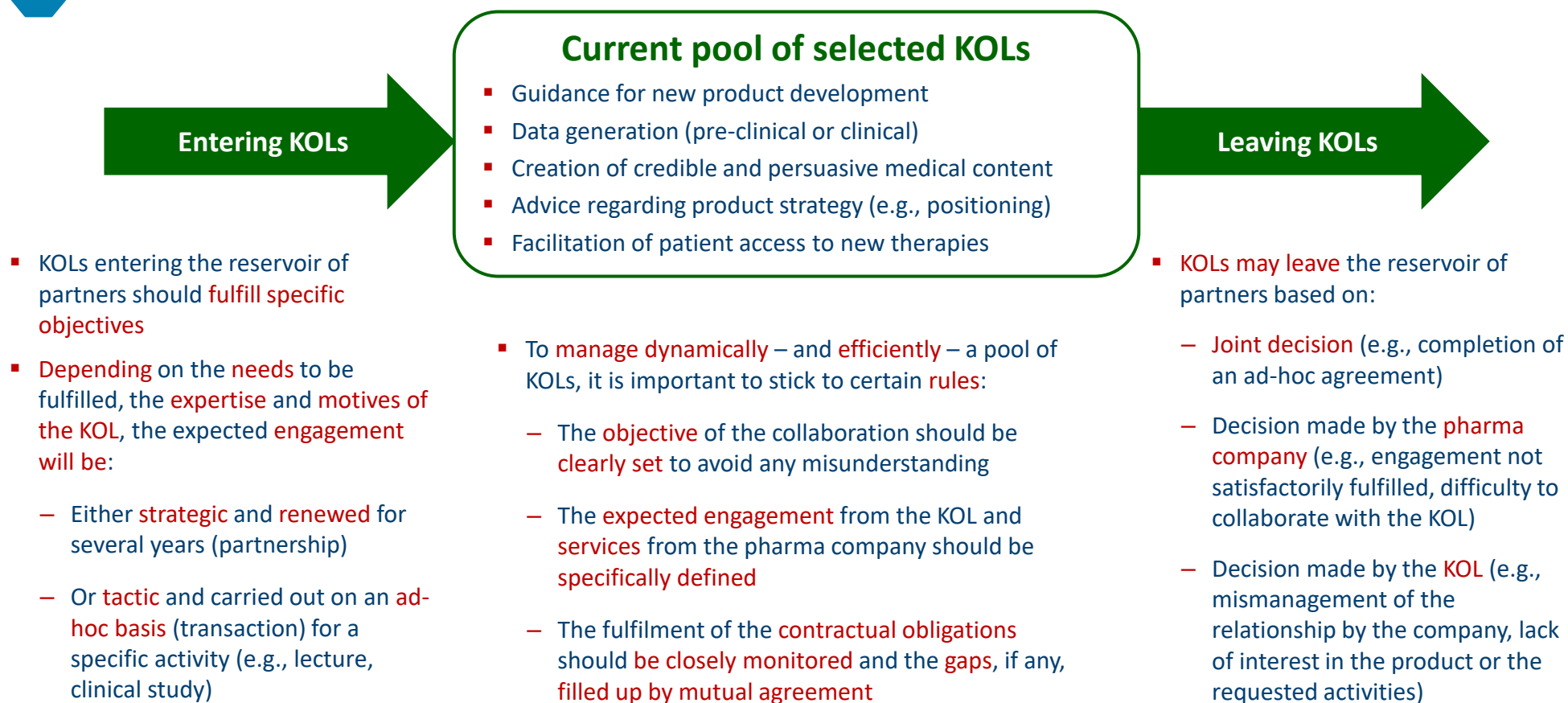
What should pharma companies propose to KOLs?

- Based on KOLs professional expectations, pharma companies can **propose ideas** of “**win-win**” **activities** to be carried out through engagements
- The **benefits** the **KOLs** will draw in terms of **personal awareness** and **competence development** through the engagement should be **emphasized**:
 - **Opportunity to participate in publication** of articles, **interviews** in media, **presentations** during congresses, lectures during medical meetings, etc.
 - **Provide expert opinion/guidance and/or...**
 - **... opportunity to participate in clinical research (e.g., clinical trials) or to carry out IITs¹**
 - **Professional development** through the **access to recent information**, to **high education programs²**, by working in **new research/medical areas**, etc.

Pharma companies should be able to manage dynamically their selected KOLs by attracting newcomers and putting an end to some existing collaborations

Dynamic management of selected KOLs

2



Pharma companies should balance what they expect from KOLs in terms of activities and what they give them in terms of services to ensure a win-win partnership

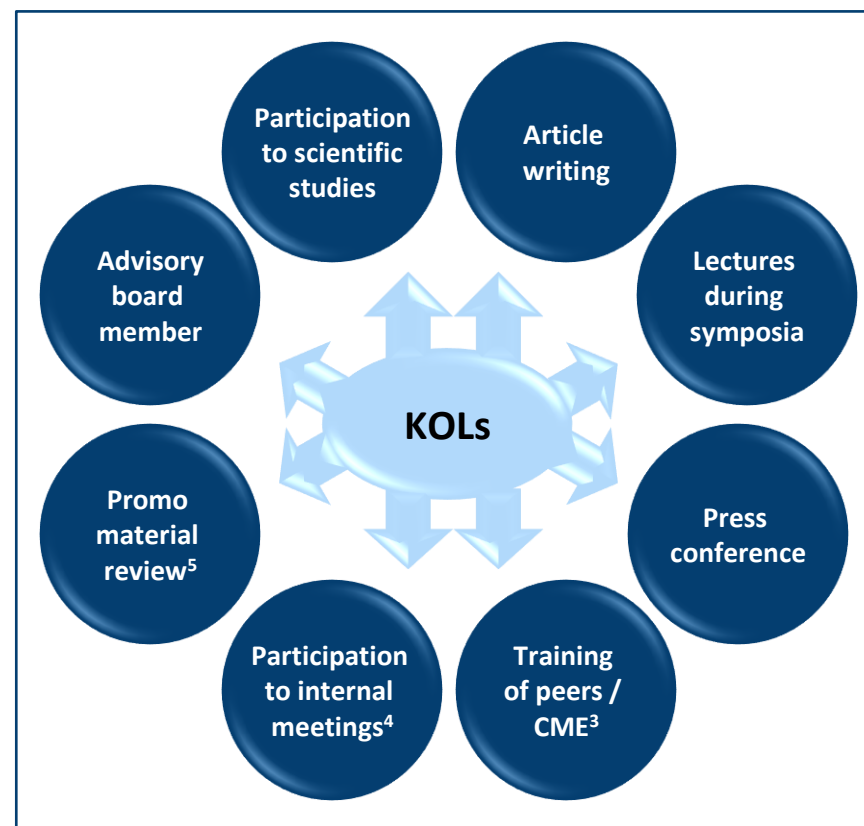
Services proposed to & activities carried out by KOLs

3

Services proposed to KOLs (Illustrative)



Activities carried out by KOLs (Illustrative)



If KOLs share the objective of the pharma company and accept to communicate, the following means can influence medical practices and help better position products

Potential value of KOL activities (1/2)

3

Article writing

- KOLs may support the pharma company priorities by communicating in scientific journals, professional magazines or lay press regarding:
 - New medical approaches, new guidelines, patient management, etc.
 - The position of its products in the therapeutic strategy

*Perceived reliability by readers: **H***
*Number of exposed readers: **L-H***

Lectures during symposia

- While giving lectures, KOLs may accept to cover topics of interest for the company...
- ... and/or to position its product vs. direct competitors or indirect therapeutic alternatives based on scientific data/ rationale
- KOLs may also share their own experience as a prescriber of the company products

*Perceived reliability by participants: **M***
*Number of exposed attendants: **L***

Press conference

- Press conferences enable to have indirectly access to a larger number of readers
- The messages conveyed by KOLs may sometimes be modified by journalists
- It is rare for KOLs to make strong statements in favor of a product during a press conference

*Perceived reliability by readers: **M***
*Number of exposed readers: **M-H***

Training of peers / CME¹

- KOLs may communicate to HCPs during training sessions regarding:
 - Medical topics of interest for the pharma company
 - The position of its products in the therapeutic strategy
- In such circumstances, KOLs may convey strong messages, if they decide to do so

*Perceived reliability by participants: **M-H***
*Number of exposed attendants: **M***

H: Higher – **M:** Medium – **L:** Lower

KOLs can be of great value through direct collaboration (by training, informing, giving advice, etc.) with medical and marketing teams of the pharma company

Potential value of KOL activities (2/2)

3

Participation to internal meetings

- KOLs may play an effective role during internal meetings by:
 - Informing / training medico-marketing teams about scientific trends and position of competitors
 - Being invited as a “guest star” to show collaborators the ability of the pharma company to partner with top medical leaders
 - Playing a role with sales reps (e.g., selling forums)

Participation to scientific studies

- KOLs, especially if they are supposed to sign or co-sign the corresponding publication, may be very helpful to:
 - Participate to the design of the study
 - Carry out the study (either about a given pathology only or a pathology & its treatments involving the pharmaceutical company product)
- Involvement of KOLs in medical/clinical studies will depend on their field of interest

Advisory board member

- Advisory board meetings with KOLs should be preferred to individual meetings with KOLs when the objective is to get advice on:
 - **Estimating** the impact of key **market trends**:
 - Scientific innovation
 - New product development
 - Evidence generation
 - Market access strategy
 - Marketing strategy (positioning)
 - New **ideas** or **concepts**

Promo material review

- KOLs may collaborate with the marketing team by contributing to the creation of promotional materials
- Thus, they can create value by:
 - Suggesting messages
 - Developing a scientific rationale to support messages/claims of the products
 - Assessing and editing the content of promotional materials (visual aid, booklet...)

A comprehensive KOL engagement strategy requires from pharma companies to gain an in-depth understanding of KOL challenges, motivators and expectations

KOLs challenges – motivators – expectations

3

Challenges

- **Trusting pharma:** product efficacy and safety, corporate reputation and service quality
- **Pharma engagement approach:** transactional arrangement vs. real relationship, multiple contact points
- **Time and doctor/patient ratio**
- **Regulation:** compliance, accountability, disclosure of compensation from pharma companies

Motivators

- Prestige and renown
- Better healthcare outcomes
- Scientific journals and publications
- Membership in advisory boards, steering committees
- Formulation of guidelines and medical policies
- Speaking opportunities at congresses, symposia
- Participation in clinical trials and academic researches

Expectations from pharma companies

- Fair market value remuneration
- Presence in KOLs field of expertise
- Consistency, communication, support and interaction
- Value-adding interactions with pharma companies' collaborators
- Research assistance
- Credibility and commitment to patient care
- Continuous engagement
- Genuine involvement & meaningful partnerships
- Transparency

“One goal that most KOLs share is to capture attention and prestige within their community”

In general, the most common criticisms by KOLs at pharma companies are related to absence of true partnerships and of cohesive internal strategy and processes

Top 10 poor pharma companies' practices & key learnings

3

Top 10 poor practices

1. "30-page confidentiality agreement"
2. Unclear unspoken objectives
3. Inconsistent honoraria payments across projects
4. Strong commercial bias in discussions about treatments
5. Lack of listening
6. Lack of on-going communication
7. Sporadic approach: "No follow-up to show how they used our input or what they did"
8. "17 different people from the same company contacted me in the course of one month"
9. Changes in staff: "I never know who is who"
10. Relationship held by the CRO



Key learnings

- Set clear objectives
- Favor partnership-based to transactional agreements
- Consider what KOLs want from a relationship with pharma companies
- Ensure a transparent communication
- Have a clear demarcation between commercial, medical and clinical needs (and others, if needed)
- Ensure a consistent and coordinated communication between the pharma company and the KOLs

The development of a KOL Engagement Plan is a centerpiece to maximize the probability of success while partnering with KOLs

KOL engagement plan (1/2)

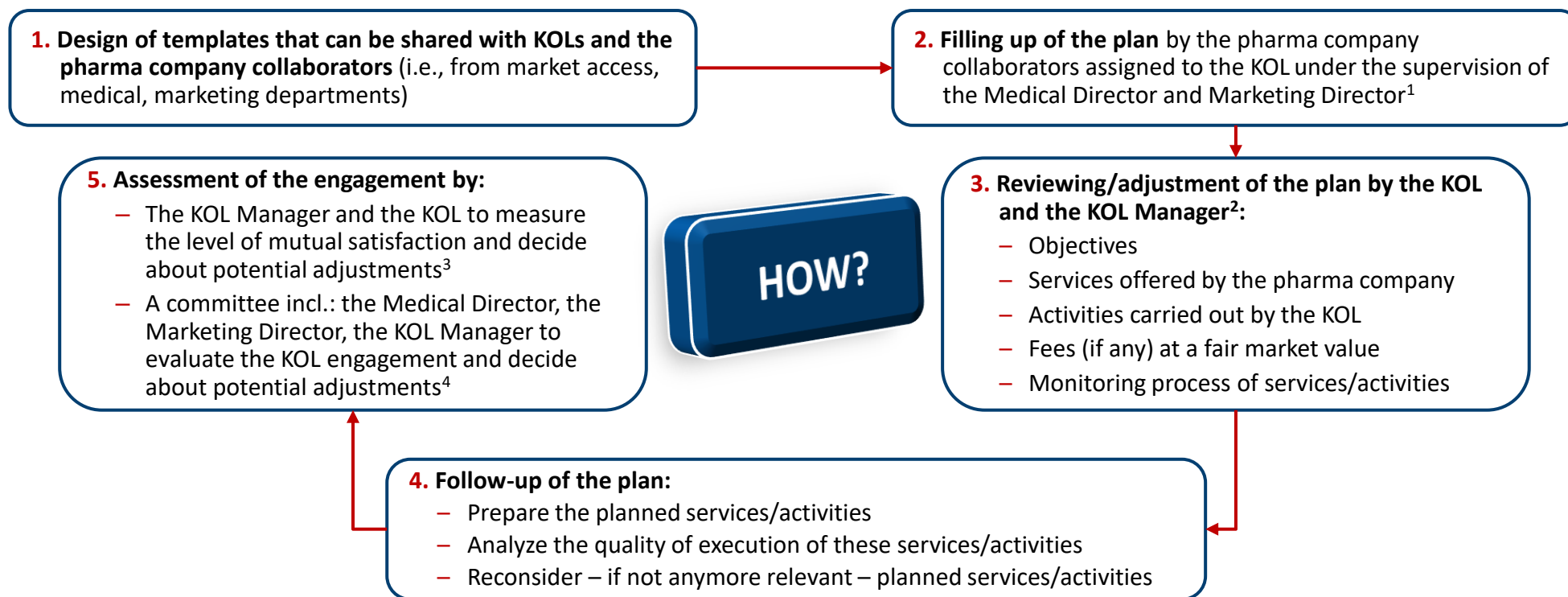
3WHY?

- The development of a clear – precise – concise and shared engagement (activity) plan, between KOLs and pharma companies – will ensure that:
 - Objectives of collaboration are well understood and agreed upon
 - Reciprocal expectations are well defined and accepted
 - Respective commitments are fulfilled and in due time
- The preparation of an engagement plan increases the probability of success of the partnership over time...
- ... and minimizes the risks of mutual disappointments
- The KOL Engagement Plan (KEP) will facilitate the coordination and the communication across the pharma company and thus optimize synergies across market access, medical and marketing departments

To build a useful and effective KOL Engagement Plan,
 it is recommended to follow the 5-step process proposed here-below

KOL engagement plan (2/2)

3



“To find common ground is a key success factor in KOL engagement”

Individual KOL Engagement Plans should be co-developed by the KOL and the pharma company to avoid any misunderstanding and subsequent disappointments

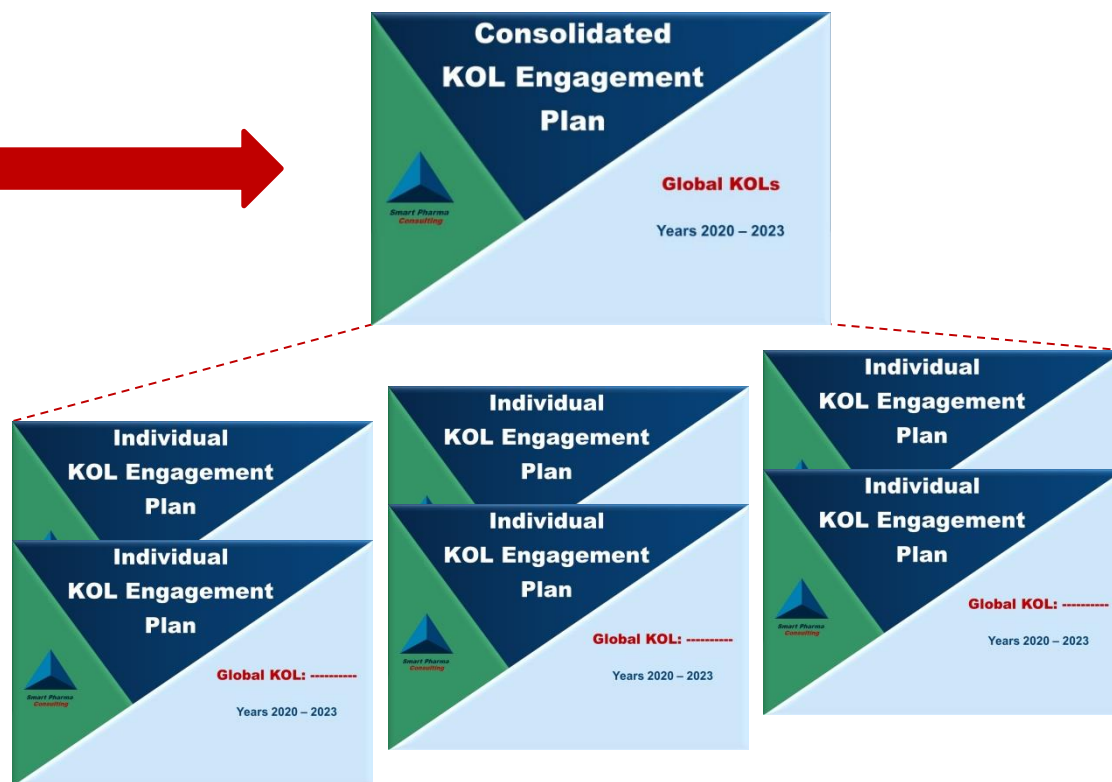
Development of KOL Engagement Plans

3

**Strategic Brand Plan
(2020 – 2023)**



- The KOL engagement plan should be developed to support the Brand Strategic Objective as per the Strategic Brand Plan
- Each individual KOL engagement plan should be designed accordingly and be consolidated in a single document
- The Consolidated KOL Engagement Plan can cover a period lasting from one year to 3 or even 5 years, depending on the product position on its life cycle



The KOL Engagement Plan should be formalized in a document that could be structured as proposed in the table of contents, here-below

Structure of a Consolidated KOL engagement plan

3

Illustrative



Table of Contents

- Introduction
 - Brand Strategic objective (vision)
 - Brand Strategic Imperatives & Critical Success Factors
 - Brand development priorities (3-year perspective)
- Expected contribution from the pool of Global KOLs
- Expected contribution from individual Global KOLs
 - Type of agreement (ad-hoc, partnership, duration, etc.)
 - Key activity selection (e.g., advisory board meeting, lecture, clinical study, peer-to-peer trainings)
 - Key activity description (e.g., objective, timing, accountability, budget)
 - Key activity monitoring (e.g., KPIs¹ and KEIs²)

The KOL Engagement Plan should include key information extracted from the KOL database, specify the objectives of the collaboration, its scope and duration

Individual KOL engagement plan – ID Card

3
Illustrative

KOL name	First name – surname	Medical status	MD – head of medical department – professor of medicine, etc.		Medical setting	Private hospital – Public hospital – Teaching hospital
Expertise	E.g., therapeutic area, organ, pharmacology, academic and/or clinical research, scientific advisory boards, etc.	Awareness	Publications – Lectures – Communication skills - Network		Impact Index¹	Numerical scale to be determined
Degree of Interest	Low – Moderate – High	Points of vigilance	E.g., mobility, adherence to deadlines, quality of presentation documents, etc.		Ranking	

Primary objectives of the collaboration	•			
Specific activities planned within the engagement¹	•	•	•	•

Type of agreement		Duration of the agreement	
• Transactional agreement:		• Annual:	from: ---/---/--- to: ---/---/---
• Partnership agreement:		• Multi-year:	from: ---/---/--- to: ---/---/---

The KOL Engagement Plan should describe the activities the KOL is engaged to carry out to meet specific objectives, and it should include monitoring indicators

Individual KOL Engagement Plan – KOL Activity Card

3 4

Illustrative

KOL Activity	<ul style="list-style-type: none">Lecture, training of peers, advisory board, press conference, article writing, IIS, clinical study, etc.	Objectives	<ul style="list-style-type: none">	Pharma company contact point	
Key implementation steps		Timing	Points of caution	Expected output / value of the activity for...	
<ul style="list-style-type: none">			<ul style="list-style-type: none">	... the KOL herself/himself	... the pharma company
<ul style="list-style-type: none">			<ul style="list-style-type: none">	<ul style="list-style-type: none">	<ul style="list-style-type: none">
<ul style="list-style-type: none">			<ul style="list-style-type: none">		
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<ul style="list-style-type: none">			<ul style="list-style-type: none">		
<ul style="list-style-type: none">			<ul style="list-style-type: none">		... 3 rd parties -----
Feasibility (High – Moderate – Low)		Key Execution Indicators		Key Performance Indicators	
Technical	<ul style="list-style-type: none">	<ul style="list-style-type: none">These indicators measure the quality of execution of the activity		<ul style="list-style-type: none">These indicators measure the impact (output/value/benefit) of the activity for the different targets (the KOL, the pharma company and possibly for 3rd parties, like peers, patients, PAGs)	
Regulatory	<ul style="list-style-type: none">				
Financial	<ul style="list-style-type: none">				

The KOL Engagement Plan should also describe, plan and follow up the services proposed to the KOL, as a constituent of the partnership-based agreement signed

Individual KOL Engagement Plan – Partnership-based Service Card

3

4

Illustrative

Pharma company services	<ul style="list-style-type: none"> Access to scientific information, technical support to publish articles, provision of training/teaching materials, organization of peer meetings, etc. 	Objectives	<ul style="list-style-type: none"> 	Pharma company contact point	
-------------------------	--	------------	--	------------------------------	--

Key implementation steps	Timing	Points of caution	Expected output / value of the service for...	
<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> 	... the KOL herself/himself	... the pharma company
<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none">
<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> 		
<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> 		
<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> 		

Feasibility (High – Moderate – Low)		Key Execution Indicators		Key Performance Indicators	
Technical	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> These indicators measure the quality of execution of the service provided to the KOL 		<ul style="list-style-type: none"> These indicators measure the impact of the service provided to the KOL 	
Regulatory	<ul style="list-style-type: none"> 				
Financial	<ul style="list-style-type: none"> 				

Key execution and performance indicators are essential to optimize the chance of a proper execution of services / activities and of a win-win partnership

Examples of tools to monitor engagements with KOLs (1/2)

4

KOLs activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Lecture during symposia or congresses 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) Practicality (10-point scale) Implementation¹ (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of attendees (10-point scale) Inclination of attendees to support & prescribe the product: <ul style="list-style-type: none"> Number of lectures/trainings/publications Quality/objectivity of messages conveyed to peers, pharmacists, PAGs, etc.
<ul style="list-style-type: none"> Training of peers 		
<ul style="list-style-type: none"> Article writing 	<ul style="list-style-type: none"> Acceptance by recognized journals (scientific, medical, or in lay press, etc.) Post on highly regarded websites 	<ul style="list-style-type: none"> Impact factor and Altmetrics² (for scientific / medical journals) Number of broadcasted issues for lay press Number of views / likes on Internet Contribution of content to support the product
<ul style="list-style-type: none"> Press conference 	<ul style="list-style-type: none"> Number and quality of press conferences conducted 	
<ul style="list-style-type: none"> Participation in scientific studies 	<ul style="list-style-type: none"> Implementation (number of patients recruited, timing, actual costs vs. budget) 	<ul style="list-style-type: none"> Publication of an article in a renowned scientific journal Impact of the publication on product reputation

Key execution and performance indicators are essential to optimize the chance of a proper execution of services / activities and of a win-win partnership

Examples of tools to monitor engagements with KOLs (2/2)

4

Pharma company services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> Access to scientific information 	<ul style="list-style-type: none"> Interest (10-point scale) Utility (10-point scale) Practicality (10-point scale) Implementation² (10-point scale) 	<ul style="list-style-type: none"> Global level of satisfaction of KOLs (10-point scale) Inclination of KOLs to support the pharma company products: <ul style="list-style-type: none"> Number of lectures / trainings / publications Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc. Increased level of KOLs awareness and reputation Increased level of products awareness and reputation
<ul style="list-style-type: none"> Organization of peer meetings with top global / international KOLs 		
<ul style="list-style-type: none"> Publications' support 		
<ul style="list-style-type: none"> IIT¹ support 		
<ul style="list-style-type: none"> Slide kits for training / teaching programs 		
<ul style="list-style-type: none"> Ad hoc support on demand basis 		

Future trends in KOL Engagement Planning

- **Fewer** opportunities for **transactional** and agreements (e.g., ad-hoc contributions such as lecture at a symposium)
- **Greater independence** of KOLs and **increasing pro-bono contribution** where mutual benefits lie (e.g., research program, lectures reinforcing their awareness)
- **More independent collaboration** projects, indirectly or not connected to a specific product (e.g., research program, education program, best practice sharing)
- **Increasing presence**, awareness and influence of **KOLs on Internet**
- **Broader definition of KOLs** from clinical expert to patient advocate, payor, academic institution, charity, etc.
- **Evolving internal policies** to foster **transparency** and **compliance** with industry code of practice

Recommendations for a Successful KOL Engagement Planning

1. Define **clear** and **precise objectives** for each KOL
2. Build a **relationship** based on an **exchange of services / activities** (vs. fee-for-service deal)
3. Make sure that **services** provided to KOLs **contribute to fulfill** their **needs/expectations**
4. Ensure an **open** and **transparent relationship**
5. Do not ask **KOLs** to **promote** your **products**, you would affect their reputation and yours
6. Make the **best use** of **KOLs limited time** by organizing useful exchanges
7. Assign a **KOL Manager** who is the KOL-preferred contact point and who ensures alignment and information sharing between all collaborators of your company in contact with her/him
8. Create a **technology platform** to **store**, **structure** and **share data** relative to KOL profiles and engagements (planned and achieved)

*Define **internal guidelines** and a **control process** to prevent any **compliance issues** that could damage your corporate reputation*

2023 Pharma Training Programs...

CATALOGUE

... for Medical Teams

The Smart Pharma Institute of Management offers a large array of training programs for high potential executives from pharma and biotech sectors

Introduction

Training Program Offering

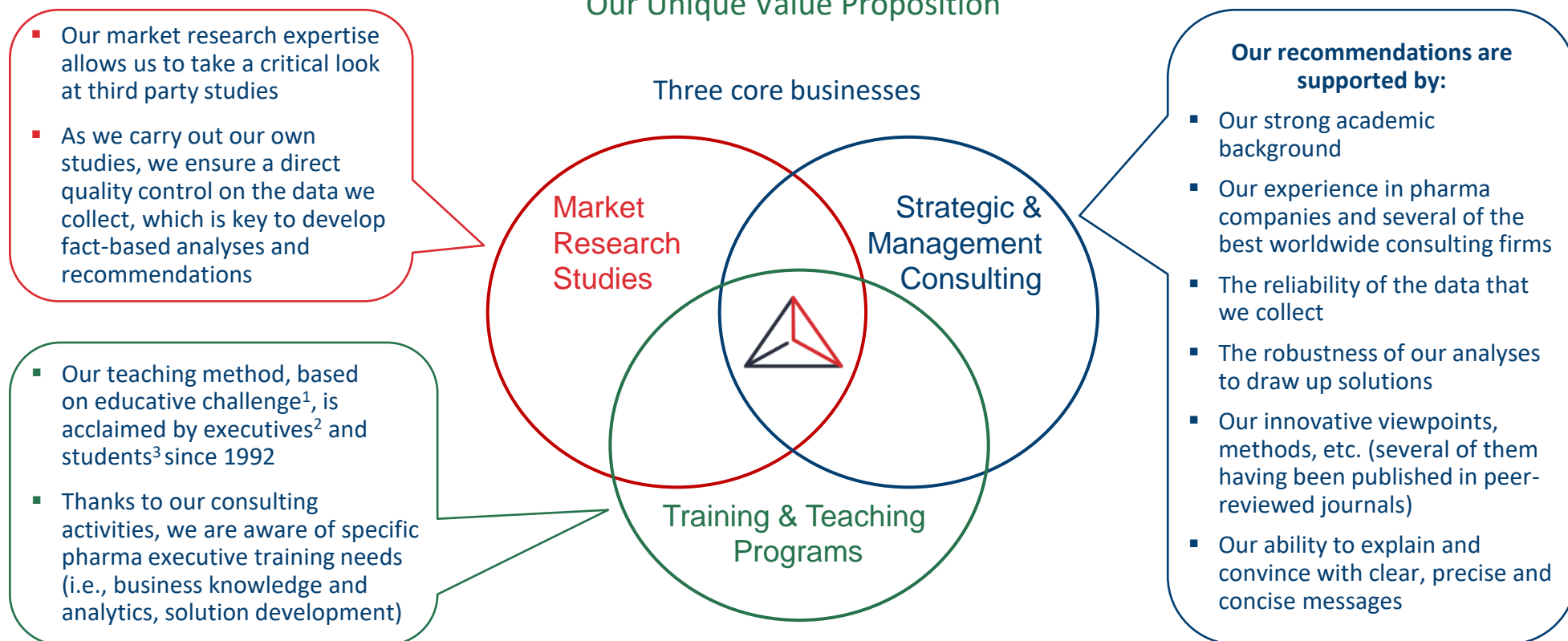
- Our training programs are developed and carried out by the “Smart Pharma *Institute of Management*” which is our professional training center
- Smart Pharma *Institute of Management* is a division of Smart Pharma Consulting that offers training programs to high potential executives from pharma and biotech sectors
- Those high-level training programs have been designed for professionals who are willing to reinforce their skills in Strategy, Tactics and Management in both national and international contexts

*“The **Smart Manager** knows **where, why and how to go**”*

Our training & teaching programs are unique because they are built on our market research and consulting expertise in the pharma sector and delivered by experts

Introduction

Our Unique Value Proposition



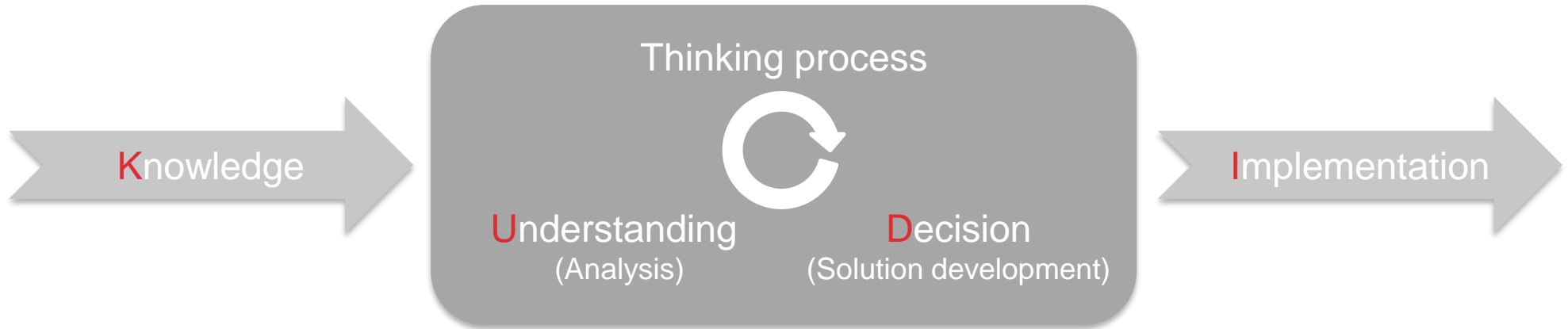
Smart Pharma is a certified Training Organization since 2002

Our training and teaching programs have been designed to boost the knowledge of participants, their ability to understand, to make decisions and to implement them

Introduction

“Smartness Formula” (1/2)

Smartness = **K**nowing x **U**nderstanding x **D**eciding x **I**mplementing



“Any fool can know. The point is to understand” – Albert Einstein

The “Smartness Formula” has shown to be effective to diagnose development needs of participants and to structure development programs

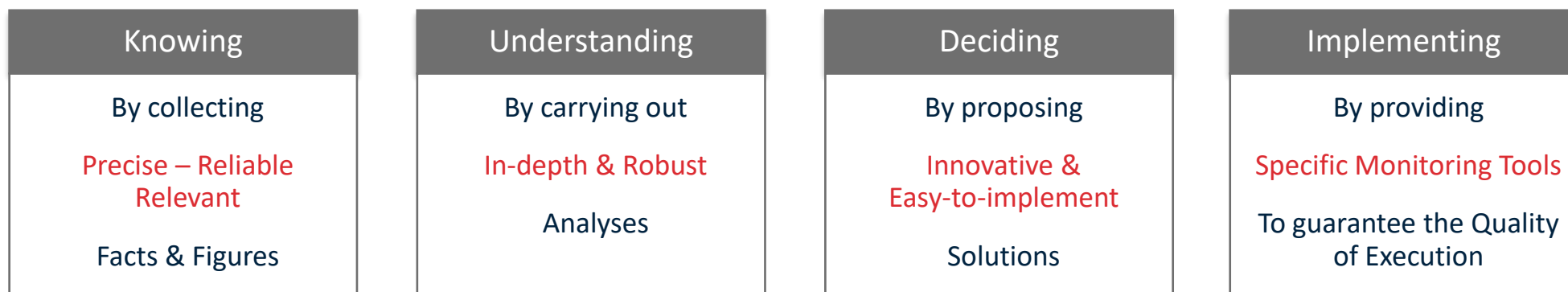
Introduction

“Smartness Formula” (2/2)

- The “**Smartness Formula**” provides a structure to identify development needs and organize in an effective and more efficient manner

Smartness = **K**nowing x **U**nderstanding x **D**eciding x **I**mplementing

Smartness components



All programs are led by Jean-Michel Peny, President of Smart Pharma Consulting and Program Faculty Director of the Smart Pharma Institute of Management

Introduction

Jean-Michel Peny

■ Experience:

- 1 year as pharmacist at Begin hospital blood bank
- 7 years as General Manager for pharma companies:
 - 3 years in Sri Lanka (Servier)
 - 3 years in India (Servier)
 - 1 year in France (Novartis Generics)
- 31 years as Consultant specialized in Strategy and Management in the pharmaceutical sector (Bain & Co, Arthur D. Little, AT Kearney, ISO Health Care Consulting, Smart Pharma Consulting)
- 32 years of teaching activity:
 - Lecturer: ESCP B-School, ESSEC B-School, Paris Pharmaceutical and Medical Universities
 - Former affiliate Professor of Strategy & Marketing at HEC B-School
 - 1992-2001: Master “Pharma & Biotech Management” – ESCP B-School

– 22 years of training activity:

- Intra-company programs since 2002
- Inter-company programs since 2006

■ Education:

- Pharm. D. – Nantes University
- MBA – HEC Business School
- Executive programs:
 - Strategic Marketing – Harvard Business School
 - Corporate Strategy – Sloan School of Management
 - Management of small corporations – Stanford B-School
- Master 2, International Trade – IAE Lyon 3 University
- Master 2, Pharmaceutical Marketing – Paris 5 University

■ Publications:

- 6 books
- 41 articles
- ~150 position papers

We have specifically designed Masterclasses to offer in-depth trainings to pharma company executives on a specific topic

Training Programs – Intra-companies

Masterclass¹: Principles

Concept

- Masterclasses offer participants the opportunity to focus on a specific subject and apply innovative concepts, useful methods and practical tools to real-life situations, to learn by doing
- Masterclasses are moderated by Jean-Michel Peny, who has been, for 28 years:
 - Teaching students at the best French Business Schools and Universities of Pharmacy and Medicine
 - Training executives from the pharma industry
- Each Masterclass is limited to a maximum of 12 participants and lasts from 1 to 4 days

Organization

- **Pre-Masterclass session**
 - Participants will receive a specific documentation including concepts, methods and tools
- **Masterclass session (1 to 2 days)²**
 - Part 1: Review of the concepts, methods and tools that will be used
 - Part 2: Lecture by and discussion with a “guest speaker” expert in the topic covered
 - Part 3: Implementation of the concepts, methods and tools through real-life case studies
 - Part 4: Co-development with participants of key learnings
- **Post-Masterclass**
 - Structuration of the key learnings of the Masterclass session to be sent to participants

This masterclass provides a method and tools to help MSLs increase their efficacy and efficiency, especially when interacting with KOLs

Training Programs – Intra-companies

Masterclass¹: Best-in-Class MSLs

Day 1

9:00	Introduction
9:15	Reminder of MSLs role & responsibilities taking into account the national regulatory framework
10:00	Presentation: MSLs issues & challenges
10:30	Presentation: Recruitment and Management of KOLs
11:15	<i>Break</i>
11:30	Workshop #1: “ KOLs mapping ”
12:30	<i>Lunch</i>
13:30	Workshop #2: “ KOLs relationship management ”
14:30	Workshop #3: “ Creation of high impact interactions ”
15:30	<i>Break</i>
15:45	Workshop #4: “ Contribution of the MSL to the enhancement of pharma company’s reputation ”
16:45	Plenary discussion: “ How to improve collaboration with medical reps and KAMs? ”
17:30	Conclusion
18:00	End of day 1

Day 2

9:00	Introduction
9:15	Presentation: MSLs’ strategic & operational plans (best practices – models)
10:00	Presentation: Changes in the healthcare system and in the pharma market by 2020
10:45	Workshop #5: “Analysis of the regional environment ” (ARS, KOLs, hospital services, healthcare networks)
11:30	<i>Break</i>
11:45	Workshop #6: “Analysis of the regional activities of MSLs ” (partnerships, projects, quality of interactions with KOLs)
12:15	Presentation & practical exercises “ SWOT analysis in the scope of MSLs ”
13:00	<i>Lunch</i>
14:00	Workshop #7: “ Objectives setting, definition of a strategy and of operational activities monitoring ”
16:00	<i>Break</i>
16:15	Conclusion
17:00	End of the masterclass

The Physician Experience Program will provide participants with ready-to-implement solutions for in-field and back-office collaborators of pharma companies

Training Programs – Intra-companies

Masterclass¹: Implementing a Physician Experience Program

Content & Organization

- The program will include basic definitions, recommendations, key tools, practical exercises and case studies related to the pharmaceutical industry
- The program content will be customized according to the specific needs of the client
- The program duration will be of one day, one day and a half or two days, according to the client needs and desire

Target Audience

- Any collaborators from pharmaceutical companies, whatever their level of responsibility and seniority
- Participants can be part of the medical, marketing, commercial, market research, strategic,... departments

Example of a One-Day Program

9:00	Introduction to the program
9:10	Definitions, concepts, methods, tools related to Experience
10:40	<i>Break</i>
11:00	Exercises: Defining a shared vision & ambition – Crafting a strategy – Mapping physician journeys and selecting the most relevant
12:30	<i>Lunch</i>
13:30	Case study #1: Rethinking medical calls experiences
15:00	<i>Break</i>
15:20	Case study #2: Rethinking medical meetings
16:50	Conclusion and key takeaways
17:30	End of the program

This masterclass provides Good Managers with tips to become Smart Managers and thus boost their performance and the performance of their collaborators

Training Programs – Intra-companies

Masterclass¹: Smart vs. Good Managers

Day 1

9:00	Introduction to the masterclass
9:10	Review of and discussion about the seven tips to be mastered to become a Smart Manager (pre-read sent to participants)
10:30	Lecture by and discussion with an expert: "Managers vs. Leaders"
11:45	Break
12:00	Workshop #1: Purpose – Mission – Values – Vision
13:00	Lunch
14:00	Workshop #2: Strategy crafting
15:00	Workshop #3: Management by mutual benefits
16:30	Break
16:45	Workshop #4: Use of the Smart Index
18:15	End of day 1

Day 2

9:00	Introduction to the 2 nd day
9:10	Workshop #4: Use of the Smart Index (cont.)
10:45	Break
11:00	Workshop #5: Dynamic management of collaborators
13:00	Lunch
14:00	Workshop #6: Stimulation of job passion
15:30	Break
15:45	Workshop #7: Management model selection
17:15	Conclusion of the masterclass
18:00	End of the masterclass

This program helps participants significantly improve their time management through the application of simple and effective good practices

Training Programs – Intra-companies

Masterclass¹: Time Management

Day 1

9:00	Introduction to the masterclass
9:10	Review of and discussion about the 8 tips to better manage time at work (pre-read sent to participants)
10:30	<i>“Why is your time at work so precious?”</i>
11:45	<i>Break</i>
12:00	Workshop #1: <i>How well do you manage your time? – Express Self-diagnosis</i>
13:00	<i>Lunch</i>
14:00	Workshop #2: <i>Situation analysis: Time wasters identification</i>
15:30	<i>Break</i>
16:00	Workshop #3: <i>Management of time wasters</i>
17:30	End of day 1

Day 2

9:00	Introduction to the 2 nd day
9:10	Workshop #3: <i>Management of time wasters</i> (cont.)
10:45	<i>Break</i>
11:00	Workshop #4: <i>Planning and implementation</i>
12:00	Workshop #5: <i>Tracking & sharing outcomes</i>
13:00	<i>Lunch</i>
14:00	Case study #1: <i>“Manager Time”</i>
15:30	<i>Break</i>
15:45	Case study #2: <i>“Pharma Time”</i>
17:15	Conclusion of the masterclass
17:30	End of the masterclass

This program helps participants significantly improve their project management through the application of simple and effective good practices

Training Programs – Intra-companies

Masterclass¹: Project management

Content & Organization

- The program will include basic principles, key tools, practical exercises and case studies relative to the pharmaceutical industry
- The program content will be customized according to the specific needs of the clients
- The program duration will be of one day, one day and a half or two days, according to the clients needs and desire

Target Audience

- Any collaborators from pharmaceutical companies having the responsibility to manage projects that are more or less complex
- Participants can be part of the medical, marketing, commercial, market research, strategic,... departments

Example of a One-Day Program

9:00	Introduction to the program
9:10	Review of the basic principles and key tools to properly manage projects
10:40	<i>Break</i>
11:00	Exercises: Familiarization with the key tools
12:30	<i>Lunch</i>
13:30	Case study #1: Application to a simple project
15:00	<i>Break</i>
15:20	Case study #2: Application to a moderately complex project
16:50	Conclusion and key takeaways
17:30	End of the program

Consulting firm dedicated to the pharma & MedTech sectors operating in the complementary fields of strategy, management and organization

1 Strategy

- **Assessing the attractiveness of markets** (Hospital / retail innovative products - Vaccines - OTC - Generics)
- **Growth strategy**
 - Optimization of marketing / sales investments
 - Development of a company in the hospital market Business
 - Valuation for acquisition
 - Portfolio / franchise assessment
- **Extension of product life cycle performance**
 - Improvement mature products performance
 - Adaptation of price strategy
- **Defense strategies vs. new entrants**
- **Competitive strategies in the hospital market**
- **Strategic partnerships companies / pharmacies**

2 Management

- **Facilitation and structuring of strategic thinking for multidisciplinary product teams**
 - Key challenges identification
 - Strategic options formalization
 - Resource allocation optimization program
- **Training of marketing and market research teams to sales forecast techniques (modeling and scenarios development)**
- **Development and implementation of a "coaching program" for area managers**
 - Sales reps coaching
 - Regional action plans roll-out
- **Development and implementation of a "sales techniques program" for sales forces (STAR¹)**

¹ Sales Techniques Application for Results

3 Organization

- **Rethink of operational units' organization**
- **Improvement of sales force effectiveness**
- **Improvement of the distribution channels covering the hospital and retail markets**
- **Development of a strategic planning process**