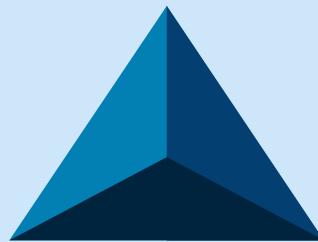


# The Best of Smart Pharma 2016

Concepts

Methods

Tools



**Smart Pharma**  
**Consulting**

## 1. Strategy

- Corporate Reputation
- Patient Centricity
- Market Access
- Creativity & Performance

## 2. Medical Affairs

- KOL Partnership Model
- MSL Best Practices

## 3. Marketing & Sales

- Brand Preference
- High Impact Interactions
- Mature Brand Management

## 4. Management (Bonus 2017)

- Smart vs. Good Managers

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Patient Centric Strategy	p. 23	Mature Brand Management	p. 172
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<b>2. Medical Affairs</b>	<b>p. 85</b>		
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***“Becoming Smarter is our ambition – Delivering Smarter Services our mission –  
Being Innovative our obsession”***

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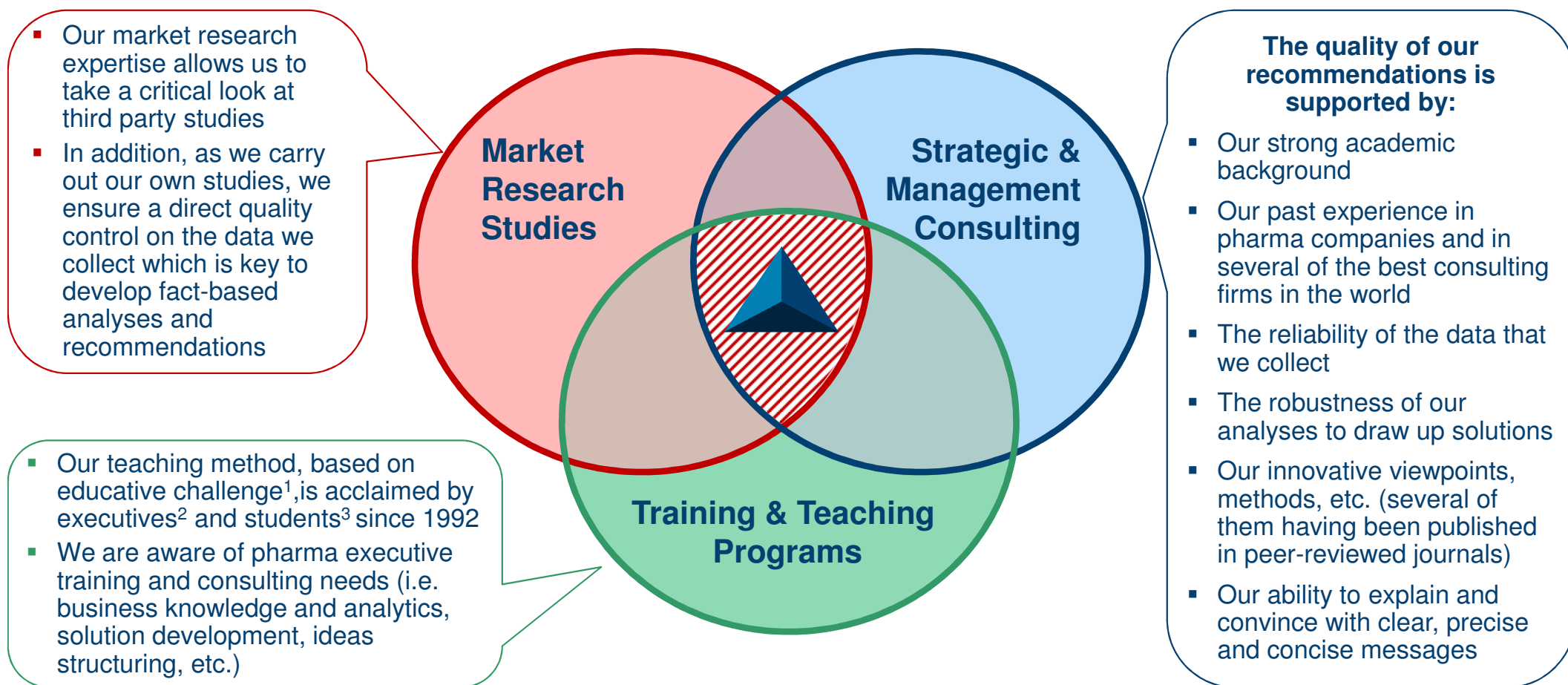
**Key features**

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- For the past 15 years, **becoming Smarter** has been our **corporate ambition**...
- ... and **providing our clients with Smarter services** has been our **corporate mission**
- Smart Pharma Consulting has strived to allocate its resources and to develop its capabilities to:
  1. **Generate** and **disseminate high quality insights** regarding healthcare environment and pharmaceutical market
  2. **Share knowledge** and **thoughts** through **training** and **teaching activities**, as well as through **numerous publications** such as reports, books, articles, position papers
  3. **Offer innovative viewpoints, concepts, methods, tools** and **solutions** that **outperform mainstream ones**

**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**



Sources: Smart Pharma Consulting

<sup>1</sup> Challenge of participants (e.g. analytical rigor, relevance of recommendations, quality of the oral presentations, etc.) – <sup>2</sup> ~800 executives trained – <sup>3</sup> More than 1,750 students trained

The following selection of concepts / methods, tools and opinions, that are available on our website<sup>1</sup>, illustrates our “innovative power”

### Smart Pharma Consulting innovations

	Concepts / Methods	Tools	Opinions
Strategy	<ul style="list-style-type: none"> <li>4Ws</li> <li>Preference-driven Strategy</li> </ul>	<ul style="list-style-type: none"> <li>Development Strategy Matrix</li> <li>Corporate ID Card</li> <li>Advanced SWOT</li> <li>Customer Preference Card</li> <li>Pharma Reputation Index</li> </ul>	<ul style="list-style-type: none"> <li><i>The mirage of the BRIC<sup>2</sup></i></li> </ul>
Marketing / Sales	<ul style="list-style-type: none"> <li>4Ws</li> <li>Brand Preference Mix (BPM)</li> <li>Behavioral Prescriber Segmentation (BPS)</li> </ul>	<ul style="list-style-type: none"> <li>Brand Preference Mix Index</li> <li>Behavioral Prescriber Segmentation (BPS)</li> <li>KEIs<sup>3</sup> vs. KPIs<sup>4</sup></li> <li>Portfolio Strategic Matrix</li> <li>High Impact Interactions (H2I)</li> </ul>	<ul style="list-style-type: none"> <li><i>Brand Preference supersedes Brand Satisfaction</i></li> <li><i>Med Reps are Key to drive Physician Preference</i></li> </ul>
Medical	<ul style="list-style-type: none"> <li>4Ws</li> </ul>	<ul style="list-style-type: none"> <li>KOL ID Card</li> <li>KOL Partnership Plan (K2P)</li> <li>Integrated Regional Strategic Plan</li> </ul>	<ul style="list-style-type: none"> <li>NA</li> </ul>

Sources: Smart Pharma Consulting analysis

<sup>1</sup> [www.smart-pharma.com](http://www.smart-pharma.com) – <sup>2</sup> Brazil, Russia, India, China –

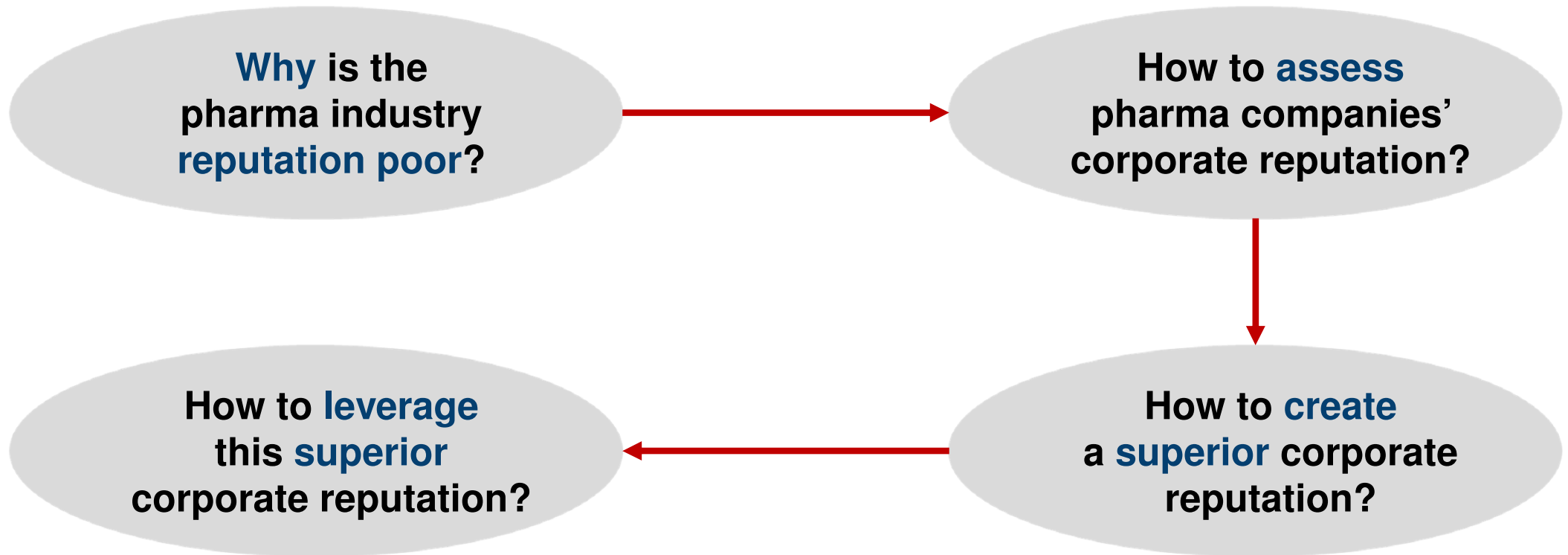
<sup>3</sup> Key execution indicators – <sup>4</sup> Key performance indicators

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Introduction	p. 2	3. Marketing & Sales	p. 129
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This section proposes a practical approach to help pharma companies create a superior corporate reputation and make it a sustainable competitive advantage

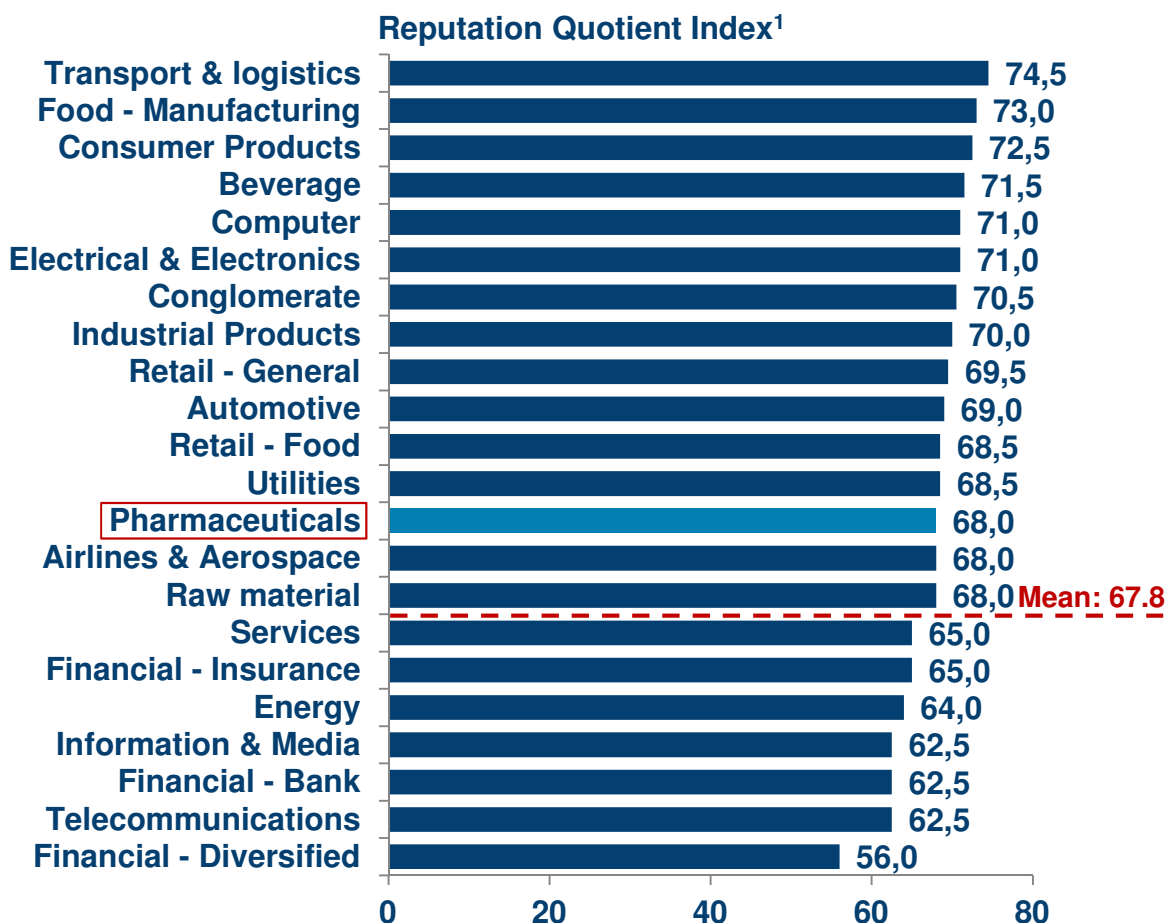
**Key issues addressed**



***“A corporate reputation must not only be good...  
... it must be superior to that of competitors to create a competitive advantage”***

Despite its significant contribution to public health and patients quality of life, the pharma sector does not benefit from a good reputation

### Ranking of pharma industry corporate reputation in the USA (2014)



#### Main reasons for the pharma sector poor reputation

- **Culture & “Life style”:**
  - Perception of over-priced drugs (e.g. oncology drugs)
  - Excessive executive salaries and opulent offices
  - Lack of transparency (e.g. drug pricing, clinical study results, collaborations with KOLs, etc.)
- **R&D & marketing strategies:**
  - R&D priority given to “me-too” products vs. innovative ones/solutions to address neglected pathologies<sup>2</sup>
  - Poor strategy leading to pipelines issues
  - Over-intensive sales and marketing activities representing twice as much as R&D budgets
  - Illegal marketing practices (e.g. off-label promotion)
- **Financial performance:**
  - High level of profitability (10 points of percentage higher than the average of all industrial sectors, over the 2013-2015 period)<sup>3</sup>

*“Distrust of the pharma industry stems from a belief by stakeholders that the industry has deviated from its original vision of improving public health to focus on increasing company profits”*

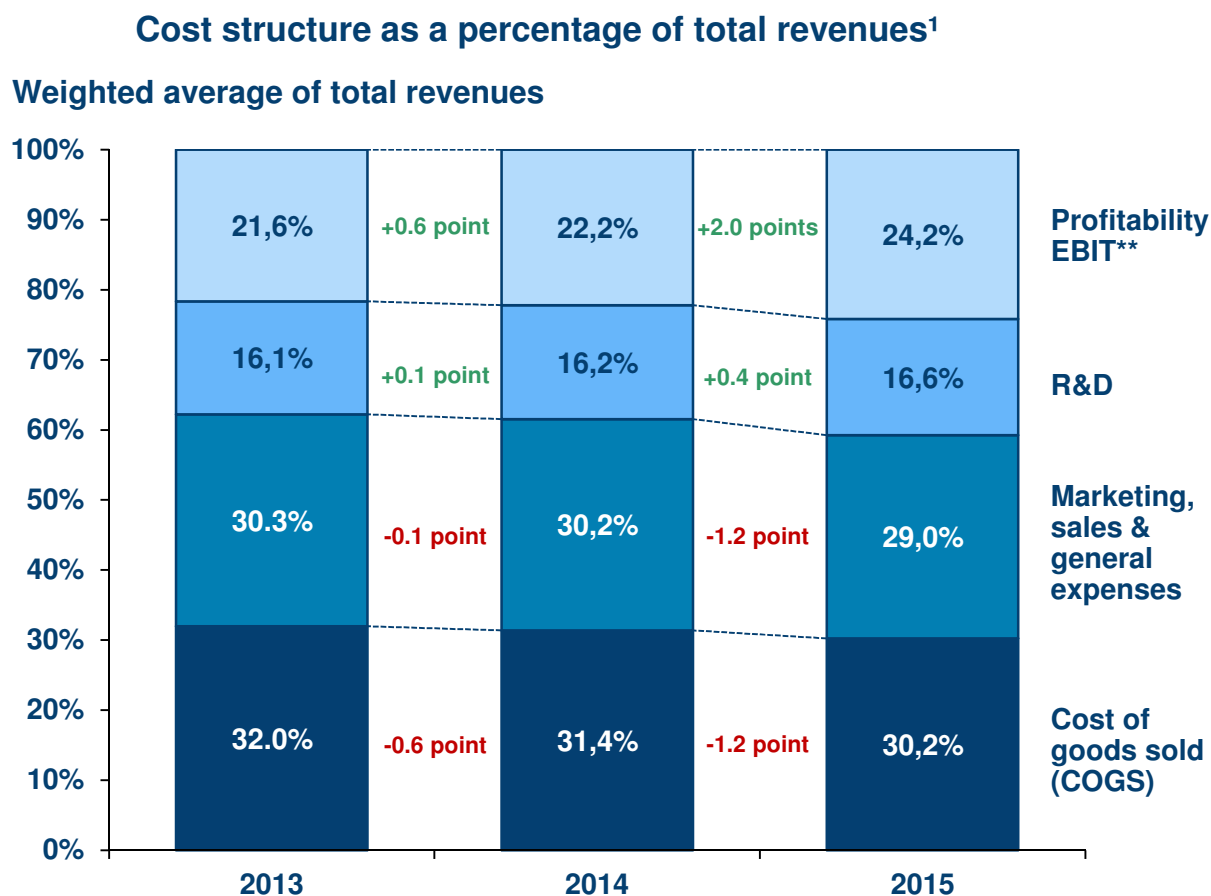
Sources: Reputation Institute 2014 and Smart Pharma Consulting analysis

<sup>1</sup> > 80 = Excellent/Top Tier, 70-79 = Strong/Robust, 60-69 = Average/Moderate, 40-59 = Weak/Vulnerable, < 40 = Poor/BottomTier – <sup>2</sup> Including pathologies widespread in developing countries – <sup>3</sup> Profitability expressed as: net profit / total revenues



Pharma companies are often criticized for investing twice as much in marketing & sales as in R&D and for making profits considered as too high\*

## Evolution of the top 30 pharma cost structure (2013 – 2015)



Comments
<ul style="list-style-type: none"> <li>The average profitability of the top 30 pharma companies in the world has increased by 2.6 points of percentage between 2013 and 2015</li> <li>This improvement can be explained by: <ul style="list-style-type: none"> <li>The restructuring of product portfolio with an increased importance of higher priced secondary care vs. primary care products</li> <li>The marketing and sales investment for these specialist-driven secondary care products which is lower than for GP-driven primary care products</li> <li>Restructuring and streamlining initiatives to improve the economic performance</li> </ul> </li> <li>These good financial performances contribute to deteriorate the reputation of the pharma sector as it is perceived by the general public and health authorities...</li> <li>... while the effect is opposite on investors and shareholders</li> </ul>

Note: panel of the 30 biggest pharma companies in terms of prescription sales as of 2014

\* 10 points of percentage higher than the average of all industrial sectors, over the 2013-2015 period

\*\* Earnings before interests and taxes

Sources: Companies annual reports – Federal Reserve annual exchange rates – Smart Pharma Consulting estimates

<sup>1</sup> Excluding Astellas, Daiichi Sankyo and Takeda for which FY2015 financial reports were not published at the moment of the study (due to their fiscal years ending in March) – Excluding for 2015 Actavis which merged with Allergan – Excluding Servier over the whole period for not publishing financial results and Boehringer Ingelheim for publishing non-standardized financial results

The global and individual reputation of pharma companies can be improved through a higher focus on innovative R&D, access programs and ethic in business practices

### Global corporate reputation of the pharma industry

#### The 3 pillars of corporate reputation in the pharma industry

Involvement in R&D and innovation	Access initiatives & CSR <sup>1</sup>	Ethic in business and marketing practices
<ul style="list-style-type: none"> <li>Focus investments on current unmet medical needs rather than on market potential only</li> <li>Keep an R&amp;D / marketing &amp; sales investment ratio &gt;1</li> <li>Invest in R&amp;D and in manufacturing in countries of interest</li> </ul>	<ul style="list-style-type: none"> <li>Ensure access to the medicines to every patient (through performance-based pricing agreements with payers, financial support for uninsured patients)</li> <li>Propose initiatives focused at patients aiming at improving education / compliance / use</li> <li>Focus on your employees satisfaction at work</li> </ul>	<ul style="list-style-type: none"> <li>Communicate transparently regarding R&amp;D costs and results, pricing and marketing practices</li> <li>Avoid over-claim and provide objective information</li> <li>Patient-focused initiatives aiming at a better education / compliance / products good use</li> </ul>

**Communication** (direct by pharma companies and indirect by external influencers)<sup>2</sup>

***“Reputation and trust are not a given!***

***They are earned through actions, results, and the way companies communicate to stakeholders”***

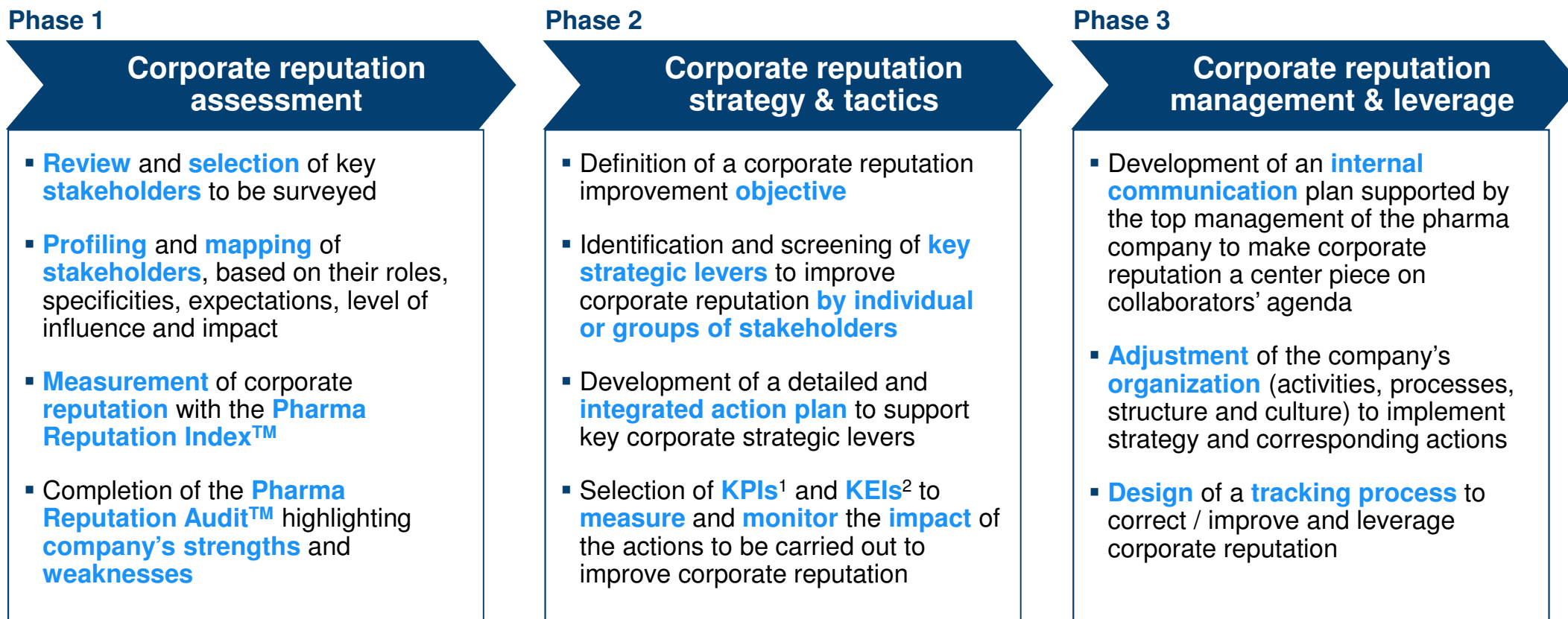
Sources: “The reputation, image and influence of the pharmaceutical industry: Regaining credibility”, Journal of Medical Marketing, 2007 – Smart Pharma Consulting analysis

<sup>1</sup> Corporate Social Responsibility –  
<sup>2</sup> Politics, pressure groups including patient advocacy groups, activists, journalists,

Smart Pharma Consulting has developed a specific approach to leverage corporate reputation to create a sustainable competitive advantage

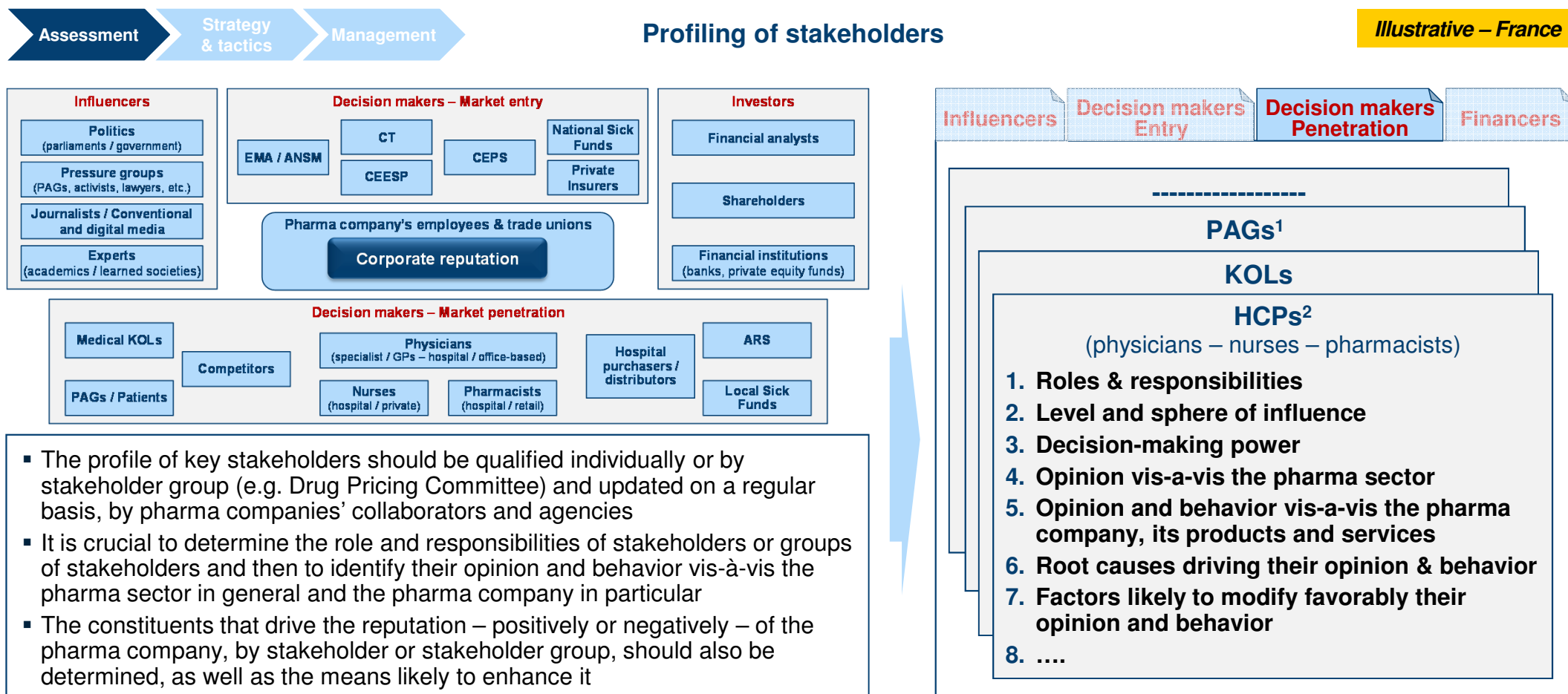
## “Pharma Corporate Reputation Booster™”

From diagnosis to strategy implementation



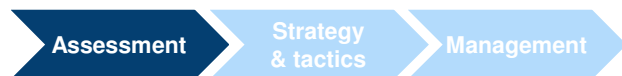
**Key stakeholders need to be carefully and precisely profiled, on an on-going basis, before any attempt to measure the reputation of the companies**

**Phase 1: Corporate reputation assessment**



Corporate reputation depends on drivers that need to be measured by individual or groups of stakeholders with tools such as the Pharma Reputation Index™

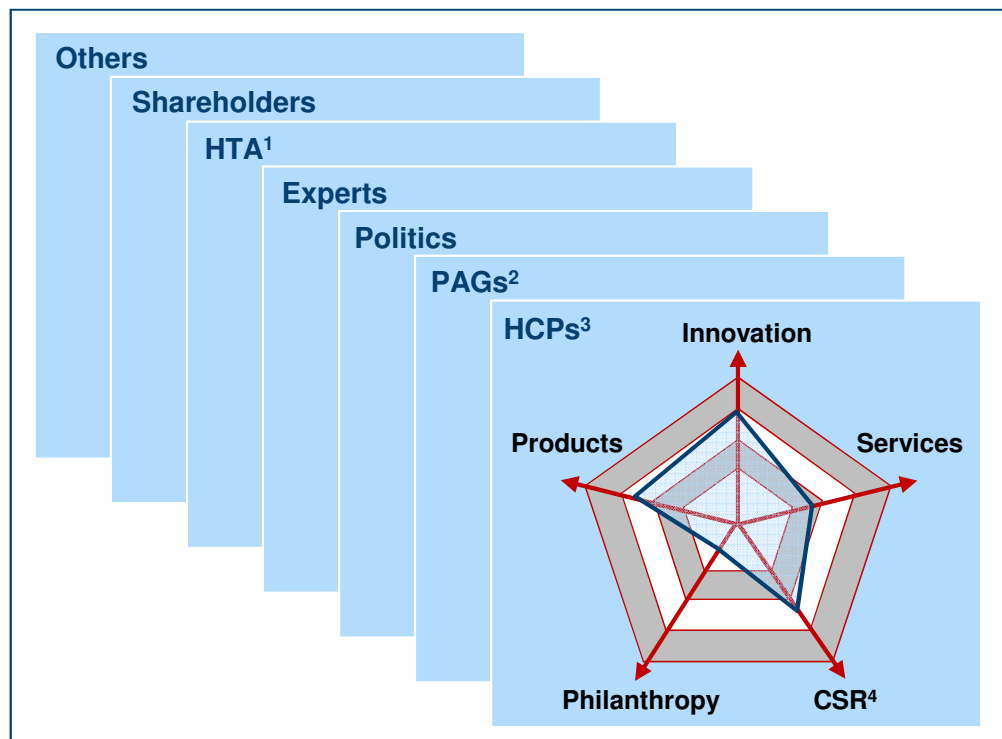
**Phase 1: Corporate reputation assessment**



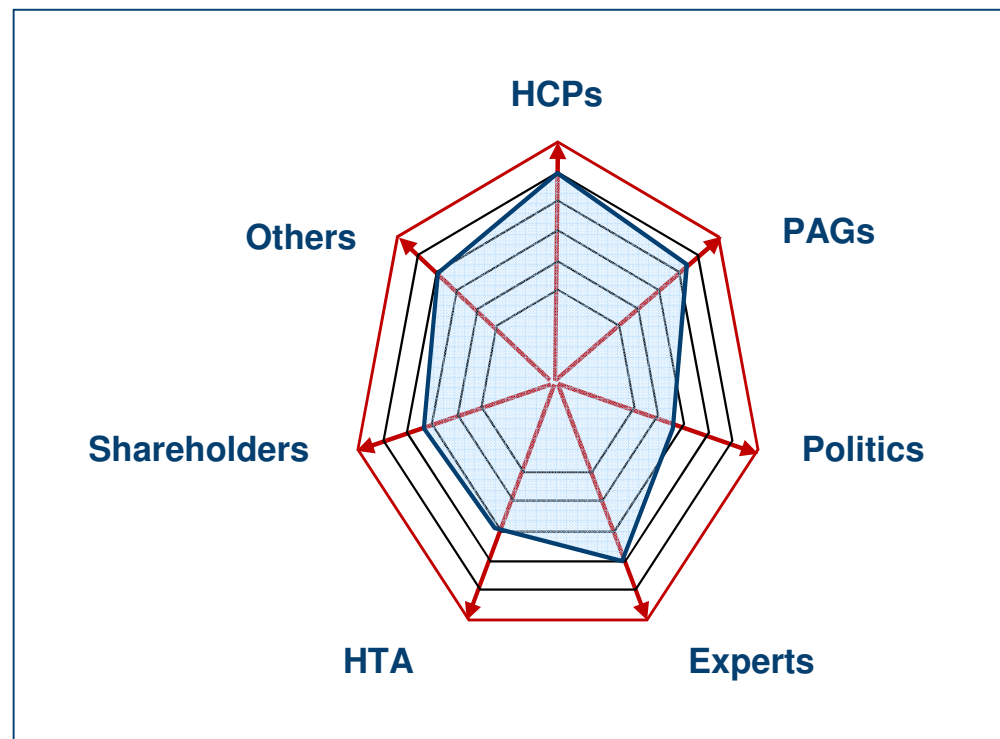
**Pharma Reputation Index™**  
Measurement of corporate reputation

*Illustrative – France*

Specific reputation drivers by stakeholder



Global reputation index by stakeholder group



The Pharma Reputation Audit™ developed by Smart Pharma Consulting facilitates the identification of key challenges to create superior corporate reputation

## Phase 1: Corporate reputation assessment



Pharma Reputation Audit™  
Strengths & weaknesses highlight

Illustrative – France

Influencers	Decision makers Entry	Decision makers Penetration	Financers						
EMA <sup>1</sup> / ANSM <sup>2</sup>	CT <sup>3</sup>	CEESP <sup>4</sup>	CEPS <sup>5</sup>	National Sick Funds	Private Insurers				
Corporate reputation drivers per stakeholder group									
Item		Description				Relative performance <sup>6</sup>			Corporate reputation challenges
						Superior	Equal	Inferior	
1. R&D and innovation							✓		
1.1 Response to unmet medical needs							✓		
1.2 Robustness of clinical data								✓	
2. Services “around the pill”						✓			
3. Business & marketing ethics							✓		
4. Corporate Social Responsibility						✓			
5. -----						✓			

Sources: Smart Pharma Consulting analyses

<sup>1</sup> European Medicines Agency – <sup>2</sup> French national agency for medicines and health products safety – <sup>3</sup> Transparency commission – <sup>4</sup> Health economic evaluation committee – <sup>5</sup> Drug pricing committee – <sup>6</sup> Vs. other pharma companies, including competitors or vs. previous period

The Pharma Reputation Strategy Card™ can be filled up for one or several groups of stakeholders, from whom an improvement in reputation is expected

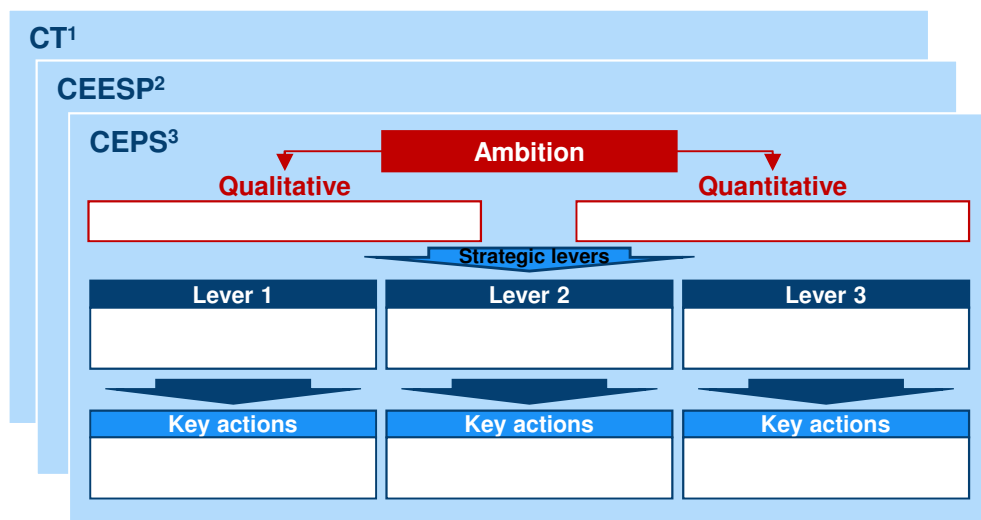
**Phase 2: Corporate reputation strategy & tactics**



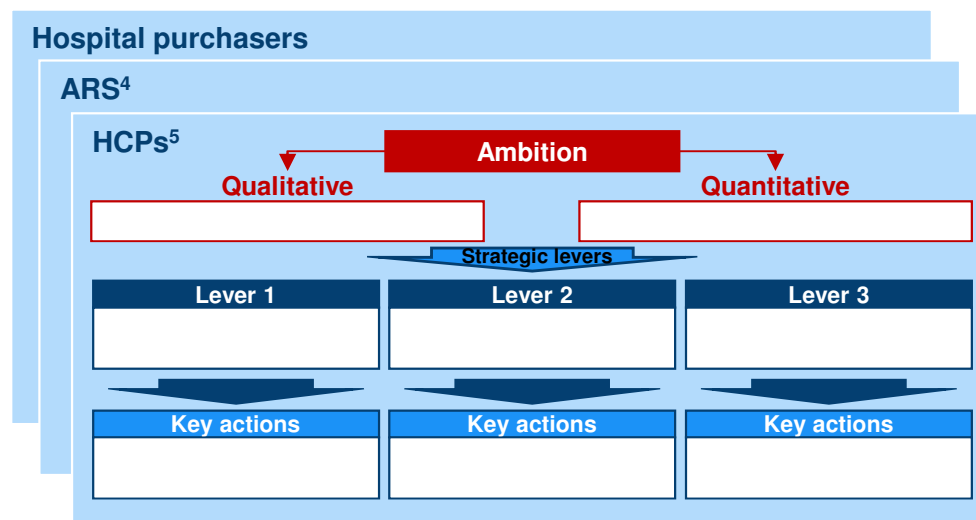
**Pharma Reputation Strategy Card™**

*Illustrative – France*

**Decision makers – Market entry**



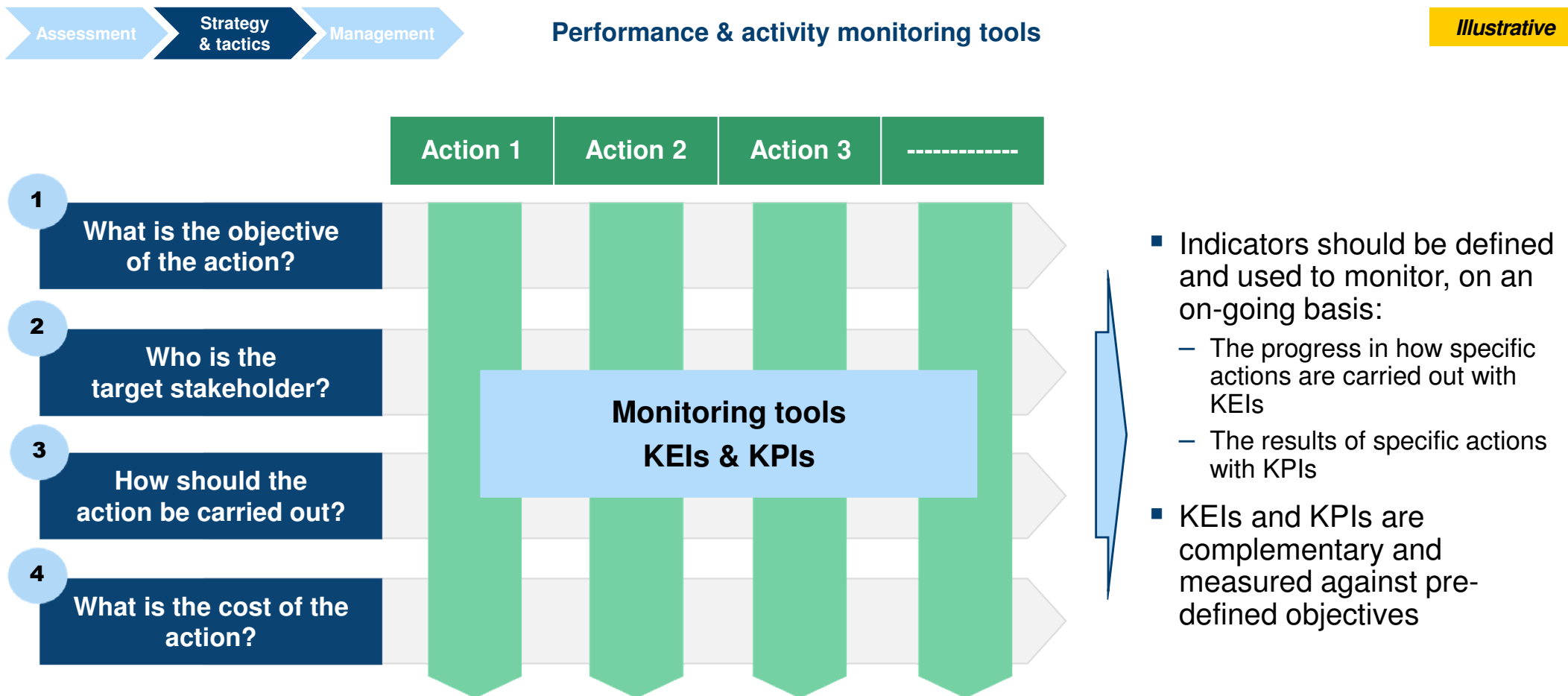
**Decision makers – Market penetration**



- Strategy and related actions aim at achieving the set ambition in terms of corporate reputation improvement
- The Pharma Reputation Strategy Card™ can be applied for one stakeholder group (i.e. CT, CEESP, CEPS, etc.) or for one individual stakeholder (i.e. the President of the CEPS)
- Strategic levers correspond to strengths on which the company should capitalize or weaknesses to be corrected to reinforce its competitive position

KEIs<sup>1</sup> are used to evaluate the quality of implementation of the actions likely to enhance the corporate reputation, while KPIs<sup>2</sup> measure the impact of these actions

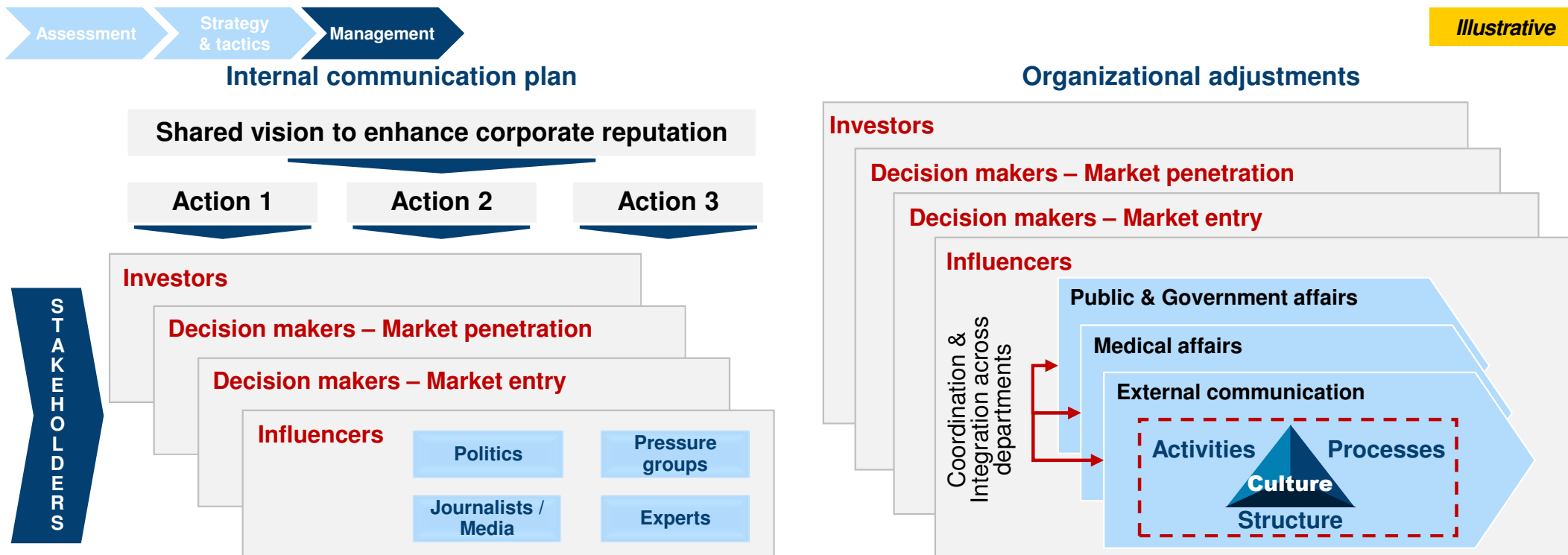
**Phase 2: Corporate reputation strategy & tactics**





The proper management of corporate reputation is conditioned by internal mobilization of collaborators and adjustment of the company's organization

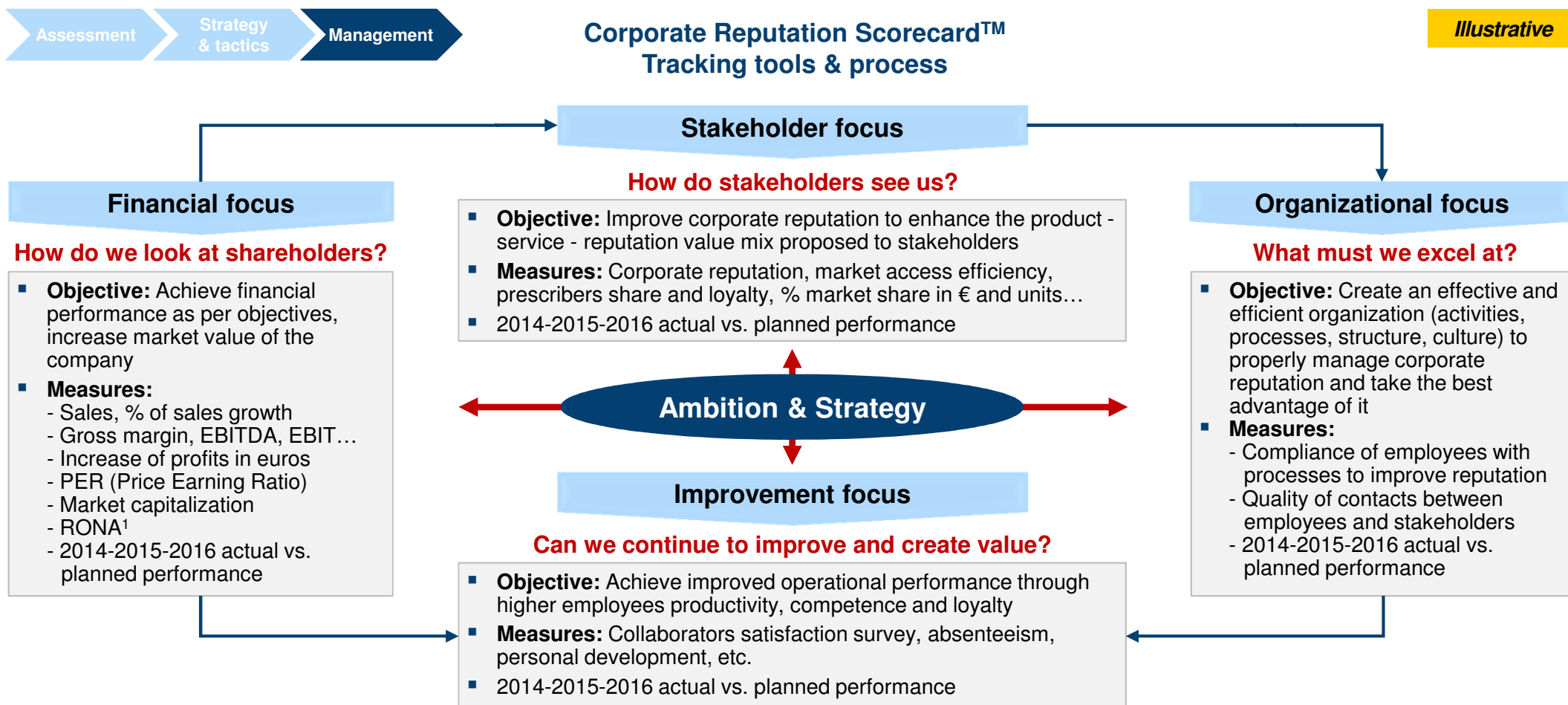
**Phase 3: Corporate reputation management**



- A common vision, instilled by the top management and consistently communicated across the company, is a prerequisite to create the desired corporate reputation
- Corporate vision should be translated into specific and relevant actions implemented by collaborators
- Collaborators interacting with the same stakeholders should share information and coordinate their actions for a better efficiency and efficacy, and thus contribute to reinforce the corporate reputation

The corporate reputation management and its impact on the a company performance should be tracked with tools such as the Corporate Reputation Scorecard™

**Phase 3: Corporate reputation management**

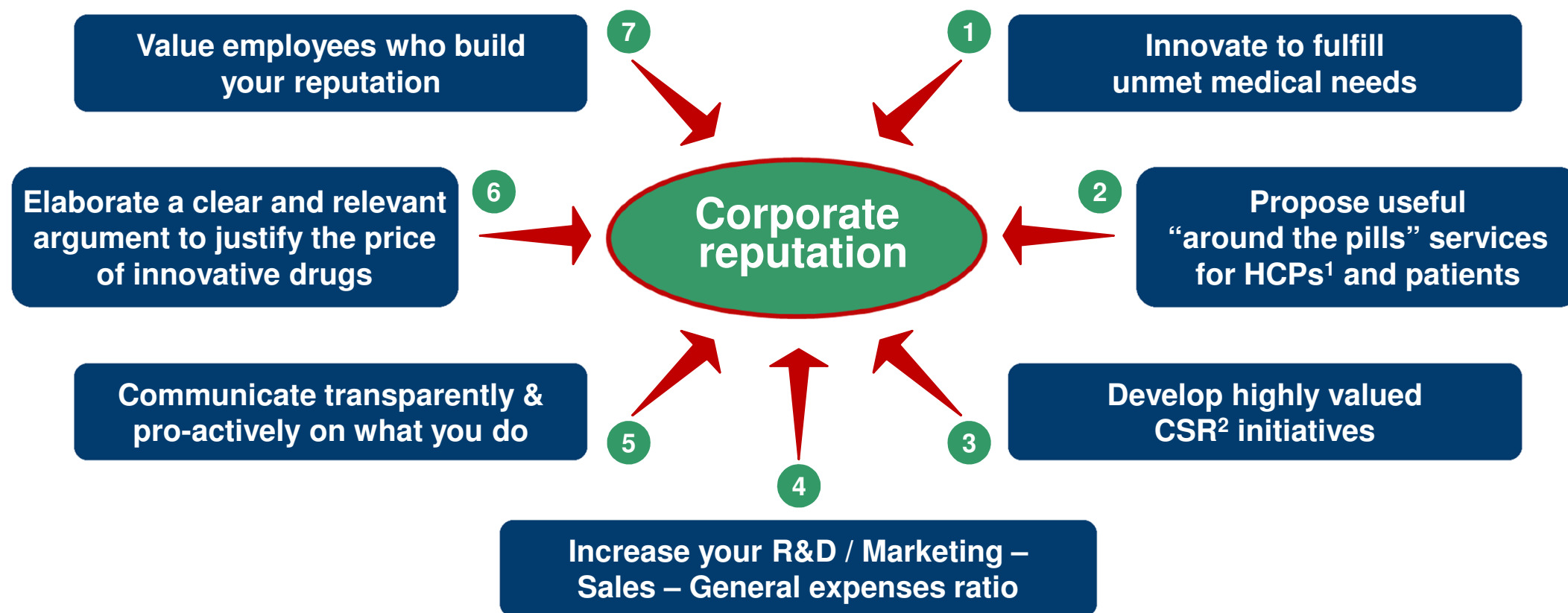


Sources: Adapted from R. Kaplan and D. Norton 1996 by Smart Pharma Consulting

<sup>1</sup> Return On Net Assets

Pharma companies must put customers (especially patients) in the center of their strategy and be as transparent as possible to get trusted and esteemed by stakeholders

**7 tips to improve the reputation of pharma companies**

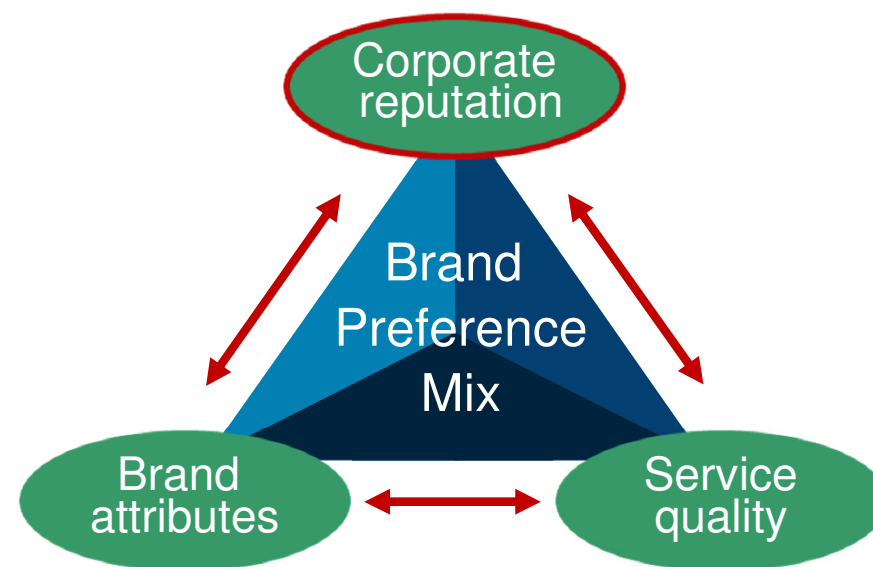


***“Don’t let anyone communicate on your behalf: tell yourself who you are and what you do”***

**With dwindling product differentiation, corporate reputation contributes to strengthen the preference of stakeholders (e.g. authorities, payers, HCPs, patients, investors)**

**Why superior corporate reputation creates competitive advantage?**

- Correlation between financial performance and corporate reputation has been clearly evidenced<sup>1</sup>
- A 5 point increase in reputation has shown to result in a 8.5% increase in stakeholders' recommendations<sup>2</sup>
- A high corporate reputation, perceived as superior to that of competitors', will:
  - Lead to a more favorable position to negotiate with health authorities and payers resulting in better prices and earlier market entries
  - Strengthen the brand preference by HCPs, KOLs, PAGs, patients, etc., resulting in market share gains
- Companies' experience / expertise in certain therapeutic areas must be communicated with robust scientific support to enhance the perception of individual brands value by decision makers at market entry and penetration levels
- Strong positive reputation is built on credibility, reliability, responsibility, trust and transparency



***“A strong corporate reputation is characterized by trust and esteem, which generates stakeholders’ preference”***

## Smart Pharma Consulting's know-how and methodology can help pharma companies strengthen their corporate reputation and use it as a competitive lever

### How can Smart Pharma Consulting boost your corporate reputation?

Smart Pharma Consulting can support pharma companies throughout all the phases that participate to build a strong corporate reputation and transform it into a sustainable competitive advantage:

- Research and assessment of current corporate reputation among stakeholders, at local, national or international level
- Definition of a realistic corporate reputation enhancement objective by group of stakeholders
- Development of an appropriate strategy and selection of the corresponding actions to achieve the target reputation
- Selection of the KEIs<sup>1</sup> and the KPIs<sup>2</sup> to measure the gap between the current and the target reputation
- Development of an internal communication plan and of a management program to create a stakeholder-focused company
- Adjustment of the company's organization (activities, processes, structure, culture) to efficiently implement the pre-set strategy and the corresponding actions, and to leverage the benefits of a positive corporate reputation
- Design of a tracking process to improve and leverage corporate reputation

***“Select two or three dimensions and strive to be recognized as a role model by stakeholders to differentiate your company from the other pharma companies”***

If you have ticked one “No box” or more, it means that there is a room to enhance your corporate reputation and differentiate yourself from other pharma companies

### Pharma superior corporate reputation self-assessment in 10 questions

Most of stakeholders (influencers – decision makers – investors)<sup>1</sup> esteem ...

		YES*	NO*
1	... Your high level of R&D investment and your effort to fulfill medical unmet needs	<input type="checkbox"/>	<input type="checkbox"/>
2	... The quality of your product portfolio	<input type="checkbox"/>	<input type="checkbox"/>
3	... The quality of services you propose to HCPs <sup>2</sup>	<input type="checkbox"/>	<input type="checkbox"/>
4	... The quality of services you propose to patients (services “around the pill” for better results and quality of life)	<input type="checkbox"/>	<input type="checkbox"/>
5	... Your involvement in “Corporate Social Responsibility” initiatives	<input type="checkbox"/>	<input type="checkbox"/>
6	... Your philanthropic initiatives	<input type="checkbox"/>	<input type="checkbox"/>
7	... The transparency of your corporate communication	<input type="checkbox"/>	<input type="checkbox"/>
8	... The professionalism and the ethical behavior of you collaborators	<input type="checkbox"/>	<input type="checkbox"/>
9	... The working atmosphere of your company, as testified by your employees	<input type="checkbox"/>	<input type="checkbox"/>
10	... The good and sustainable financial performance of your company	<input type="checkbox"/>	<input type="checkbox"/>

\* If stakeholders do not know or if you do not know what do they think, in both cases tick the box NO

This section proposes guidelines to define a patient-centric strategy and the corresponding initiatives to create value for all stakeholders

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**Key issues addressed**

---

1. **What** does patient centricity **mean**?

2. **Why** is patient centricity **essential**?

3. **How** to **craft** a patient-centric **strategy**?

4. **How** to **implement** patient-centric **initiatives**?

*“Put patients first and profits will follow”* – George W. Merck<sup>1</sup>

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<sup>1</sup> Adapted from the following quote of George W. Merck, Former President & Chairman of Merck & Co: “We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we have remembered it, the larger they have been”

More and more pharma companies have been communicating over the past years that patients are at the heart of their strategy

### Is it a buzzword? (1/3)



*“Our business is focused on making the most meaningful difference to patient health through great medicines”*

Illustrative<sup>1</sup>

*“We are dedicated to improving the quality of human life by enabling people to do more, feel better and live longer”*



*“Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world”*

*“We make products and services with the purpose of making a difference and having an impact in people’s everyday lives”*



*“Our mission is to discover new ways to improve and extend people’s lives”*

*“UCB is inspired by patients and driven by science. Patients are at the heart of everything we do”*



*“Everything we do - from producing pharmaceuticals to offering numerous other relevant services - is patient-driven”*



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**If patient-centricity is a stated priority, it has taken on different meanings and led to different types of projects of variable scope, depending on the pharma companies**


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**Is it a buzzword? (2/3)**

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- The concept of patient centricity is widely used in the pharma sector and can be defined as:

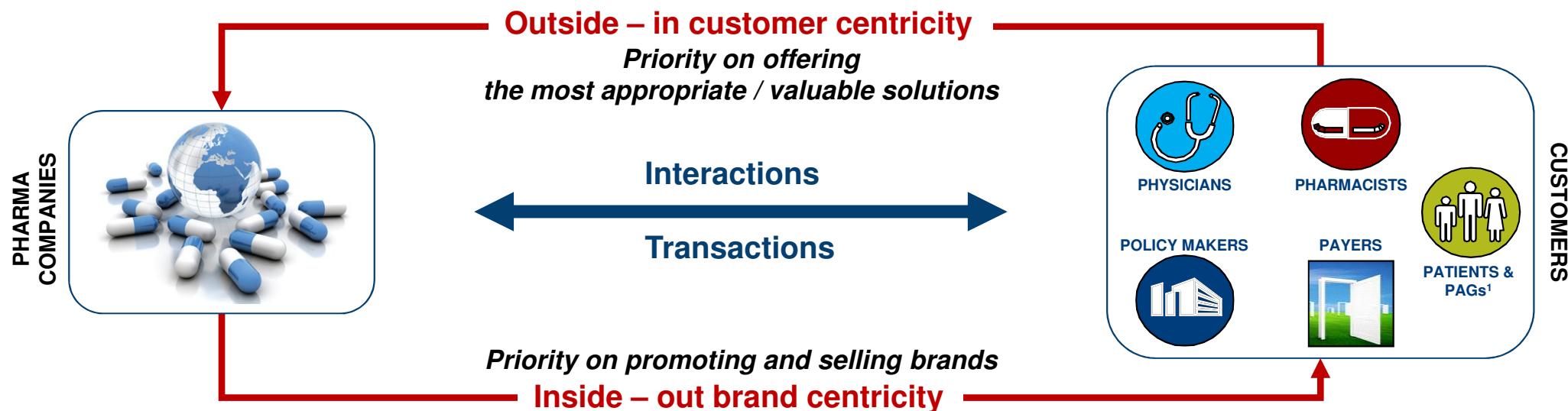
*“Offering solutions (products and/or services) – directly or indirectly – to patients from which they can benefit in terms of medical results and / or quality of life”*

- In practice, patient-centric strategies have been materialized in business initiatives very different in nature and importance, ranging:
    - From publishing disease-related documents
    - To involving patients in key decisions all along the life cycle of a drug
    - Via bringing a support along the patient journey with specific services
- 
- Patient-centricity should not be just another buzzword because it is relevant for pharma companies:
    - To craft their business strategy, based on the end customers' needs and wants, i.e. the patients
    - To make sure that patients will get the best medical outcomes and quality of life, considering their disease and the treatment they have been prescribed by physicians and this, along the patient journey

**Patient centricity is one component of the customer centricity strategy which consists in going that extra mile to provide entire satisfaction to customers**

**Is it a buzzword? (3/3)**

- Patient centricity is part of the customer centricity concept which has become one of the strategic pharma companies' priorities for a decade or so
- Customer centricity is about building positive experiences with customers through the quality of interactions and/or the benefits provided by products or related services offered by the companies
- Amongst the different customers, patients occupy a particular position in the sense that they are the end customers and as such the customers of all the other stakeholders of the pharma market

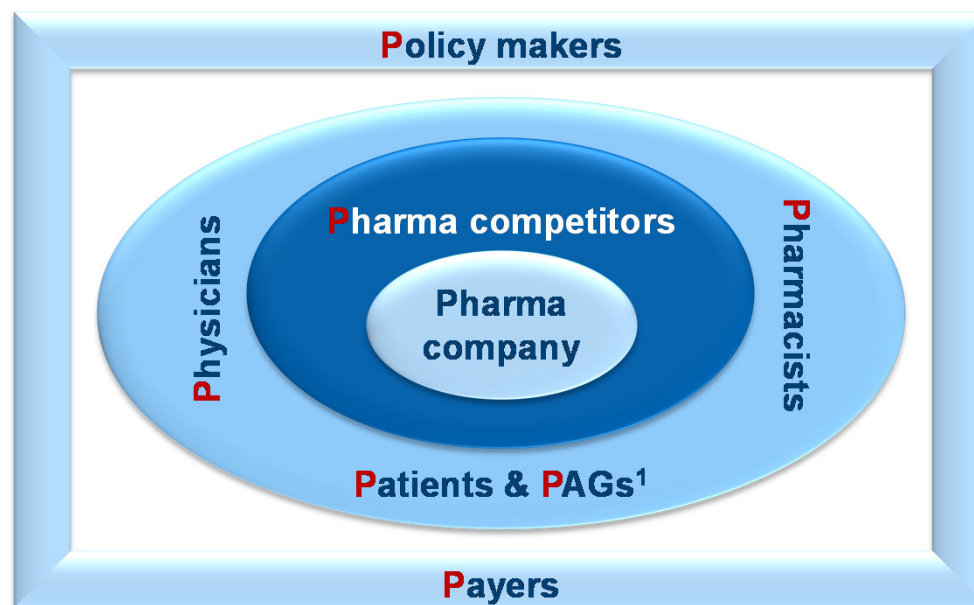


**Patients and patients advocacy groups represent two of the seven key pharma stakeholders groups whose power of influence has recently increased**

**Importance of patients & PAGs<sup>1</sup> in the pharma business model**

Patients
<ul style="list-style-type: none"> <li>Patients are becoming more aware and knowledgeable (medical information is easily accessible on the Internet)</li> <li>Their power is increasing with digital technologies, social networks and the support of PAGs</li> <li>Patients are more demanding:                             <ul style="list-style-type: none"> <li>They want the most effective and best tolerated drugs...</li> <li>... that are easy-to-use...</li> <li>... and available at an affordable price</li> </ul> </li> </ul>

Key pharma stakeholder groups: The 7Ps



PAGs
<ul style="list-style-type: none"> <li>Patient organizations are also more influential</li> <li>They exert a growing power of influence and may be part of the policy-maker / payer decision-making processes</li> <li>Thus, PAGs can support pharma companies they have partnered with if they adhere to their strategy</li> <li>On the contrary, they can damage the corporate reputation of companies with which they don't have good relationships and with which they don't share the same strategic vision</li> </ul>

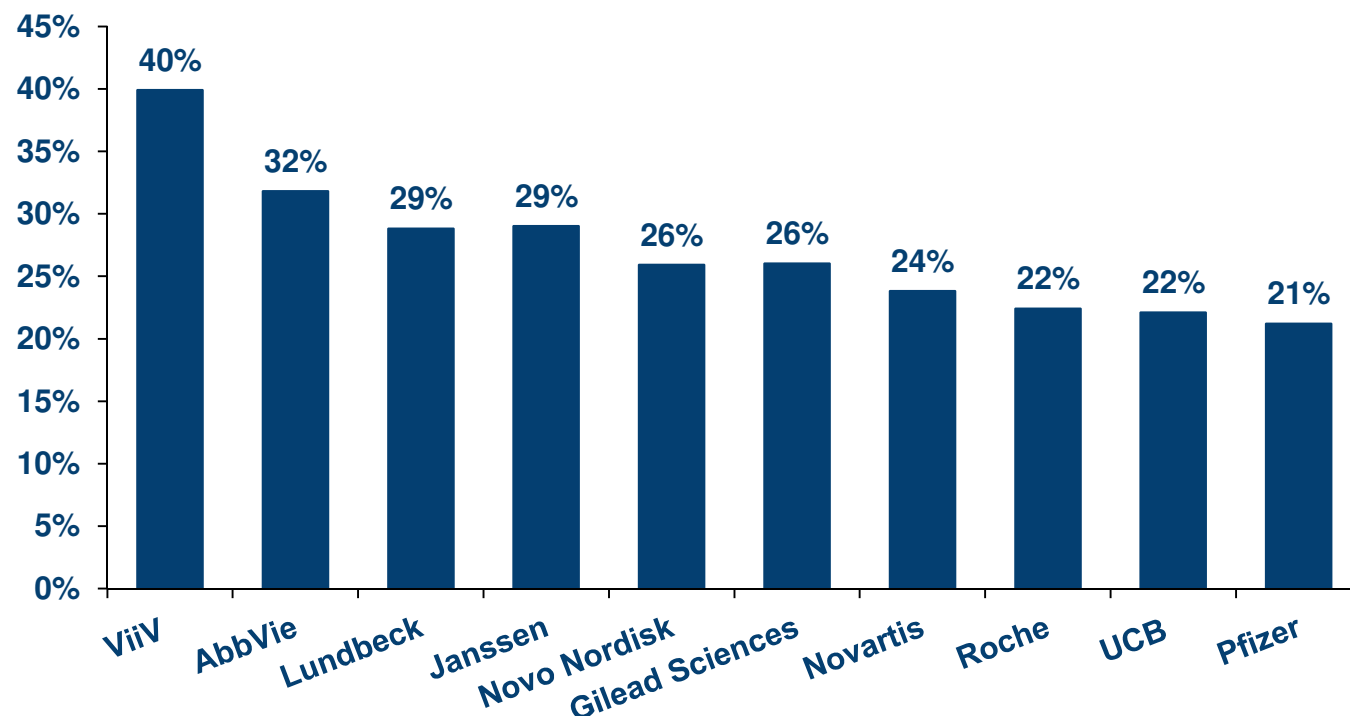
*“The patient voice gaining power and reach, it is going to play an increasing role on corporate reputation and will impact the products all along their life cycle”*

A recent survey has shown that pharma companies having the best reputation, from the patient perspective, are very active in supporting patient-centric projects

## Pharma company reputation assessment by patients (2015 – 2016)

Corporate reputation – Ranking of the 10 performers

Average score<sup>1</sup>



Viiv has built strong relationships with patients by funding numerous patient-centric projects to support communities affected by HIV, across the world, especially in Europe and Africa

- The corporate reputation of pharma companies from the patient perspective has been assessed through **six indicators**:
  1. Patient centricity
  2. Patient information
  3. Patient safety
  4. Usefulness of products
  5. Transparency
  6. Integrity
- Patient groups opinion is mainly driven by:
  - Number and value of new drugs
  - Post-patent expiry strategy (e.g. pricing, generics defense initiatives, etc.)
  - Mergers & Acquisitions (e.g. financial / tax optimization vs. strategic rationale)
  - Drug pricing and market access
  - Corporate behaviors (e.g. transparency, ethics, etc.)

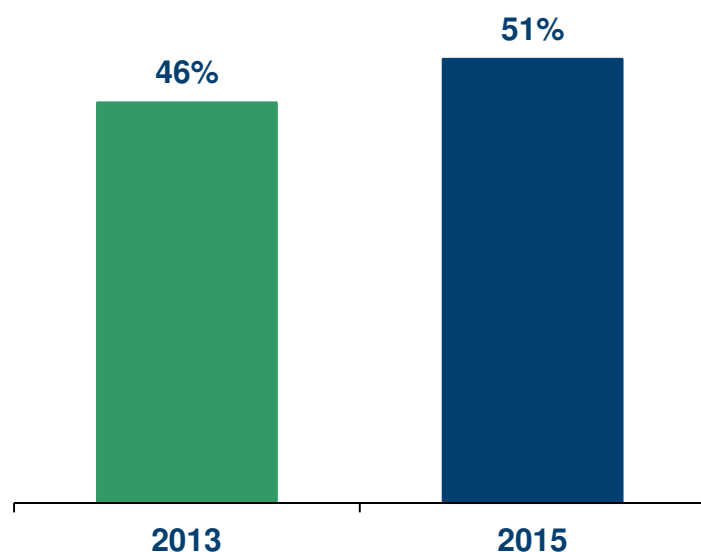
Sources: PatientView 2016 (1,075 patient groups from 72 countries have been interviewed from November 2015 to January 2016 to assess 48 pharma companies)

<sup>1</sup> The average score is obtained by adding and averaging the percentage scores (i.e. percentage of patient groups stating that the company is "best") attained by the companies across the six indicators of corporate reputation

According to pharma companies' executives, patient-centric capabilities are slightly improving while they offer a large variety of patient-centric services

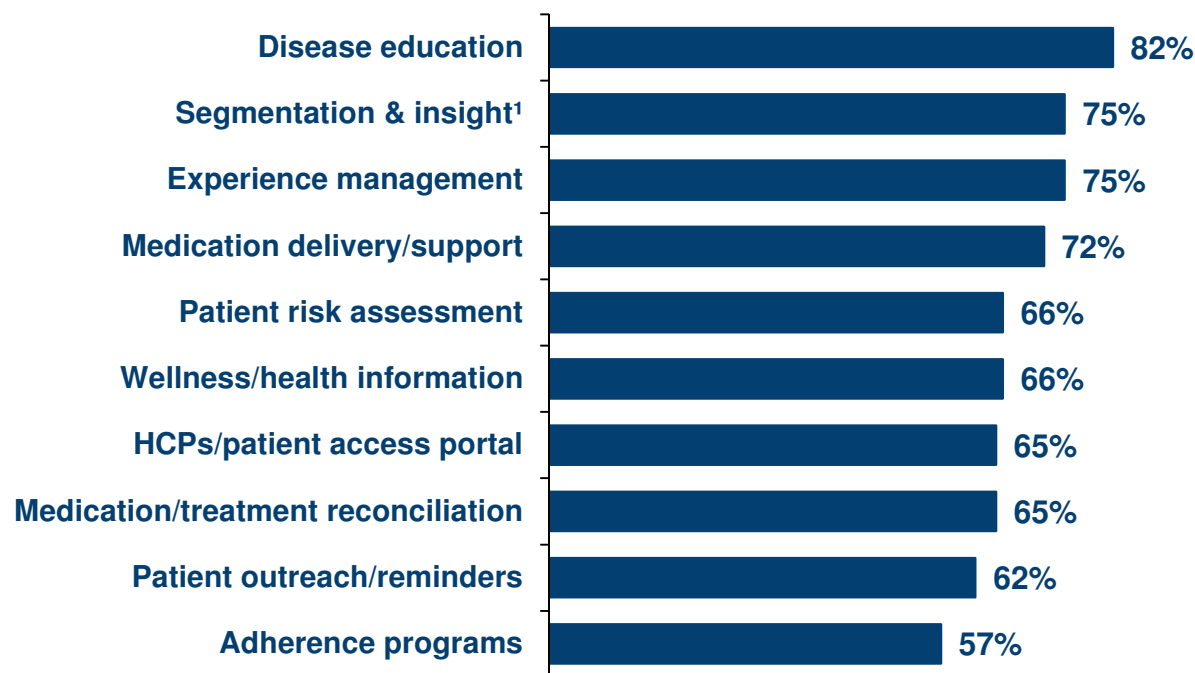
**Patient-centricity viewed by pharma companies (2016)**

Patient-centric capabilities with pharma companies



% of respondents rating capabilities as strong

Top 10 patient-centric services offered by pharma companies



% of respondents having cited these services amongst the top three

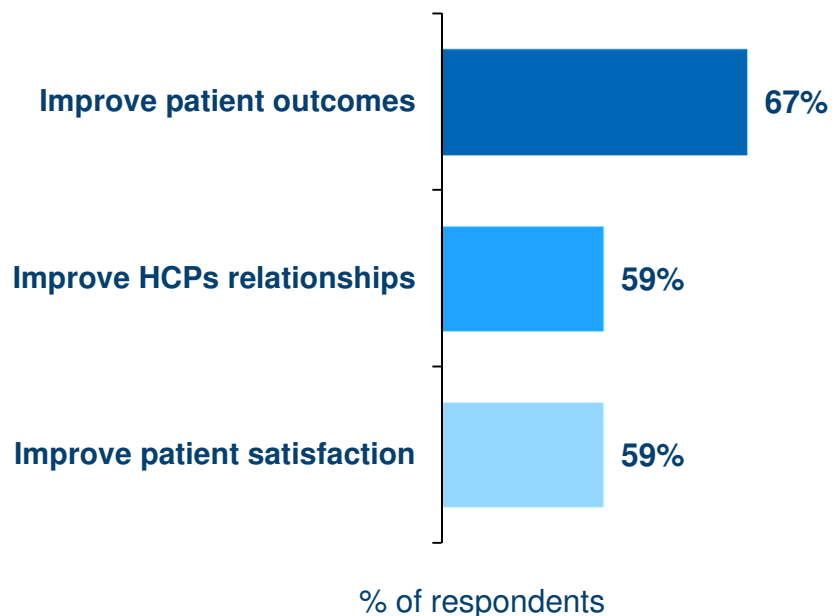
Sources: Accenture 2015 Survey regarding Patients Services delivered by pharmaceutical companies (interviews of 203 pharma executives based in the USA and Europe) – Smart Pharma Consulting analysis

<sup>1</sup> Refer to the segmentation of patients into groups sharing the same behavioral profile to better fulfil their individual needs

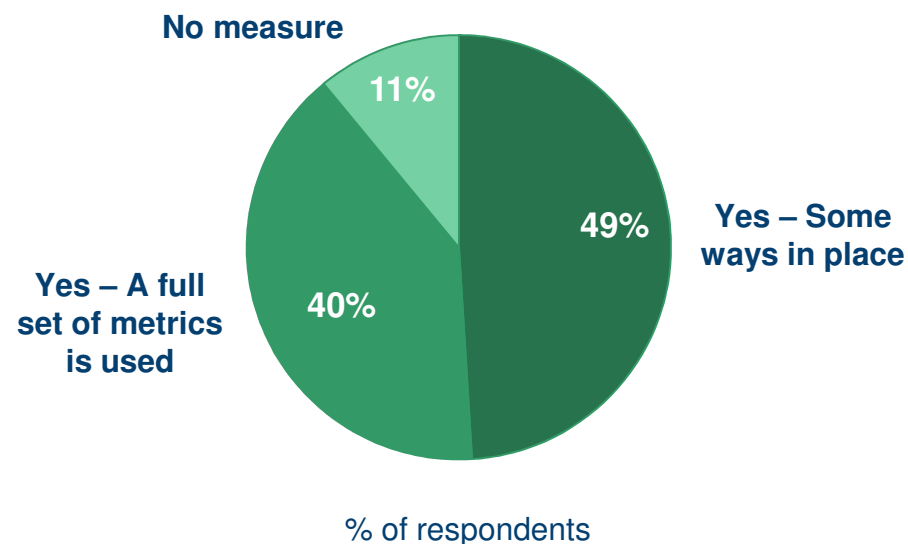
**Offering patient services is a good decision, provided these services are actually used and they demonstrate their positive impact with the help of reliable metrics**

**Objectives & impact measurement as viewed by pharma companies (2016)**

What are your objectives in offering patient services?<sup>1</sup>



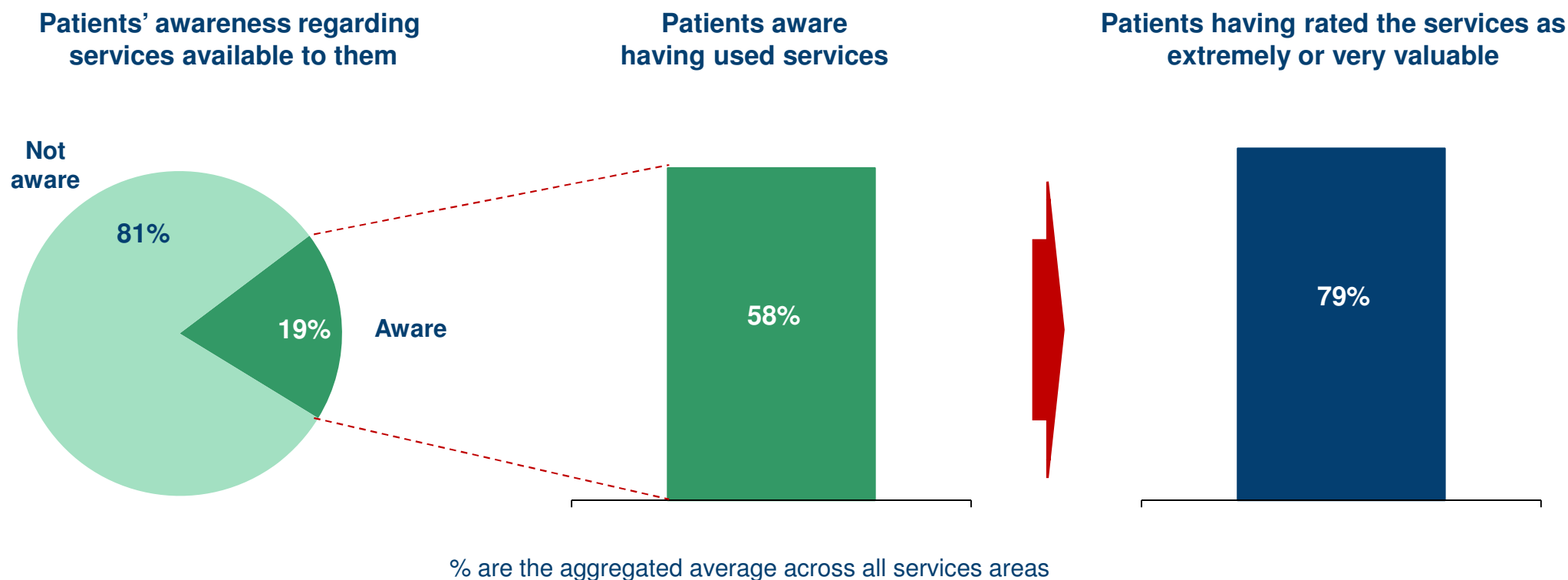
Are you able to measure the impact of these services?<sup>1</sup>



- Offering services is a good start, but it is not sufficient
- Pharma companies must prove with tangible and reliable data that the patient services they invest in have a positive impact for the patients and create value, in return, for the company

**Patients' awareness regarding services available to help them is low, but when they are aware, they use them and are in general very satisfied**

**Awareness – Usage – Valuation of patients services (2015)**

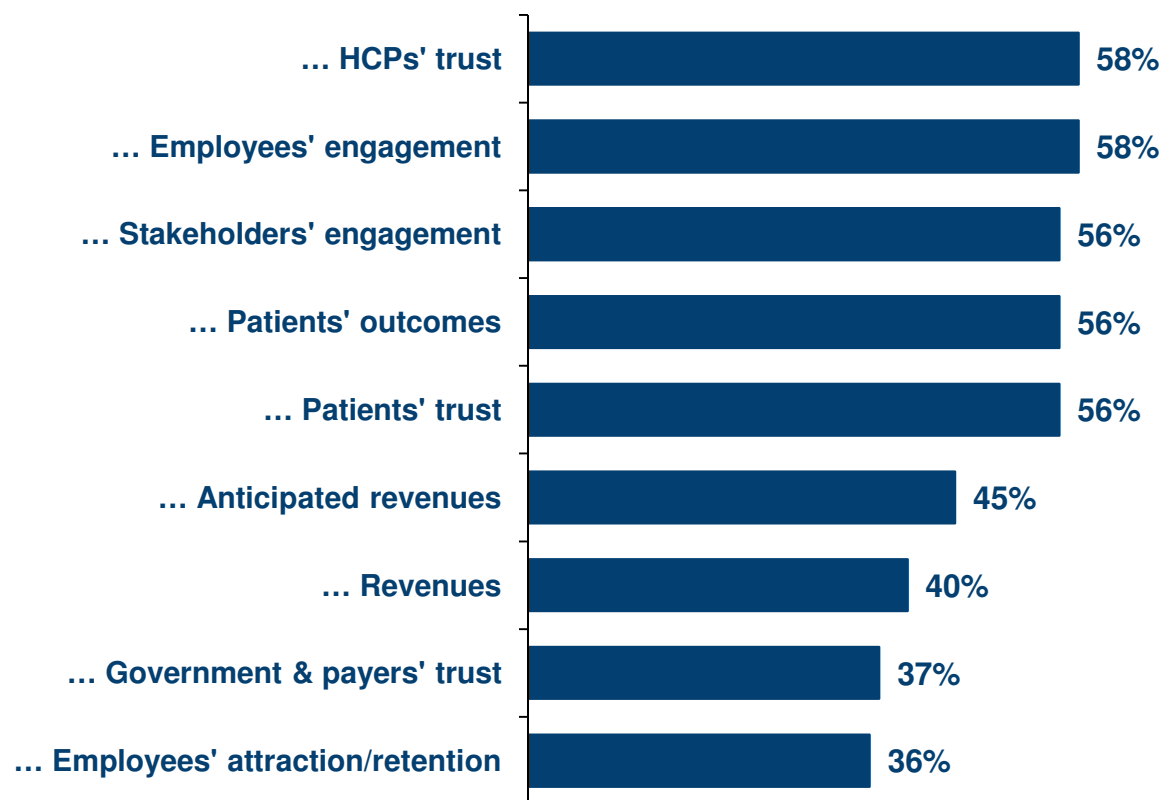


If services are associated with products marketed by pharma companies they may expect to gain trust and respect amongst the stakeholders (e.g. policy makers, payers, HCPs, PAGs)

**There is a growing body of empirical evidence to support the fact that patient-centric initiatives may have a positive impact on pharma companies profitability**

**Impact of patient services on pharma companies profitability (2016)**

93% of the 2,346 respondents believe that patient-centric strategy improves the overall pharma companies' business outcomes by increasing...



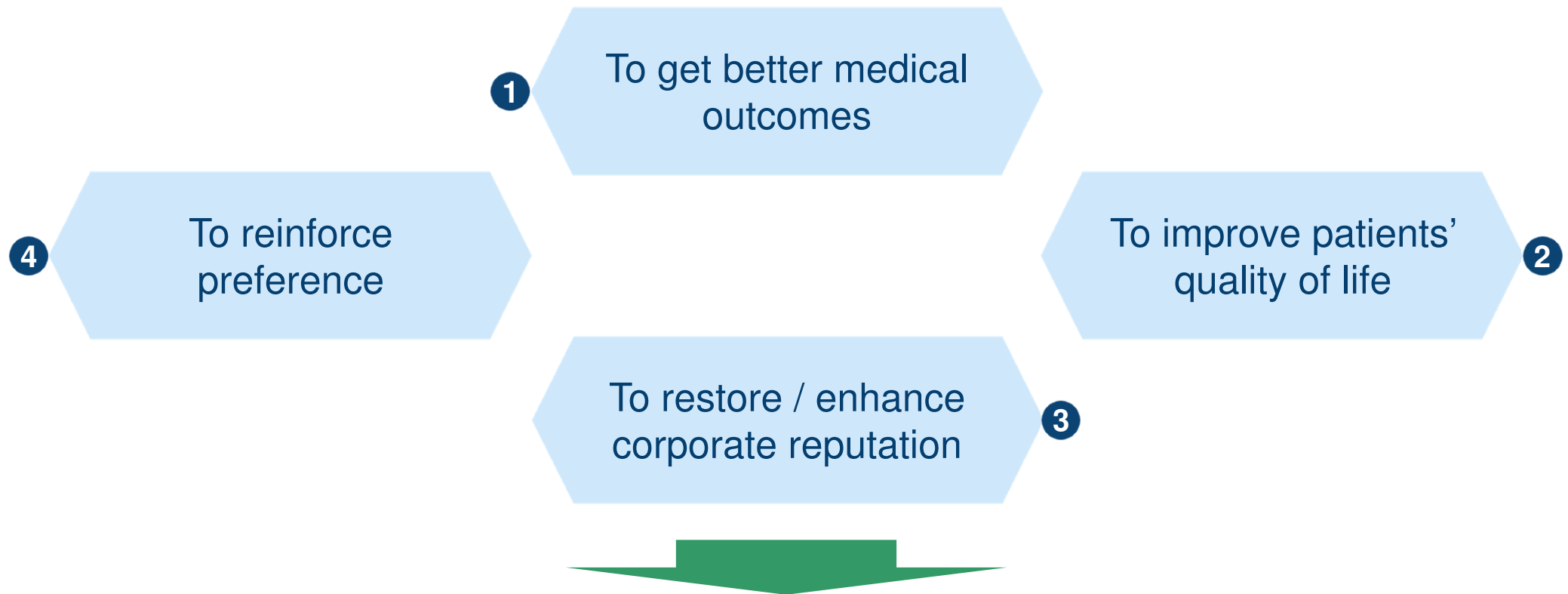
- Patient-centric strategy and the corresponding offered patient services should, in principle, fulfill:
  - Patients' ultimate needs for better health outcomes and improved quality of life
  - Pharma companies' needs for a better usage of its drugs and an increased patient satisfaction leading to an enhanced corporate reputation and a market share gain
  - HCPs' needs to prescribe the most appropriate drugs to their patients with the assurance of having a follow up along the patient journey for better results and safety conditions
- The issue for pharma companies is not anymore to wonder if they should offer patient services...
- ... but to decide which services they want to offer to create the best value for patients, HCPs, policy makers, payers, and ultimately for themselves

Sources: Eyeforpharma, Aurora Project: "Pharma's Global Patient Centricity Survey & Analysis" 2015 – Insights collected from 2,346 respondents from 84 countries, including pharma companies' executives, patients and patient groups, solution providers, etc. – Smart Pharma Consulting analysis



**Relevant and effective services to patients can contribute to improve the corporate reputation of pharma companies and thus increase stakeholders' preference**

**The four key objectives of patient services**



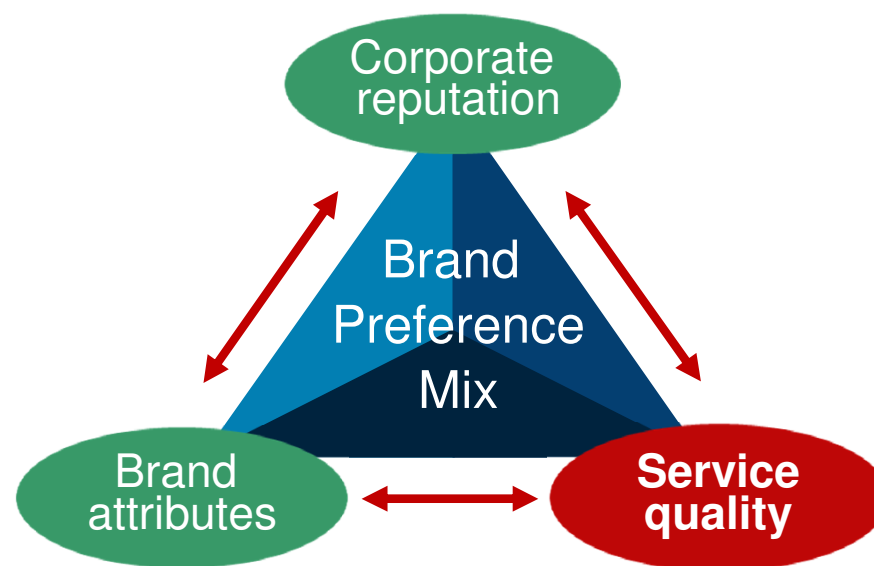
*“Why is the patient so important?  
Simply because he is the final customer and, as such, has the last say!”*

**With dwindling product differentiation, patient services contribute to strengthen the brand preference of stakeholders (e.g. patients, physicians, policy makers, payers)**

**Contribution of patient services to brand preference strengthening**

*“The more robust is the brand preference  
the more exceptional is the brand performance”*

- To strengthen the preference of customers (stakeholders) to their brands, pharma companies must, better than their competitors, **optimize the three basic components of the preference mix**:
  - **Corporate reputation**
  - **Brand attributes**
  - Quality of customer **services** (incl. patient services)
- Thus, patient services ensuring a more positive patient experience will lead to:
  - Patients’ better medical outcomes and quality of life
  - Physicians’ (and other HCPs<sup>1</sup>) increase confidence in the brand
  - Payers’ better value for money
  - Policy makers’ (and government) better fulfilment of their role



*“Offering valuable services to customers  
– especially to patients –  
reinforces corporate reputation of pharma  
companies and preference to their brands”*

## Patient services strategy should preferably focus on “around-the-pill” services, likely to strengthen brand preference by improving medical outcomes and quality of life

### “Beyond-the-pill” vs. “Around-the-pill” strategy

- While most pharma companies claim to be patient-centric and to offer patient services, they are not very clear, nor aligned on what to do in practice
- Should they provide services “beyond-the-pill” or “around-the-pill”?

#### Services “beyond-the-pill”

- “Beyond-the-pill” services are **not linked to the drugs** marketed by pharma companies and therefore have no direct impact on their value, nor on their preference
- They have been imagined as a **new source of revenues** to compensate the risk associated to drug patent expiries
- Example of services “beyond-the-pill”:
  - Commitment of GSK to reinvest 20%<sup>1</sup> of its profits made in LDCs<sup>2</sup> and to lower drug prices<sup>3</sup>
  - Co-development of smart lenses<sup>4</sup> by Novartis and Google
  - Roche taking majority stake in Foundation Medicine, which develops solutions for genomic profiling of cancers

#### Services “around-the-pill”

- “Around-the-pill” services can be **adjacent or directly linked to drugs** marketed by pharma companies
- The purpose of these services **is to optimize medical outcomes and patient quality of life** while strengthening the preference of the brands marketed by the companies
- Examples of services “around-the-pill”:
  - Trainings/tools to help physicians prescribe the right drug to the right patient
  - Programs/tools to improve adherence to medication
  - Devices to monitor treated patient condition

- Services “above-the-pills” correspond to a longer-term strategy for which the business model is not yet clearly set...
- ... while services “around-the-pill” should deliver short-term results through a better usage of marketed drugs

**Patient services, as part of pharma companies customer-centricity strategy, should be focused on initiatives to enhance medical outcomes and quality of life**

**Examples of “around-the-pill” services**

**Disease management & progression monitoring**



In 2014, Biogen partnered with PatientsLikeMe to distribute Fitbit<sup>1</sup> to 248 multiple sclerosis patients to collect data to help them create improved treatment protocols and prove the value of their medication to payers, physicians and other patients

**Connected-device to improve adherence**



In 2014, Merck launched a new device to inject Rebif, for patients with multiple sclerosis, which collects and stores data that can then be sent to a secure server. The system can prompt patients to a better **adherence** to treatment

**Community web site for lung cancer patients**



After completing a patient research survey, AZ co-developed with >100 patients a website dedicated to build a community for lung cancer patients where they can share their emotional journeys and everyday experiences and feel better

**Patient support program**

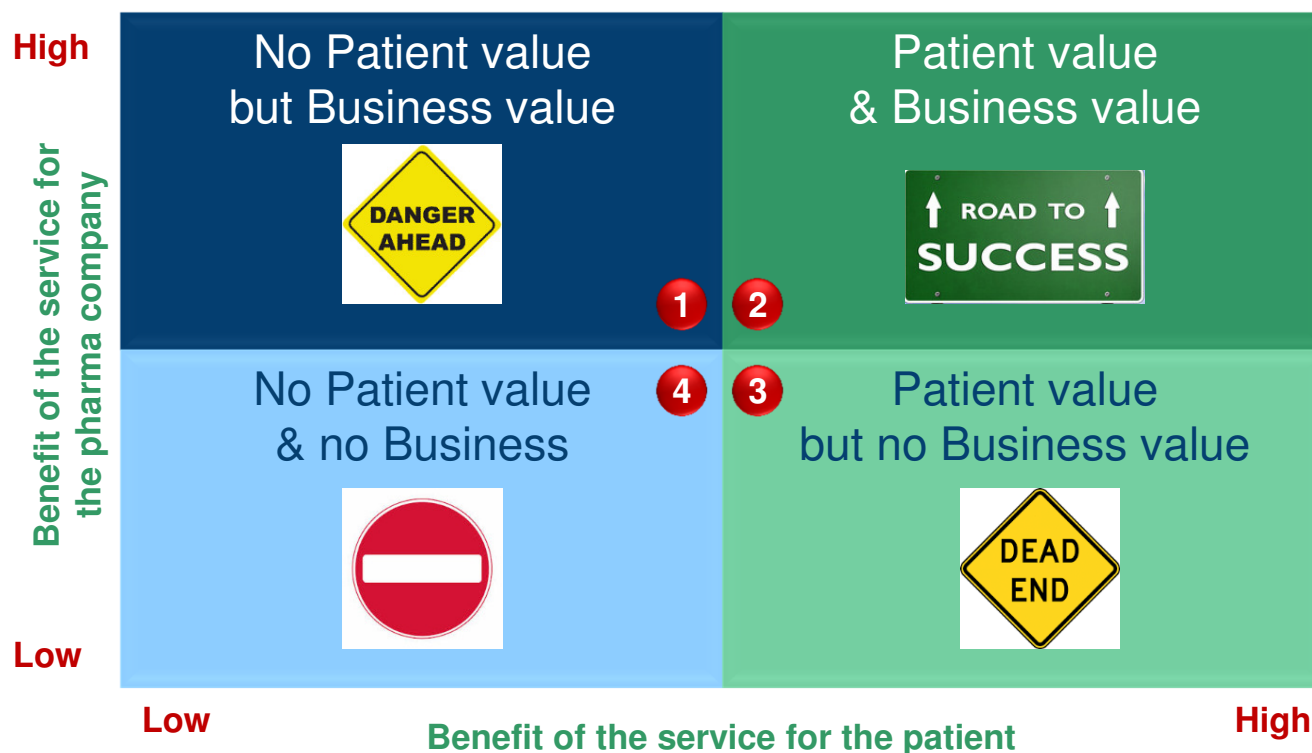


Cornerstones4Care<sup>®</sup> is an online service from Novo Nordisk providing diabetic patients with personalized tools, resources and information to help them reach their diabetic management goals and improve their quality of life

While crafting their strategy, pharma companies should give the priority to services that create tangible value for patients and that contribute to boost their performance

**Selection of a patient-centric strategy (1/2)**

Patient service strategy matrix



- While crafting their patient-centric strategy, pharma companies should keep in mind their **ultimate objective**:
  - The services which create value for the pharma company but not for the patients (quadrant #1) are not recommended because they represent a short- to mid-term reputational risk for the company
  - The services which create value for both patients and the pharma company (quadrant #2) should be favored because they represent a “win-win” option
  - The services which create value for patients but not for the pharma company (quadrant #3) should either be excluded or redefined if the problem comes from poor implementation
  - The services which do not create value for patients nor for the pharma company (quadrant #4) should be avoided because they are irrelevant

*“Patient-centric strategies must improve patients & companies outcomes”*

The “win-win” patient-centric strategies proposed by pharma companies should create value for all stakeholders, be perfectly carried out and deliver tangible results

### Selection of a patient-centric strategy (2/2)

#### Features of services delivering value for patients & pharma companies

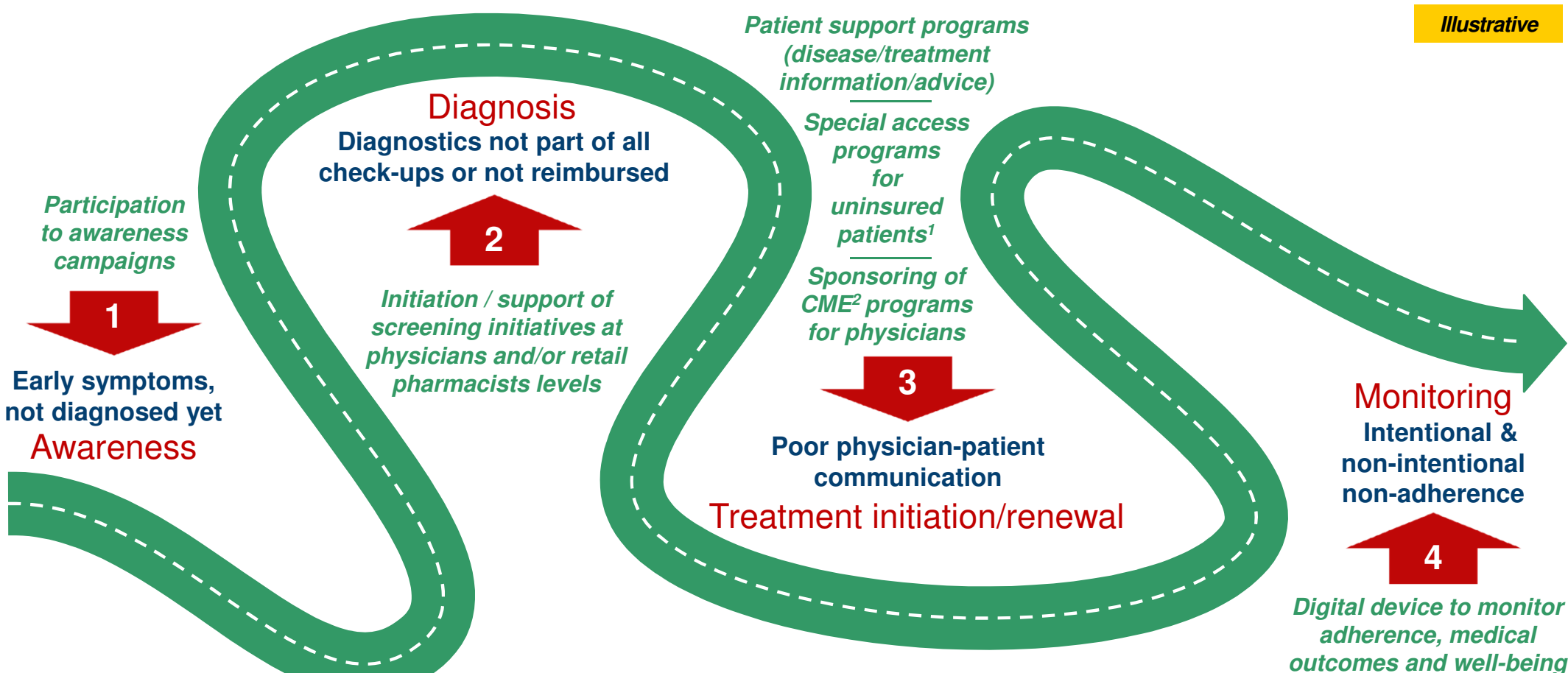
Patient value  
& Business value



- The service should correspond to a need expressed by the great majority of patients and acknowledged by the other key customers of the pharma company (i.e. HCPs, policy makers, payers)
- Thus, the patient service must **create value for**:
  - **Patients** through better medical outcomes and improved quality of life
  - **HCPs** through better and easier management of their patients
  - **Payers** through improved cost-effectiveness results
  - **Policy makers** / government through improved public health outcomes and management
  - The **pharma company** by reinforcing its reputation and increasing the preference of stakeholders to its brands
- The service must be reasonably easy to implement<sup>1</sup> and the quality of execution irreproachable
- The expected results on patients must be significant and measurable

Services likely to be proposed to patients by pharma companies can be considered at different steps of the patient journey to address dysfunctions in patient management

**Examples of possible patient services along the patient journey**



XXX: Key steps during the patient journey – XXX: Opportunities of improvements  
– Examples of possible patient services






It is key to make sure that the service will create value for patients, other customers and the pharma company, with the help of a specific selecting tool

## How to select patient services?

Patient service selecting tool

Illustrative

Targeted patients	Who?	How many?	Objective	For patients	Description of the service			
				For company				
Estimated value ... for Patients				.... for HCPs		... for Payers / Policy makers		
Metrics*		Rationale		Metrics*	Rationale	Metrics*	Rationale	
Interest	1 2 <b>3</b> 4 5			1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5		
Usefulness	1 2 3 <b>4</b> 5			1 2 3 <b>4</b> 5		1 2 3 <b>4</b> 5		
Convenience	1 <b>2</b> 3 4 5			1 <b>2</b> 3 4 5		1 <b>2</b> 3 4 5		
Execution	1 2 <b>3</b> 4 5			1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5		
<b>Total</b>	1 2 <b>3</b> 4 5			1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5		
Feasibility		Rationale		Patients KPIs <sup>1</sup>		Company KPIs	Decision	Rationale
Technical		• Implementation		• Biological indicators • Medical outcomes • Quality of Life • MPR <sup>2</sup> • Etc.		• Corporate reputation • Brand Preference Mix index • Brand market share • Etc.	GO	
Regulatory		• Compliance					No GO	
Economic		• Estimated cost and return						

\* 1 & 2 below competitors – 3 as competitors – 4 & 5 above competitors



**The successful implementation of patient-centric initiatives requires to adjust the organization, communicate extensively and measure the impact in a rigorous way**

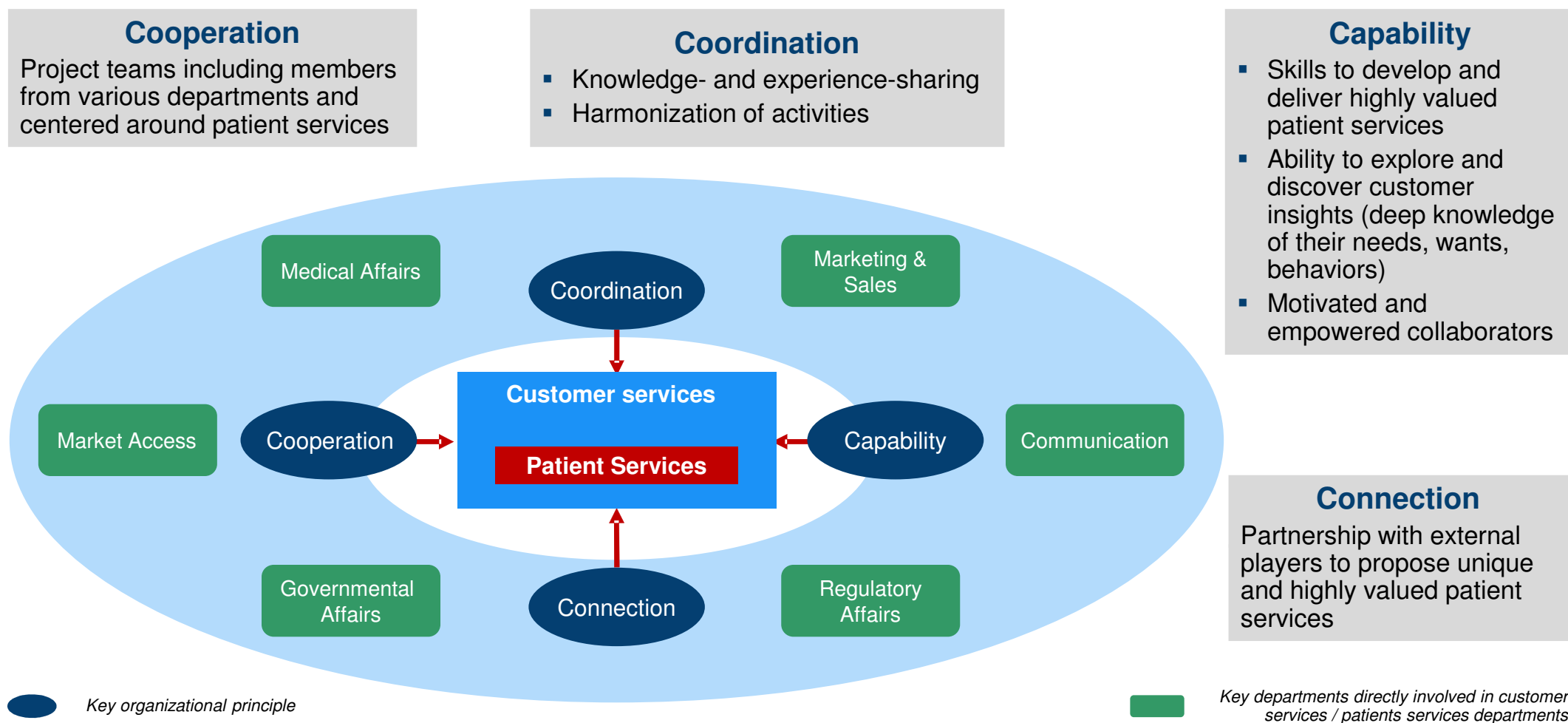
### **Key challenges: Overview**

The three challenges to be addressed to successfully implement patient-centric initiatives		
Organization	Communication	Execution & Measurement
<ul style="list-style-type: none"> <li>▪ Patient-centric initiatives are most often managed by the marketing or medical department...</li> <li>▪ ... which are not necessarily the optimal options to establish a cross-functional team...</li> <li>▪ ... which is a “must have” to ensure an effective and efficiency implementation</li> </ul>	<ul style="list-style-type: none"> <li>▪ 81% of pharma companies go through healthcare providers to make patients aware of their services...</li> <li>▪ ... 19% of patients are aware of patient services proposed by pharma companies</li> <li>▪ Patient services may be viewed by stakeholders as a means to sell more drugs by delivering (free) services</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient services are often complex and poorly executed</li> <li>▪ 60% of pharma companies do not measure the impact of their patient services on medical outcomes</li> <li>▪ In the absence of reliable data and systematic measurement, the investment made will not be valued by stakeholders and...</li> <li>▪ ... therefore will not be sustainable</li> </ul>

*The question is not anymore: “Should we offer patient services”, but “Which ones to offer and how to execute them?”*

**A patient services department, managed by a senior executive, should be defined to work cross-functionally with other departments to develop high value initiatives**

**Key challenges: Patient-centric organization (1/2)**

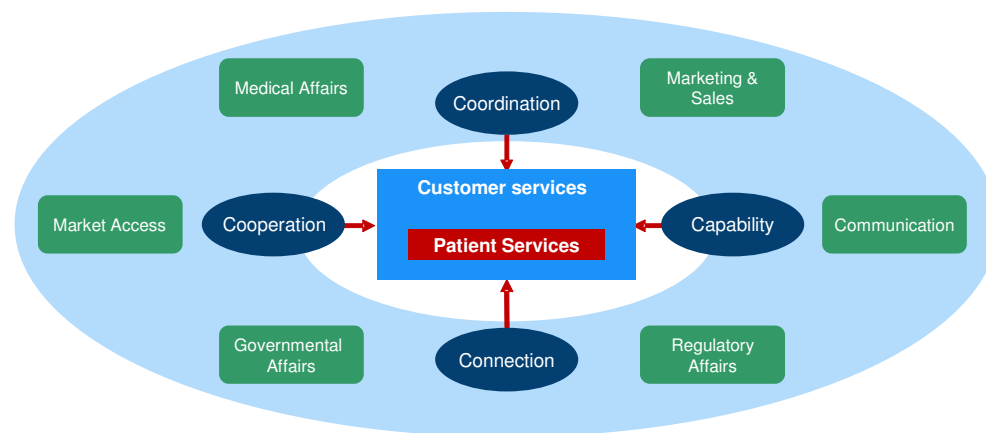


Sources: Smart Pharma Consulting – Adapted from R. Gulati (HBR 2007)

**A customer-centric mindset should be pervasive at every level of the organization, from customer-facing collaborators to the management committee level**

**Key challenges: Patient-centric organization (2/2)**

- A patient-centric organization must be **communicated without any ambiguity** – internally and externally – by the senior management as a long-term strategic priority
- To remain engaged in a patient-centric culture, **collaborators should regularly be kept informed** about the initiatives put in place and their outcomes
- The head of the customer (or patient) service department must be a member of the management committee and **work cross-functionally** with the other key departments heads of the company (e.g. medical, marketing, etc.)
- Besides, collaborators dedicated to patient services must be part of the brand teams to **ensure that the services benefit not only to patients but also to the brand**, directly, or indirectly by reinforcing the corporate reputation
- Irrespective of the department they belong to, of their activities (front vs. back office) or their experience (senior vs. junior position), all collaborators of pharma companies should be committed to deliver **high service quality to customers**, and especially to patients



*“Patient services being in general delivered in partnership with other customers of the pharma companies, they require the alignment and coordinated efforts of all departments”*



Key organizational principle



Key departments directly involved in customer services / patients services departments

**It is essential for pharma companies to communicate their patient-centric strategy clearly and precisely to internal and external customers, in order to get their support**

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**Key challenges: Communication**

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- Pharma companies should define and share their vision – mission – ambition related to their customer-centric strategy with their internal (their collaborators) and external customers (their stakeholders)

**Illustrative****Vision**

- *Being recognized by patients and other customers (HCPs, payers, policy-makers) as the company offering the most valuable patient services*

**Mission**

- *Improve medical outcomes and quality of life of patients treated with our drugs or affected by a pathology for which we propose drugs*

**Ambition**

- *Get tangible results demonstrating the value of the patient services and, as a result, increase the preference of stakeholder for our brands*

*“Communicate openly about your patient services: What are your intentions? What are the results you obtained? Don’t be afraid, if you do the right things right, your reputation will be strengthened!”*

**Patient services being complex to execute, skillful collaborators with a robust experience in transversal and project management are required**

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**Key challenges: Execution & Measurement (1/2)**

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**Patient service execution**

- **Challenge #1:** Engage HCPs, payers and policy makers, as appropriate, to execute the patient services
- **Challenge #2:** Make patients aware of the services offering and of the benefits they will get
- **Challenge #3:** Keep patients as users and other relevant customers<sup>1</sup>, as partners (e.g. HCPs may recommend a website, enroll patients in adherence programs, track the clinical outcomes, etc.) engaged over the long run in the service
- **Challenge #4:** Collect reliable data, on a regular basis, to be able to objectivize the value brought by services to patients, other customers<sup>1</sup>, and to the pharma company
- **Challenge #5:** Collaborate with many partners, internally (from different departments) and externally (social networks, data integrators, apps developers, HCPs, etc.) to deliver the service
- **Challenge #6:** Position the patient services to avoid head-to-head competition
- **Challenge #7:** Execute the service to create superior value than competitors, in a context of commoditization of patient services

**Rigorous measurement of relevance, quality of execution and outcomes of patient services are essential to objectivize the value created for stakeholders**

## Key challenges: Execution & Measurement (2/2)

### Patient service measurement tool

Targeted patients	Who?	How many?	Objective	For patients	Description of the service				
				For company					
Customers valuation					Pharma company self-valuation				
Metrics*	Patients	HCPs	Payers / Policy makers	Rationale	Metrics*	Rationale			
Interest	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5				
Usefulness	1 2 3 <b>4</b> 5	1 2 3 <b>4</b> 5	1 2 3 <b>4</b> 5		1 2 3 <b>4</b> 5				
Convenience	1 <b>2</b> 3 4 5	1 <b>2</b> 3 4 5	1 <b>2</b> 3 4 5		1 <b>2</b> 3 4 5				
Execution	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5				
Total	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5	1 2 <b>3</b> 4 5		1 2 <b>3</b> 4 5				
Patients KPIs <sup>1</sup>			Gap analysis	Recommendations	Company KPIs <sup>1</sup>			Gap analysis	Recommendations
Metrics	O <sup>2</sup>	A <sup>3</sup>			Metrics	O <sup>2</sup>	A <sup>3</sup>		

<sup>1</sup> Key performance indicators – <sup>2</sup> Objective – <sup>3</sup> Achievement

\* 1 & 2 below competitors – 3 as competitors – 4 & 5 above competitors

*“If you can't measure it, you can't manage it”*

– Peter Drucker –

- To objectivize the value created by patient services, for the different customers and the pharma company, it is recommended to combine qualitative and quantitative metrics to measure the quality of execution and the impact of the initiatives:
  - Interest and usefulness metrics to assess the relevance of the service
  - Convenience and execution metrics to assess the quality of implementation of the service
  - Patients key performance indicators (KPIs) include metrics such as: medical outcomes, quality of life, adherence and persistence rates
  - Pharma key performance indicators include metrics such as: corporate reputation, Brand Preference Mix Index<sup>1</sup>, market share dynamics
- The performance gaps (between objectives and achievement) should be carefully analyzed and lead to specific decisions (i.e. adjustment of the execution, drop-out, continuation)

## Smart Pharma Consulting proposes a four-step process to define and implement a patient-centric strategy likely to create a sustainable competitive advantage

### Strategic patient service process

In-depth situation analysis	Strategy crafting	Service design	Implementation & Monitoring
<ul style="list-style-type: none"> <li>■ Disease-related needs</li> <li>■ Drug-related needs</li> <li>■ Patient-related needs</li> </ul>	<ul style="list-style-type: none"> <li>■ Patient &amp; Business value</li> <li>■ No Business but Patient value</li> <li>■ No Patient but Business value</li> </ul>	<ul style="list-style-type: none"> <li>■ Disease-related services</li> <li>■ Drug-related services</li> <li>■ Patient-related services</li> </ul>	<ul style="list-style-type: none"> <li>■ Quality of the implementation</li> <li>■ Measurement of the outcomes</li> </ul>
<ul style="list-style-type: none"> <li>■ Gather insights from through research studies (interviews, social networks, wearables, websites, etc.):               <ul style="list-style-type: none"> <li>— Specificities of the disease</li> <li>— Specificities of the treatments (efficacy, safety, convenience, etc.)</li> <li>— Patients and other customers<sup>1</sup> perception of illness, needs, behaviors, beliefs, life style, etc.</li> <li>— Competitors' offering</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ Set the ambition / objective of the patient service strategy</li> <li>■ Craft the service strategy:               <ul style="list-style-type: none"> <li>— Define the strategic priority (e.g. patient &amp; business value)</li> <li>— Select the types of patient services to be offered along the different steps of the patient journey, considering the perceived needs of all customers and what is proposed by competitors yet</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ Co-create services with patients (incl. PAGs) and other customers<sup>1</sup> that will be valued and accepted</li> <li>■ Design services to address issues related to the:               <ul style="list-style-type: none"> <li>— Disease (e.g. problems of screening and diagnosis)</li> <li>— Drug (e.g. side effects)</li> <li>— Patient (e.g. limited access, low rate of adherence and persistence, poor quality of life, suboptimal outcomes)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ Ensure the excellence of the execution by:               <ul style="list-style-type: none"> <li>— Partnering with all relevant customers<sup>2</sup> and suppliers<sup>3</sup></li> <li>— Allocating the right level of resources (human/financial)</li> <li>— Setting a rigorous process</li> </ul> </li> <li>■ Monitor with KEIs<sup>4</sup> the quality of implementation</li> <li>■ Measure with KPIs<sup>5</sup> the impact of services on:               <ul style="list-style-type: none"> <li>— Patients condition</li> <li>— Company's performance</li> </ul> </li> </ul>

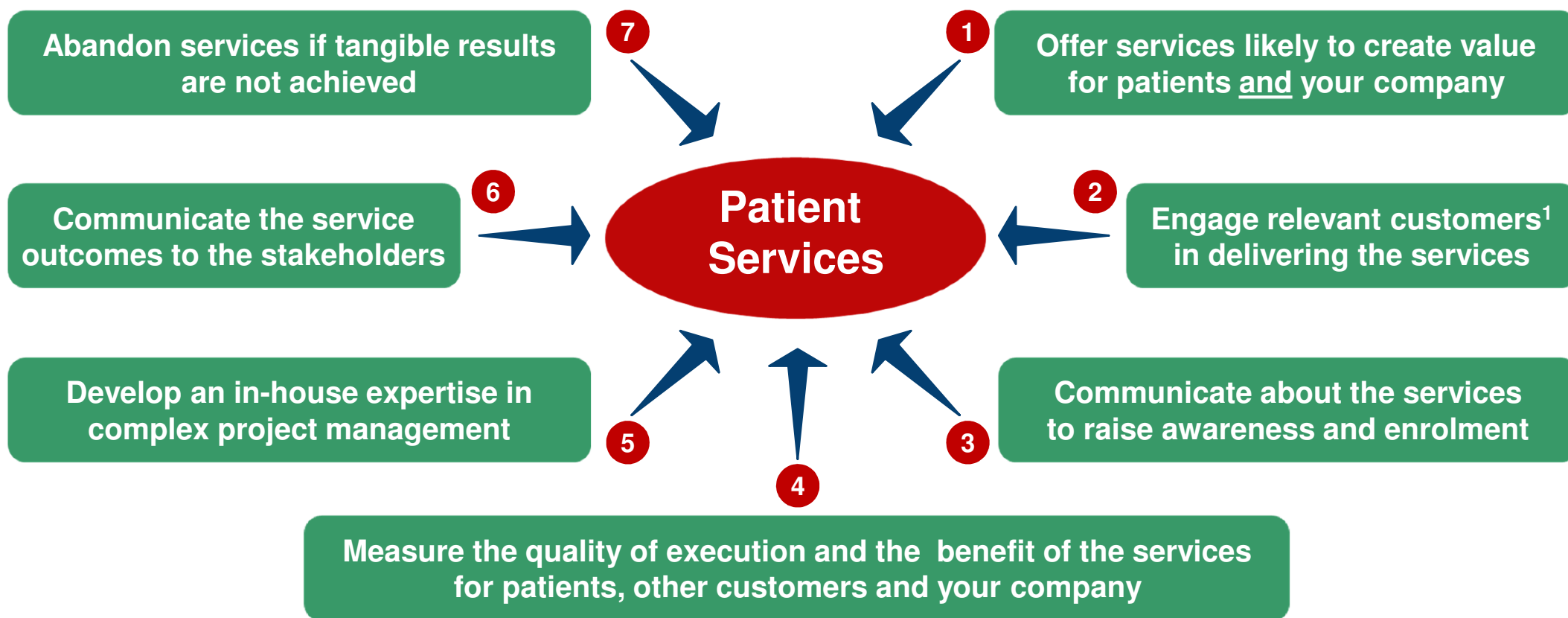
Sources: Adapted and enriched by Smart Pharma Consulting from Executiveinsight

<sup>1</sup> HCPs, payers, policy makers – <sup>2</sup> PAGs, HCPs, payers, policy makers, caregivers, etc., depending on the service to be proposed – <sup>3</sup> IT companies, data integrators, E-health agencies, etc. – <sup>4</sup> Key execution indicators – <sup>5</sup> Key performance indicators



Patient services must deliver significant and concrete results to get stakeholders' esteem and therefore enhance their preference for the pharma company and its drugs

**7 tips to create and implement a patient-centric strategy**

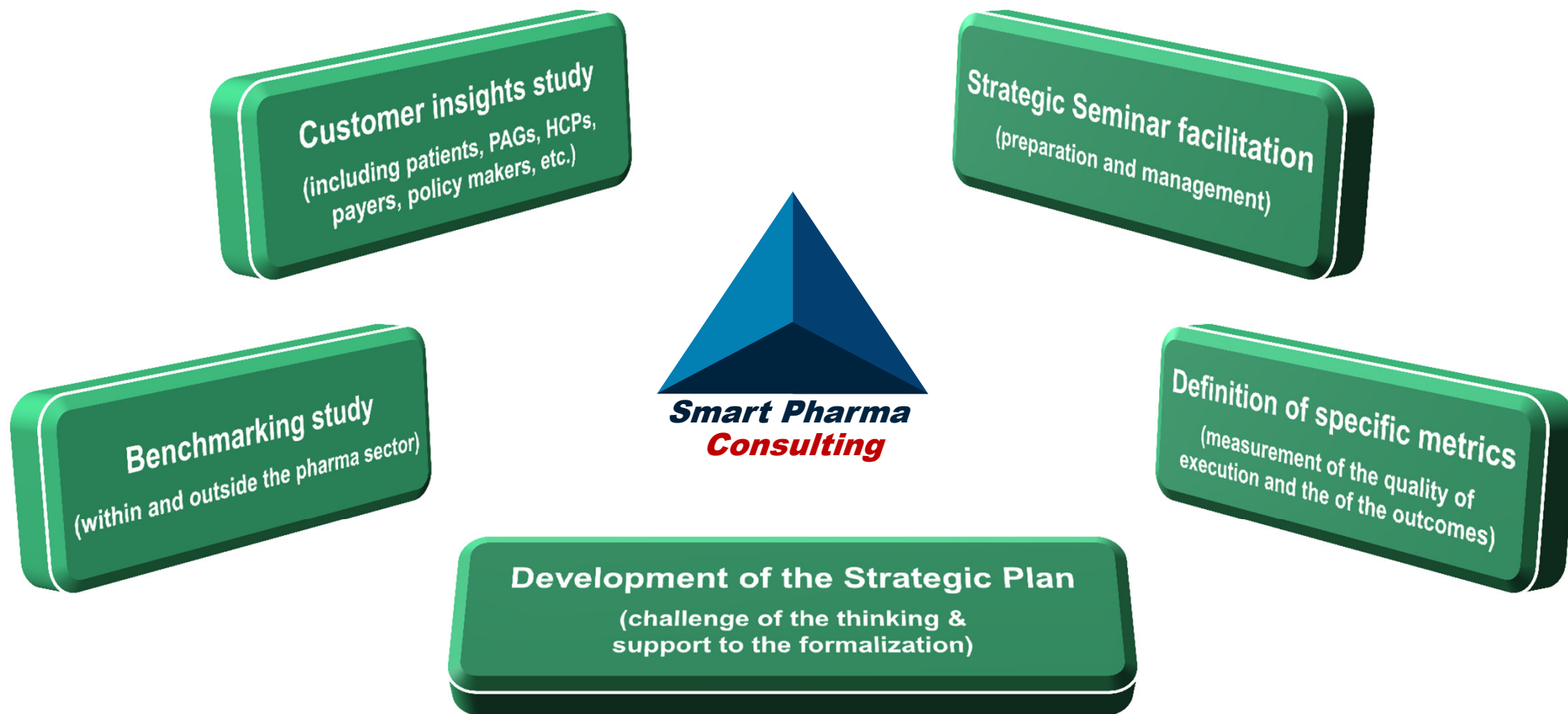


*"The right patient-centric strategy maintain a proper balance between the patient and the pharma company interests"*



Smart Pharma Consulting can help you strengthen the impact of your patient-centric strategy by stimulating your thinking process and bringing specific methods and tools

**5 ways Smart Pharma Consulting can boost your patient-centric strategy**



**The purpose of this section<sup>1</sup> is to provide key information and robust analyses to better optimize drug valuation, from the pharmaceutical companies perspective**

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**Context & Objective**

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- To slowdown the increase of healthcare expenditure, governments and public or private payers implement a large array of cost-containment mechanisms
- Drugs are particularly affected by these measures, which include:
  - Drug prices control and regulations to favor the prescription of cheaper products like generics and biosimilars
  - Capping of the prescribed volumes
  - Selective reimbursement of drugs (e.g. limitation to a subset of patients or to the most severe cases)
- However, the way these measures are applied does not allow governments and payers to guarantee access to innovation to the largest number of patients
- Thus, governments and payers have no choice but to increase their pressure on drug prices and “force” pharma companies to accept affordable prices

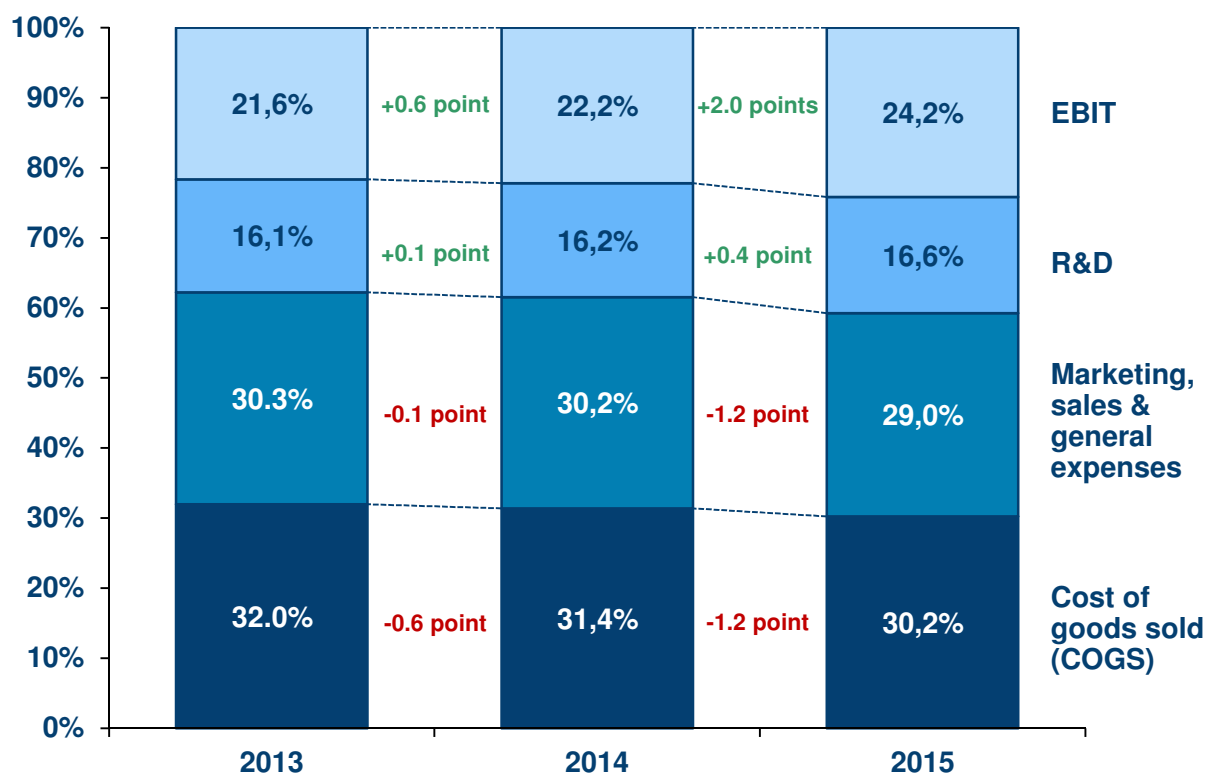
- In this context, the following questions must be raised:
  - What is the value of innovative drugs for the community?
  - What is a fair price for pharmaceutical companies?
- This report<sup>1</sup> reviews:
  - The **economic** and **healthcare environment**
  - The **R&D cost of drugs**
  - The **drug pricing strategic approaches** of pharma companies, governments and payers
  - The **health economic evaluation** methods
  - The **market access processes** in selected countries
  - The **best practices** in market access
  - The ways to **leverage the corporate reputation** of pharma companies
- Smart Pharma Consulting proposes new thoughts likely to help pharma companies to optimize the valuation of their drugs

Among the top 30 pharma companies, the trend goes toward an increase of the EBIT and of the R&D expenses while sales and manufacturing costs are slightly decreasing

**Evolution of the top 30 pharma cost structure (2013 – 2015)**

Cost structure as a percentage of total revenues<sup>1</sup>

Weighted average of total revenues



- The analysis of the top 30 pharmaceutical companies in the world shows that their average profitability has increased by 2.6 points between 2013 and 2015
- This improvement can be explained by the restructuring of their product portfolio in which the weight of high priced secondary care products has been increasing
- Besides, the marketing and sales investment for these specialist-driven secondary care products is much lower than for GP-driven primary care products
- Restructuring and streamlining initiatives have also contributed to improve the economic performance of these companies
- These good performances are the Achilles' heel of pharmaceutical companies when negotiating price and reimbursement of their drugs with governments and payers

Note: panel of the 30 biggest pharma companies in terms of prescription sales as of 2014

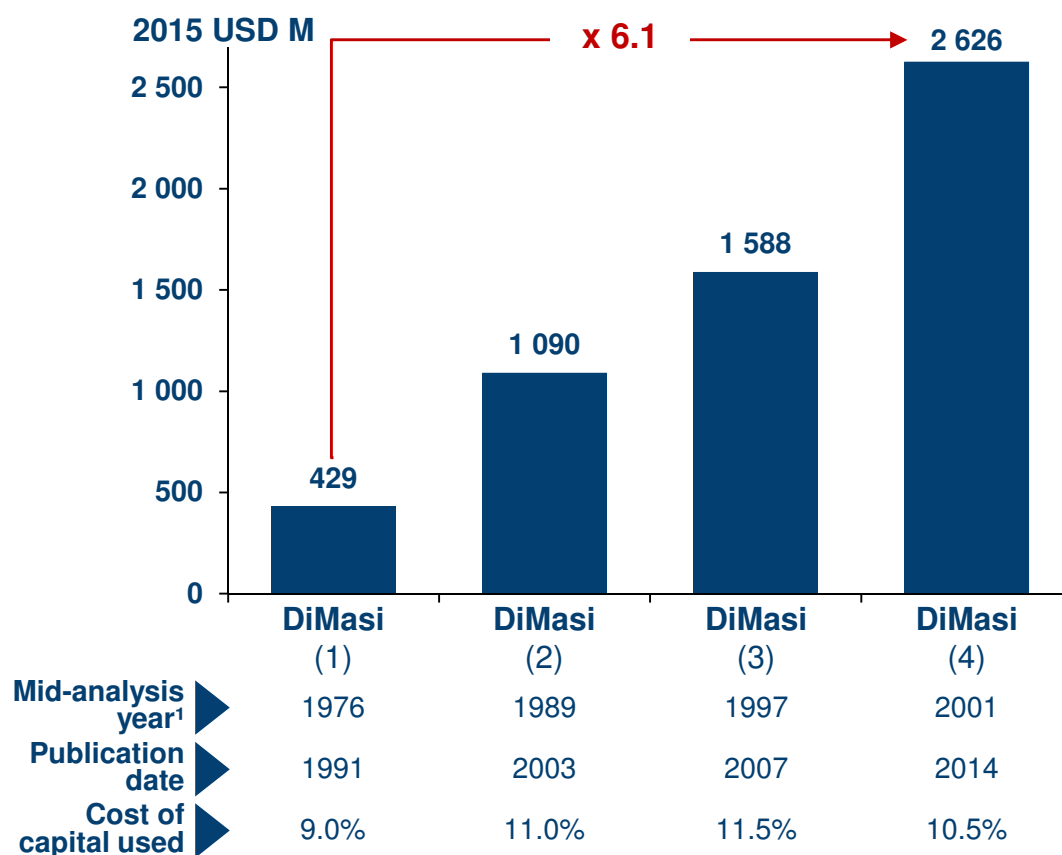
Sources: Companies annual reports – Federal Reserve annual exchange rates – Smart Pharma Consulting estimates

<sup>1</sup> Excluding Astellas, Daiichi Sankyo and Takeda for 2015, which have not published financial results at the moment of the study (due to their fiscal years ending in March) – Excluding for 2015 Actavis which merged with Allergan – Excluding Servier over the whole period for not publishing financial results and Boehringer Ingelheim for publishing non-standardized financial results

The analysis of four studies carried out with the same methodology, shows that the development cost of new drugs has more than sextupled over 25 years

## Evolution of R&D costs

Estimated capitalized cost per approved new drug (pre-tax)



- The evolution of the capitalized R&D costs per approved new drug, after neutralization of the inflation, can be mainly explained by:
  - The growth of the out-of-pocket costs, especially the growth of clinical trials spending: x10.8 between the 1991 and the 2014 estimates (vs. preclinical spending which grew less: x3.9)
  - The decrease of the success rates to reach approval from phase I, ranging from 23% in the first 1991 estimates to 12% in the 2014 estimates
  - The overall increase of the used cost of capital, even if, in the 2014 estimates a 10.5% cost of capital was used, in decrease of 1 point of percentage from the previous estimates. These assumptions of cost of capital seem overestimated compared to available data from NYU Stern School of Business for biotech products (9.2%, based on 411 firms) and for traditional pharma (7.7%, based on 157 firms)

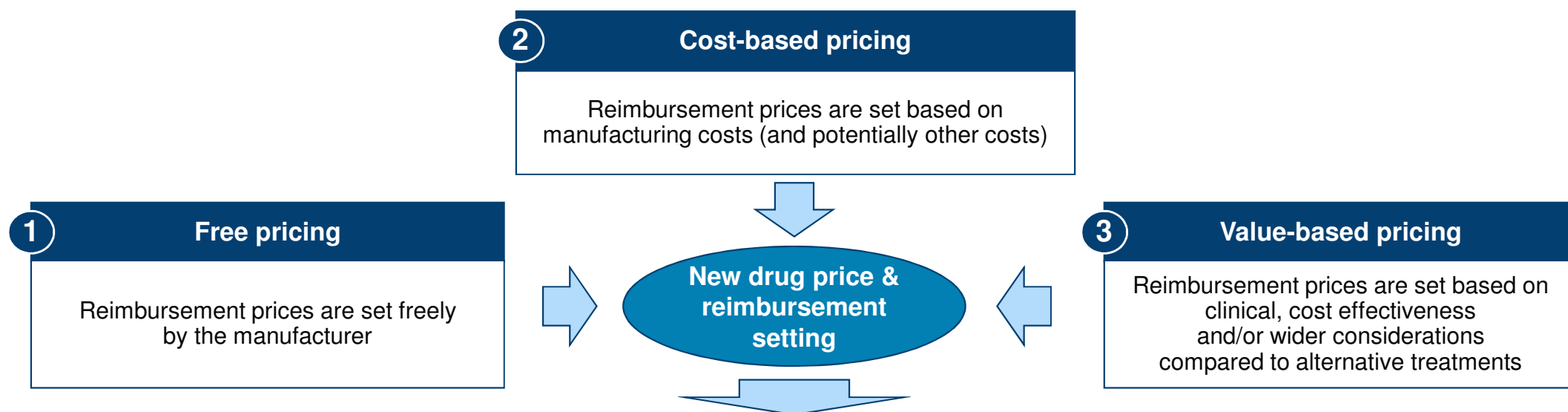
Note: For the sake of comparability, all values are adjusted to USD 2015 prices using data of the US GDP implicit price deflator from the US. Bureau of Economic Analysis. The GDP implicit deflator shows the rate of price change in the economy as a whole, being the ratio of GDP in current local currency to GDP in constant local currency

Sources: DiMasi (1991) – DiMasi et al. (2003) – DiMasi, Grabowski (2007) – DiMasi (2014) – Cost of Capital - NYU Stern School of Business, January 2016 – Smart Pharma Consulting analysis

<sup>1</sup> Products with first testing in humans over the analyzed period

The price and reimbursement of drugs are set according to three basic principles and implemented through different mechanisms during all their life-cycle

**Drug price setting approaches and life-cycle evolutions<sup>1</sup>**



**Price & reimbursement setting mechanisms during the drugs life-cycle**

Internal price referencing	International price referencing <sup>2</sup>	Managed entry agreements	Price cuts	Paybacks	Tenders	Compulsory licensing	Voluntary licensing	Tiered pricing
Reimbursement prices are set compared to prices of drugs of the same class	Reimbursement prices are set compared to prices in other countries	Price / volume agreements, risk-sharing agreements, etc.	Post-marketing reimbursement prices reevaluations	<i>A posteriori</i> rebates to healthcare system (PPRS <sup>3</sup> , safeguard clause, etc.)	Competition between similar products	Licensing imposed by a government to a third party w/o the consent of the patent holder	Out-licensing by a patent holder to a third party to produce and/or market an invention	Differential pricing reflecting the willingness to pay across countries

Sources: "Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research", OECD – "Value-based pricing for pharmaceuticals: Implications of the shift from volume to value", Deloitte – Smart Pharma Consulting analysis

<sup>1</sup> Non-exhaustive list – <sup>2</sup> Also called External price referencing – <sup>3</sup> Pharmaceutical Price Regulation Scheme

**Value-based pricing aims to set drug prices based on multiple criteria to assess their general impact on the healthcare system or on the society, as a whole**

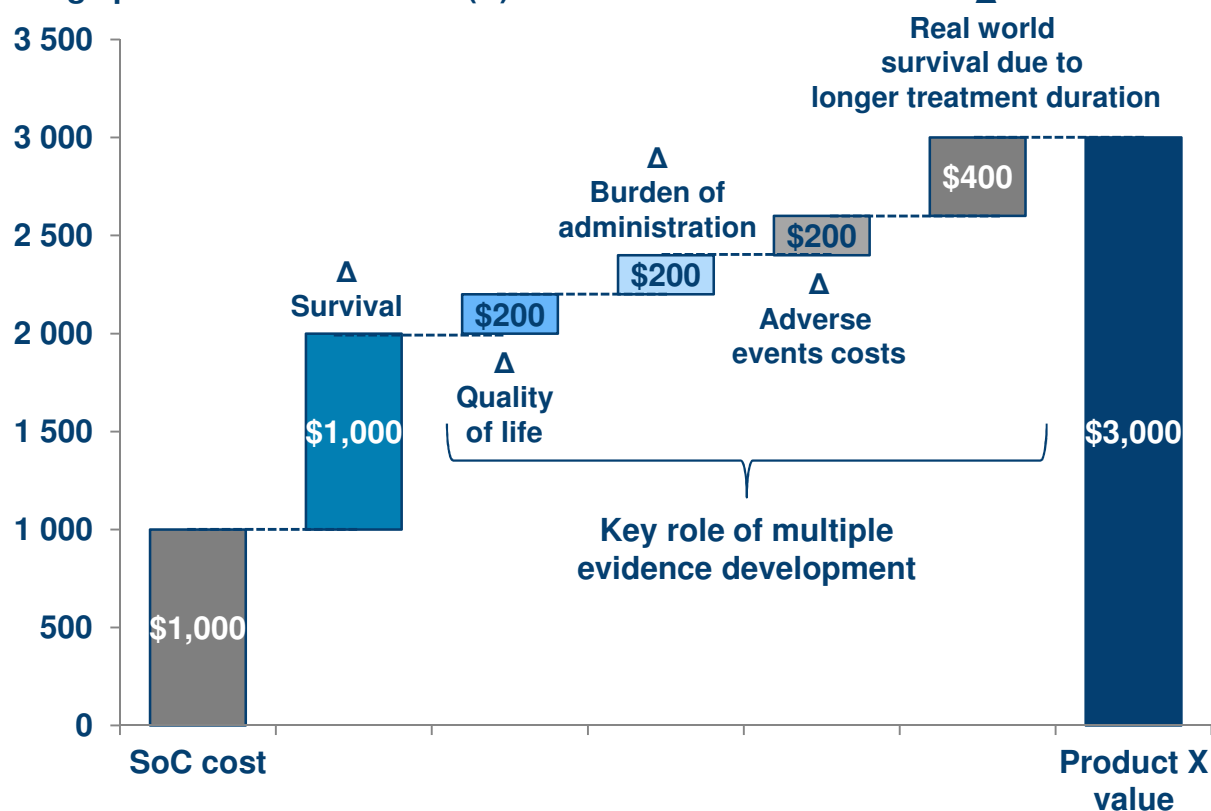
### 3 Value-based pricing – Approach

#### Definition & analysis

- Value-based pricing (VBP) sets prices based on a value assessment that takes into account several criteria such as clinical efficacy, cost-effectiveness, or a wider range of criteria including the burden and severity of the disease and the long-term benefits of the treatment
- VBP consists in negotiating prices for new pharmaceuticals based on their value for the society as assessed through Health Technology Assessments (HTA)
- By ensuring access to cost-effective drugs today and incentivizing manufacturers to invest in cost-effective products for the future, VBP seeks to provide a sustainable solution to pharmaceutical price regulation. But while it aims to reward innovation, establishing a clear relationship between the level of innovation and the price is not straightforward

#### Product X value vs. standard of care (SoC)

##### Drugs prices and incremental ( $\Delta$ ) value

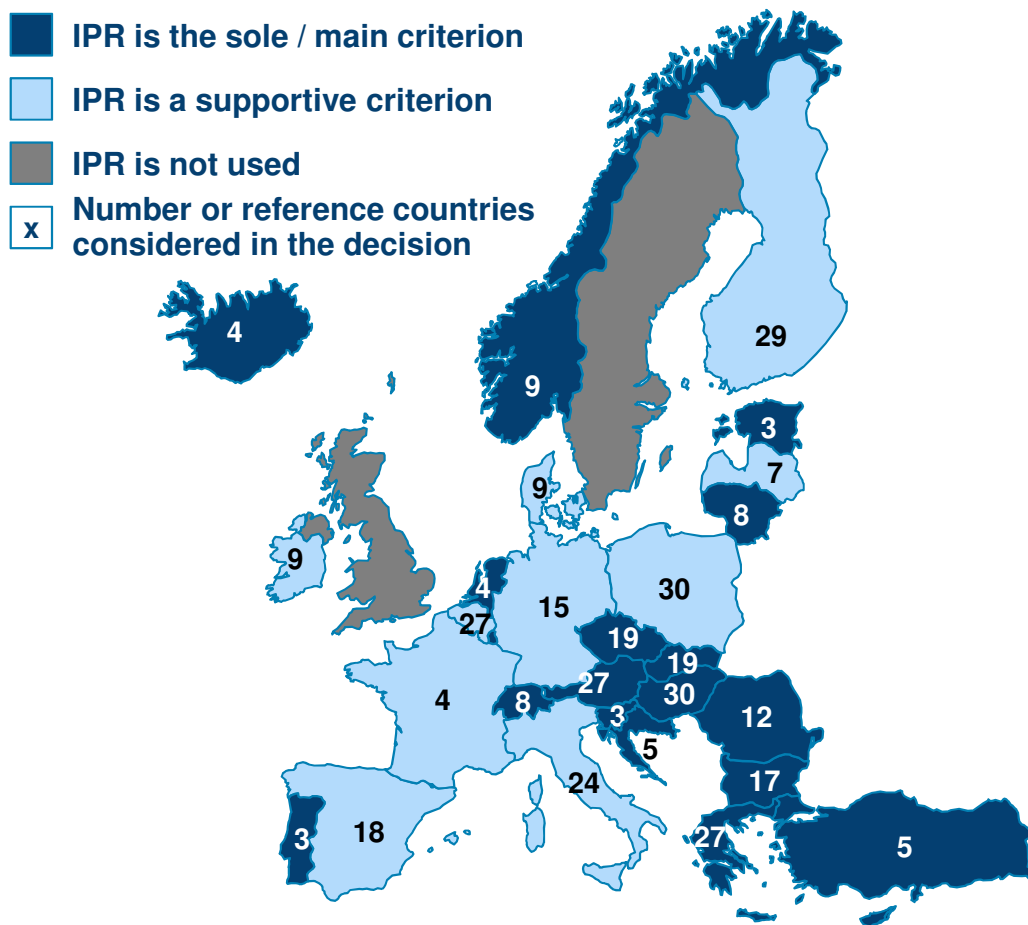


Sources: "Future strategies for pricing and market access in oncology", Analysis Group, Oct. 2014 – "Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research", OECD – Smart Pharma Consulting analysis



**International Price Referencing (IPR) is used in most European countries to set drug prices but its scope may vary from one country to another**

### International price referencing



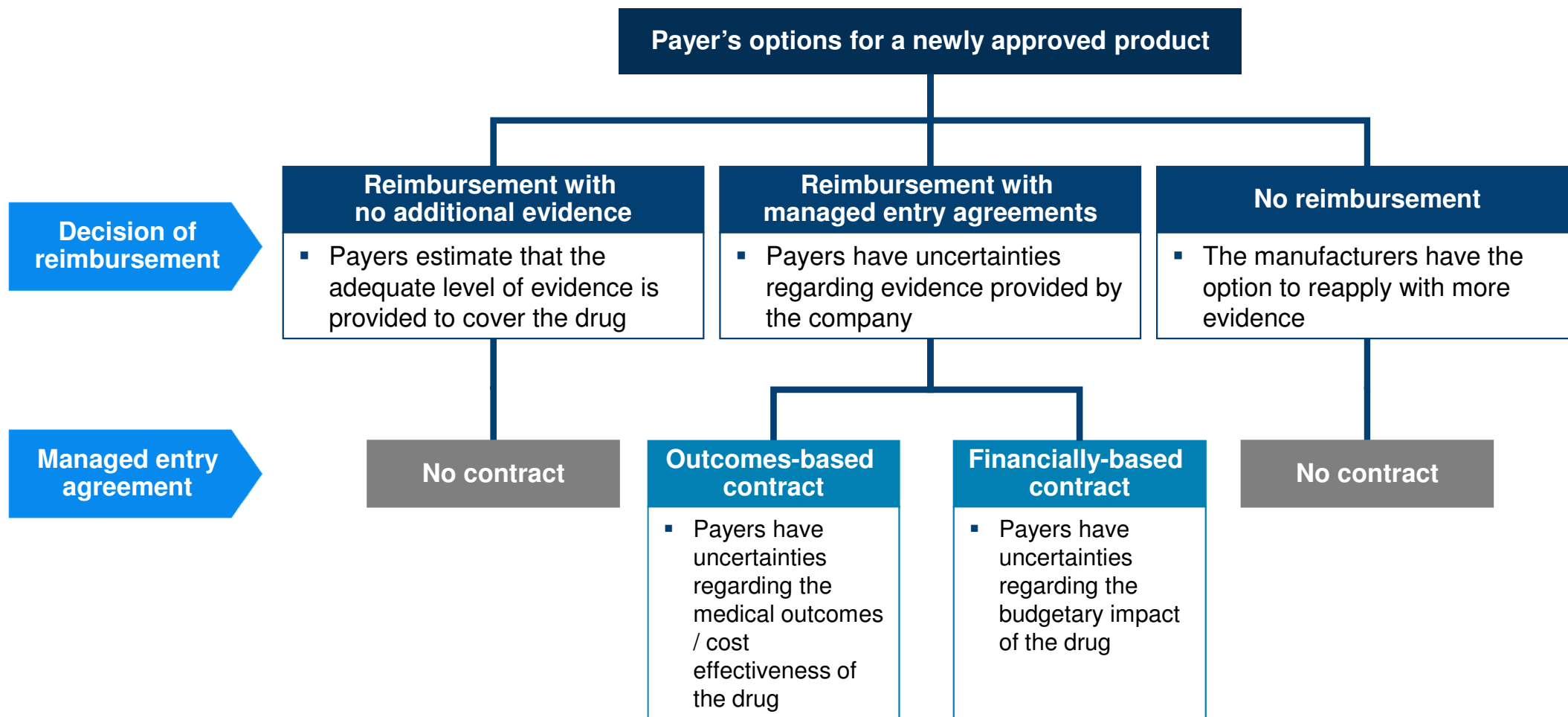
- If most European countries use the International Price Referencing to set the price of drugs, there are some disparities in its usage and calculation:
  - The scope of the use of IPR may depend on the country. For example, in Italy, all reimbursed medicines are concerned while in Spain only new reimbursed medicines with no comparator available are concerned
  - The calculation may also vary. In France, prices should be similar to those in the reference countries and should not be lower than the lowest price in one of the four reference countries while in Belgium prices are based on the average price in reference countries
  - The revision frequency might also depend on the country with bi-annual revisions in the Netherlands or annual revisions in Spain
  - Ex-factory prices are considered in most European countries but Norway, Denmark or the Netherlands consider pharmacy purchasing prices

Sources: "Study on enhanced cross-country coordination in the area of pharmaceutical product pricing", European Commission, Dec. 2015 – "External reference pricing of medicinal products: simulation based considerations for cross-country coordination", European Commission, 2014 – Smart Pharma Consulting analysis

Note: Germany should use the International Price Referencing to set drugs prices but it is not used in practice

Managed entry agreements may be considered by payers when the level of medical evidence is too low and/or the financial impact is too high

**Payer's options for a newly approved product**



Sources: "Can't Get No Satisfaction? Will Pay for Performance Help? Toward an Economic Framework for Understanding Performance-Based Risk-Sharing Agreements for Innovative Medical Products", Adrian Towse and Louis P. Garrison Jr, 2010 – Smart Pharma Consulting analysis



Managed entry agreements are expanding to reduce the risk for the payer (efficacy, safety, etc.) and/or to enable pharma companies to negotiate better prices

### Classification of the managed entry agreements

	Outcomes-based contracts		Financially-based contracts
	<ul style="list-style-type: none"> <li>Reimbursement consistent with the public interest, based on the results provided by the pharma company</li> </ul>		<ul style="list-style-type: none"> <li>Limit the economical consequences of the negotiated price</li> </ul>
Patient level	<b>1 Biomarker-linked payment</b> <ul style="list-style-type: none"> <li>Reimbursement based on the results of biomarker tests</li> <li>e.g.: Herceptin (Roche) Erbix (Merck) Enbrel, Australia (Pfizer)</li> </ul>	<b>2 Pay-for-performance</b> <ul style="list-style-type: none"> <li>Reimbursement based on clinical endpoints: <ul style="list-style-type: none"> <li>Morbidity-mortality</li> <li>Clinical efficacy</li> <li>Better adherence</li> </ul> </li> <li>e.g.: Velcade, UK (Janssen) Imnovid, FR (Celgene) Aclasta, GE (Novartis) Janumet/Januvia, USA (MSD)</li> </ul>	<b>4 Per patient cost capitation deals</b> <ul style="list-style-type: none"> <li>Maximum cost set per patient (number of doses, daily cost of treatment, total cost of treatment, etc.)</li> <li>e.g.: Lucentis, UK (Novartis)</li> </ul>
Population level	<b>3 Coverage with evidence development (CED)</b> <ul style="list-style-type: none"> <li>Funding granted if efficacy proven through real life studies</li> <li>Evidence needed to decide whether or not to maintain funding</li> <li>e.g.: Risperdal Consta, FR (Janssen), many high cost drugs in Italy</li> </ul>		<b>5 Overall sales capitation</b> <ul style="list-style-type: none"> <li>Annual sales volume agreement as part of the initial price negotiation</li> <li>Annual value capping with rebates for exceeding sales</li> <li>e.g.: highest cost drugs in France, Enbrel (etanercept) in Australia</li> </ul>

Sources: "Innovation et prix du médicament contrats d'accès au marché des médicaments remboursables : choix des schémas d'étude et des critères de jugement", Réseau d'Evaluation en Economie de la Santé, Jan. 2014 – "Unpacking Risk Sharing and Alternative Pricing Schemes", Pharmaceutical Commerce, Feb. 2010 – "Mechanism Of Coordinated Access (MOCA) and transparent value framework, managed entry agreements", AIFA – Smart Pharma Consulting analysis

Managed entry agreements enable an early access of patients to innovation while also facilitating reimbursement negotiations and limiting the budgetary risk for payers

### Opportunity analysis

	Opportunities	Relative importance <sup>1</sup>
Payers	▪ Potential to <b>re-evaluate</b> the effectiveness of the drugs at a later stage and <b>re-negotiate</b> the price based on <b>real-world evidence</b> and thus to move towards a <b>value-based pricing system</b>	5
	▪ Help <b>address post-licensing uncertainty</b> by offering flexibility in dealing with new and often expensive treatments	5
	▪ Improve the <b>cost-effectiveness</b> through a <b>discount</b> or a <b>payback</b> agreement for non-responders	4
	▪ Potential to create <b>synergies</b> with existing <b>initiatives</b> on <b>registries</b> in <b>Europe</b> : pulling evidence from different countries could allow to generate a <b>large pool</b> of data and <b>increase the statistical significance</b> of the results	3
	▪ Enable <b>different types of schemes</b> addressing <b>different needs</b> , both <b>financial</b> and <b>non financial</b>	3
Manufacturers	▪ Speed up <b>reimbursement</b> negotiations for drugs which were likely to be rejected by drug reimbursement agencies	5
	▪ Potential to benefit from a better <b>corporate reputation</b> as a result of the willingness to take responsibility for the use of the drug in real-life	4
	▪ Potential to <b>reinforce</b> the <b>long-term collaboration</b> between <b>payers</b> , <b>health authorities</b> and <b>pharmaceutical companies</b>	4
	▪ Enables <b>discounts</b> without impacting list prices	4
Patients	▪ Ability to gain <b>faster access</b> to <b>innovative medicines</b>	5

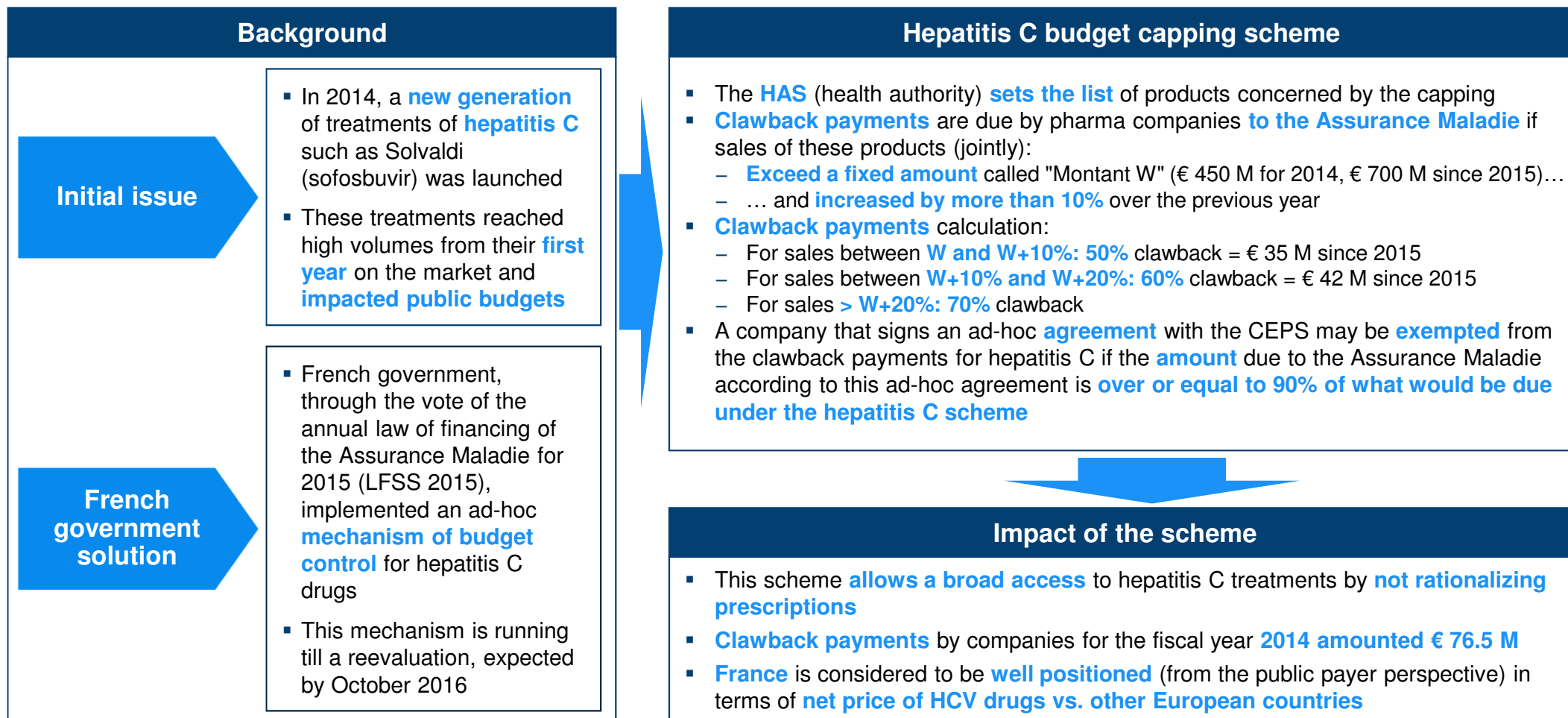
Sources: "Managed entry agreements for pharmaceuticals: the European experience", Alessandra Ferrario and Panos Kanavos, April 2013 – Smart Pharma Consulting analysis

<sup>1</sup> Rating from 5 = very important to 1 = limited importance

Due to their impact on public budgets, French authorities voted a budget capping for all innovative hepatitis C drugs sales



### Case study: HCV budget capping in France



Sources: "Contribution au titre de médicaments destinés au traitement de l'hépatite C", URSSAF – LFSS 2015 et 2016 – "Produits de santé à l'heure des comptes", APICCS – CEPS 2014/2015 annual report – Smart Pharma Consulting analysis

## UK 2014 PPRS (Pharmaceutical Price Regulation Scheme) includes one total pharmaceutical sales capping and one profitability capping for the 2014-2018 period



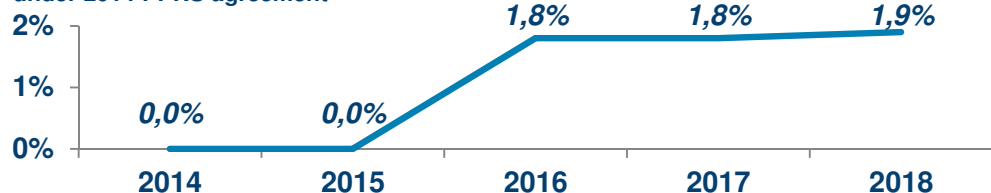
### Case study: UK 2014 PPRS

The 2014 PPRS is a voluntary agreement between the British Department of Health (DH) and the Association of British Pharmaceutical Industry (ABPI) which regulates the supply of branded medicines to the NHS<sup>1</sup> by 2018

#### Sales growth paybacks

- Due to the current state of the global economy and the **financial challenges** facing the NHS, the DH and the ABPI have agreed to introduce a **limit <on** the **growth** of the **overall cost** of the branded medicines purchased by the NHS
- Payments are made by pharma companies on a quarterly basis of net sales to the NHS of **branded medicines**, i.e. after any other discounts already given
- Smaller companies** with sales to the NHS of less than £ 5 M are exempt from payments and to stimulate innovation, **products with first sales after January 2014** are **not concerned** by this scheme either

Sales growth threshold under 2014 PPRS agreement



#### Profitability paybacks

- The scheme provides a framework for determining **reasonable limits to the profits** to be made from the supply of branded medicines to the NHS
- There are two **profitability thresholds** that pharma companies choose to refer to (they are designed to be similar):
  - One level of **return on sales** (ROS) target: **6%**
  - One level of **return on capital** (ROC) targets: **21%**
- Within either limits**, companies are **allowed to set and change prices** in line with commercial considerations and NICE<sup>2</sup> appraisals
- If companies **reach the profit threshold**, they have to **pay 50% of the additional profit** to the NHS and are **not allowed to increase their prices**
- Companies must submit an **Annual Financial Return** to the DH for **control** purpose

**An EU collaboration for Health Technologies Assessment exists since 2005 with the aim to set a better communication between HTA bodies and to standardize methodologies**



### Initiatives of assessment collaborations in Europe

#### About EUnetHTA

- EUnetHTA was established in 2005 to create an effective and sustainable network for HTAs (Health Technologies Assessments) across Europe
- EUnetHTA helps develop reliable, timely, transparent and transferable information to contribute to HTAs in European countries
- EUnetHTA supports collaboration between European HTA organizations at the European, national and regional level through:
  - Facilitating efficient use of resources available for HTA
  - Creating a sustainable system of HTA knowledge sharing
  - Promoting good practices in HTA methods and processes

#### EUnetHTA Joint Action 1 strategic objectives (2010-2012)

- To develop principles, methodological guidance and functional online tools and policies to:
  - Produce, publish, store and retrieve structured HTA information
  - Improve Relative Effectiveness Assessment (REA) by identifying areas where methodological guidance is needed and by providing it, suggesting ways to integrate REA of pharmaceuticals as a special version of the HTA Core Model (methodological framework for production and sharing of HTA information)
  - Structure exchanges and storage of information on evidence generation on new technologies (e.g. registries and trials)
- To test and implement:
  - A web-based toolkit for structured exchanges and storage of information on evidence generation on new technologies
  - The application of the HTA Core model in common production of at least 2 Core HTAs
  - A REA of (a group) of pharmaceuticals in line with the core HTA development
  - Real life support of information flow on new technologies prompting those where parallel assessments of same technologies are detected and alerting on opportunities for information sharing and closer collaboration
  - Provision of a contemporary information management system which supports collaborative HTA work and ensures rapid dissemination of HTA results

#### EUnetHTA Joint Action 2 strategic objectives (2012-2015)

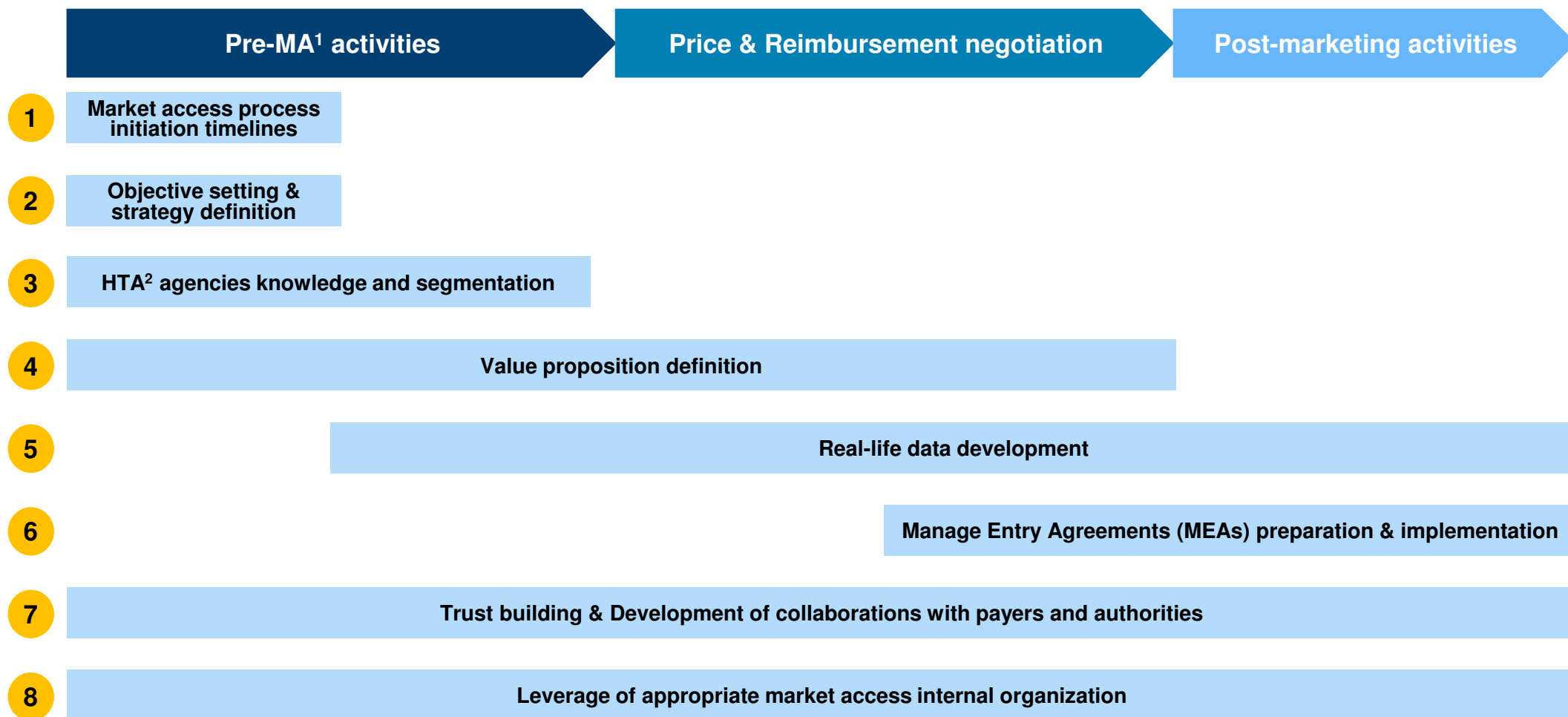
- To strengthen the practical application of tools and approaches to cross-border HTA collaboration
- To aim at bringing collaboration to a higher level resulting in better understanding for the Commission and Member States (MS) of the ways to establish a sustainable structure for HTA in the EU
- To develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration

Sources: EUnetHTA website – Smart Pharma Consulting analysis

*Note: Were implemented in Europe some other collaborative initiatives such as SEED (Shaping European Early Dialogues For Health Technologies), with the aim to implement early discussions between pharma companies and HTA bodies, to align product development with the future HTA requirements*

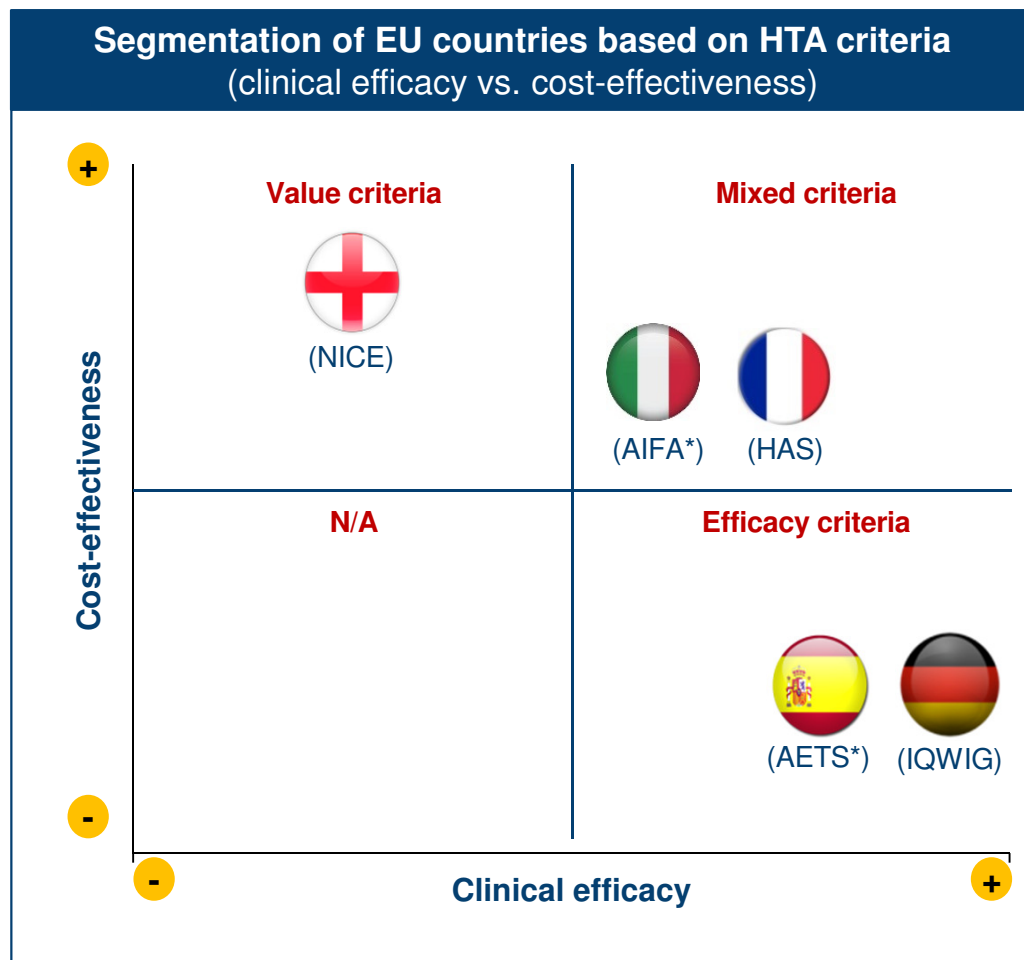
The best practices related to the market access process are well identified from the pre- to the post-marketing authorization phases of products

**Market access best practices**



Pharma companies may cluster HTA agencies according to the assessment criteria they value the most and then develop a specific value proposition for each of them

**3 Payers knowledge and segmentation**



- The first step for market access activities planning is to understand **what will drive national HTA** (Health Technology Assessment) agencies **decisions** when it comes to drug evaluation
- A good understanding of their requirements will allow to define an **appropriate value proposition** for each of them
- The **"one fits all" strategy is no longer valid** since each country has different requirements
- **HTA agencies** can be **segmented** according to the importance they grant to the following **criteria**:
  - **Clinical efficacy** vs. **cost-effectiveness**
  - **Absolute<sup>1</sup>** vs **relative therapeutic value<sup>2</sup>**
  - **Narrow** view vs. **holistic** view of the impact of the drug (Health Related Quality-of-Life, societal impact, etc.)
  - Importance of **subpopulations**

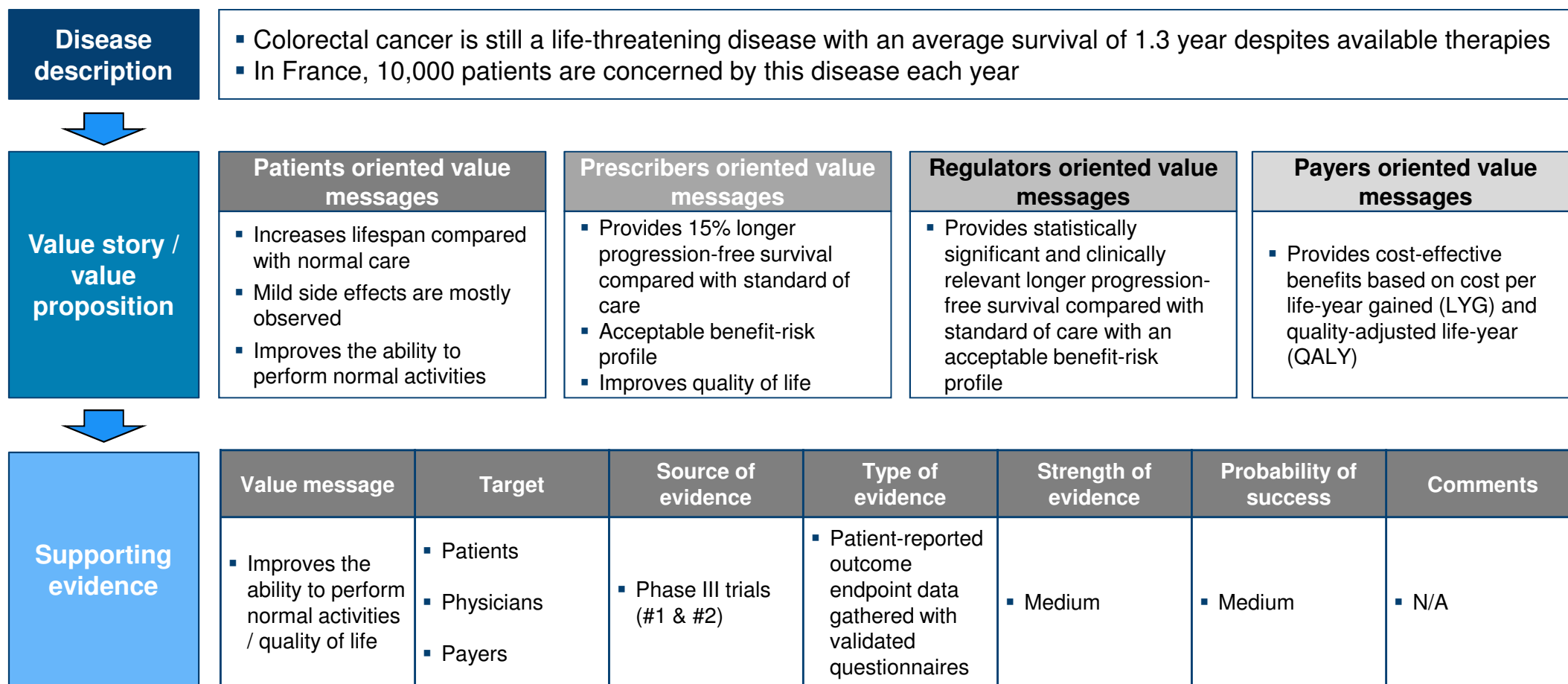
Sources: "Reimbursement Systems for Pharmaceuticals in Europe Concept Mechanism and Perspective", EMAUD – Smart Pharma Consulting analysis

\* Note: In Spain and Italy, policies may differ from a region to another  
<sup>1</sup> Disease severity and burden, unmet needs, efficacy/safety of the product –  
<sup>2</sup> Incremental efficacy/safety versus available comparators



## Value dossiers may help to develop targeted key messages for the different stakeholders

### 4 Value proposition definition – The value dossier: Example

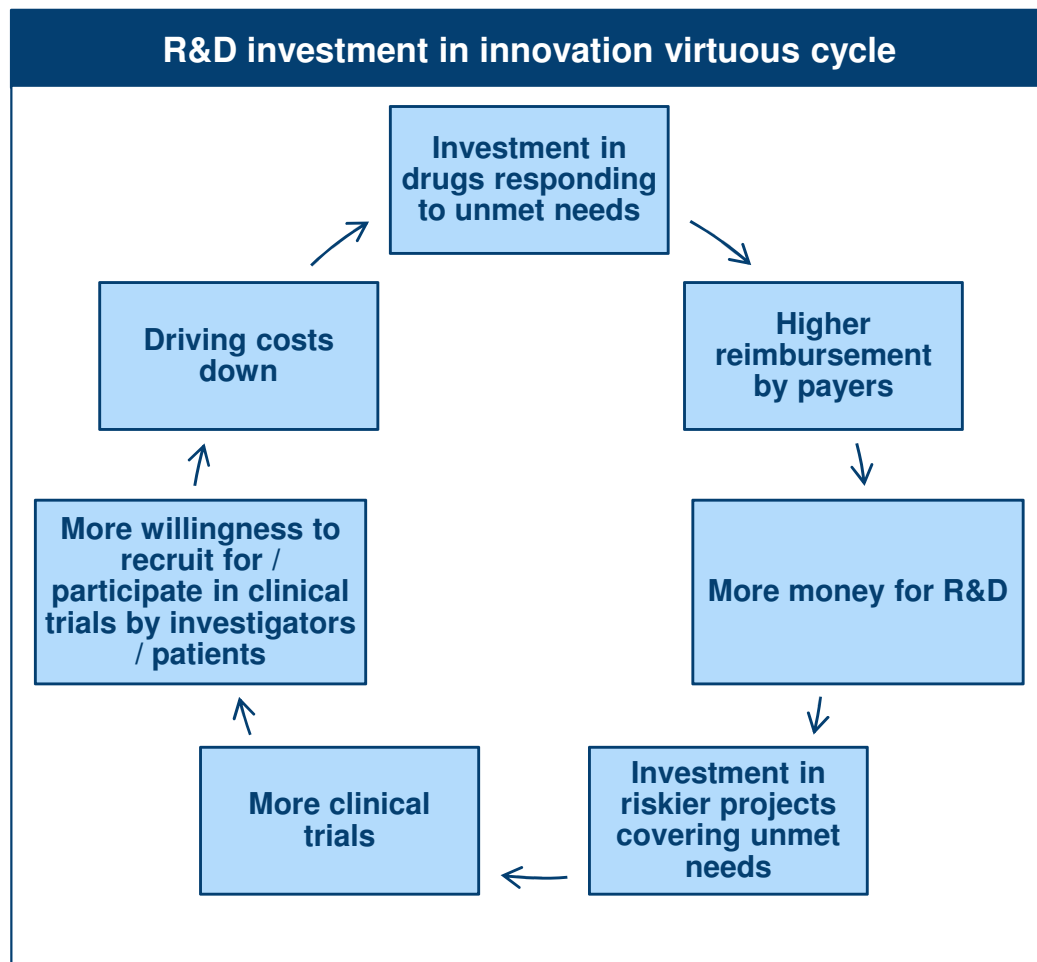


Sources: ISPOR 14<sup>th</sup> annual meeting presentation, RTI Health – Smart Pharma Consulting analysis



Pharma companies corporate reputation is directly related to their research announcements responding to previously unmet needs

### Corporate reputation building – Involvement in R&D



### Patient-centric mindset for an improved corporate reputation

- A reputation benchmark performed by Alva showed that pharma companies **reputation peaked** when were announced **patient-driven breakthrough research initiatives**:
  - **AstraZeneca**'s reputation was improved when was announced in 2014 a partnership with Eli Lilly for the development of **Alzheimer** treatments based on **genome-editing technology**. It also peaked when was announced its partnership with **PatientsLikeMe** in 2015
  - **Merck**'s reputation peaked in 2015 with the announcement of its partnership with Genea Biomedx and with Illumina for the development of **pioneering assisted reproductive treatments**
  - **GSK**'s reputation also peaked with the announcement of R&D innovations such as **Ebola vaccine** reaching phase II during late 2014 or **malaria vaccine** being approved by the EMA and soon to be used in Africa

Sources: "Pharma industry improves its tarnished reputation", CenterWatch News Online – "R&D innovation – a reputation differentiator for pharma", Alva – Smart Pharma Consulting analysis – Merck press release

## The Pharma Corporate Reputation Audit developed by Smart Pharma Consulting facilitates the identification of key challenges to improve corporate reputation

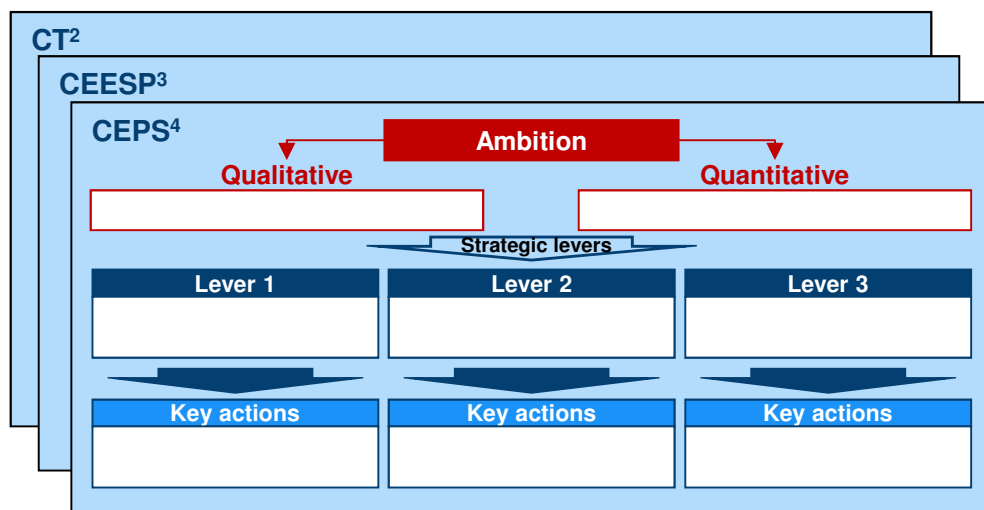
### Corporate reputation strategy & tactics



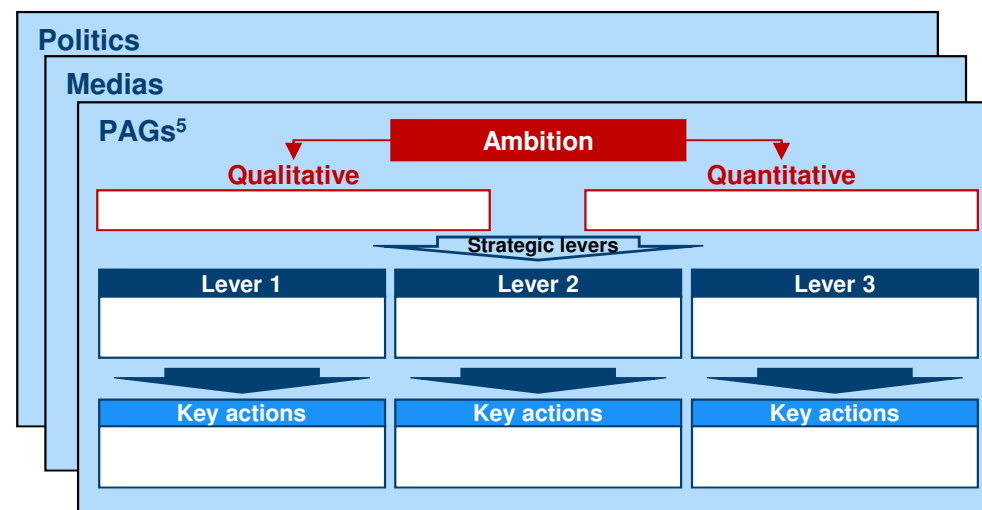
Illustrative - France

### Pharma Reputation Strategy Card

#### HTA<sup>1</sup> / Pricing



#### Access environment



- Strategy and related actions aim at achieving the set ambition in terms of corporate reputation improvement
- The Pharma Reputation Strategy Card can be applied for one stakeholder group (i.e. HTA / Pricing, Access environment...) or sub-group (i.e. CT, CEESP, CEPS, Etc.), or even for one individual stakeholder (i.e. President of the CEPS)
- Strategic levers correspond to **strengths** on which the company should capitalize to create a competitive advantage or **weaknesses** to be corrected

## Market access strategy and corporate reputation play a key role to optimize drug price valuation and to take the advantage over competition...

### Selected key takeaways

- Pressure of governments and payers on drug prices will keep on increasing but the impact within the same category of drugs will significantly differ, depending on market access strategy design and execution by pharma companies

#### DON'Ts

- Justify the price of innovation by the level of investment in R&D which is almost half the one invested in marketing, sales and general expenses
- Invoke the high level of risk, knowing that there is no case of bankruptcy amongst pharma companies
- Invest in sophisticated and expansive health economic studies which will be most likely criticized and not taken into consideration to grant you a better price
- Propose managed entry agreements for which the uncertainty associated with outcomes is high
- Underestimate the importance of corporate reputation

#### DOs

- Pharma companies should act in good faith and put themselves in governments and payers shoes
- Put forward evidence that are well-documented and articulated in a convincing argument to support the asking price
- Managed entry agreements should remain as simple as possible and generate a minimum of controlled associated costs
- Each pharma company should strengthen its corporate reputation to differentiate itself positively from competitors and thus get preferred

**... knowing that pharma companies are not considered as all equal by governments and payers in the context of drug pricing & reimbursement**

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**Pharma companies are facing a paradigm shift which forces them to reinvent in a creative way their strategy, the corresponding tactics and their organization**

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**Context – Objective – Approach**

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- Pharmaceutical companies must urgently **rethink creatively** their business model **to face** the **paradigm shift** that is occurring:
  - Health authorities keep on raising **barriers** regarding drug **registration** and **marketing conditions**
  - **Payers** have no choice but to put more **pressure on drug price**, including on innovative ones
  - **Healthcare professionals** tend to **reduce** their number of **interactions** and to become less and **less sensitive to promotion**
- To help pharma companies figure out how to leverage creativity to boost their performance, Smart Pharma Consulting will attempt to answer the following questions:
  - **Why is creativity so important?**
  - **How to craft a creative strategy?**
  - **How to build a creativity-driven organization?**

*“We are continually faced with great opportunities, brilliantly disguised as insoluble problems” – John W. Gardner*

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**In the business context, creativity stimulates discoveries, inventions and innovations that could potentially result in highly valuable products, services, organizations, etc.**

### Role of creativity in business

- Creativity is the development of ideas about products, services, organizations, business models or theories that are novel and potentially valuable
- Creativity involves the ability to break down and restructure conventional knowledge to come up with different viewpoints and insights
- Creativity can potentially lead to various discoveries, inventions and innovations

### Creativity

#### Discovery

- Discovery consists to be the first to find or observe an existing place, substance or scientific phenomenon
- Discovery can help explain knowledge that is acquired through previous scientific evidences
- Discoveries can be accidental (e.g. penicillin by Alexander Fleming) or sought after through exploration (e.g. the molecular structure of DNA)
- Some discoveries result in invention of objects, processes or techniques

#### Invention

- Inventing is an act of creativity that results in new products, services, organizations, business models or theories, starting from scratch
- Inventions could be accidental (e.g. Viagra) or intentional (e.g. Mosquirix<sup>1</sup>)
- Some inventions result from discoveries (e.g. vaccines)
- Inventions usually require a process where experimentation, “trial and error” and alternations are required in order to create the perfect invention

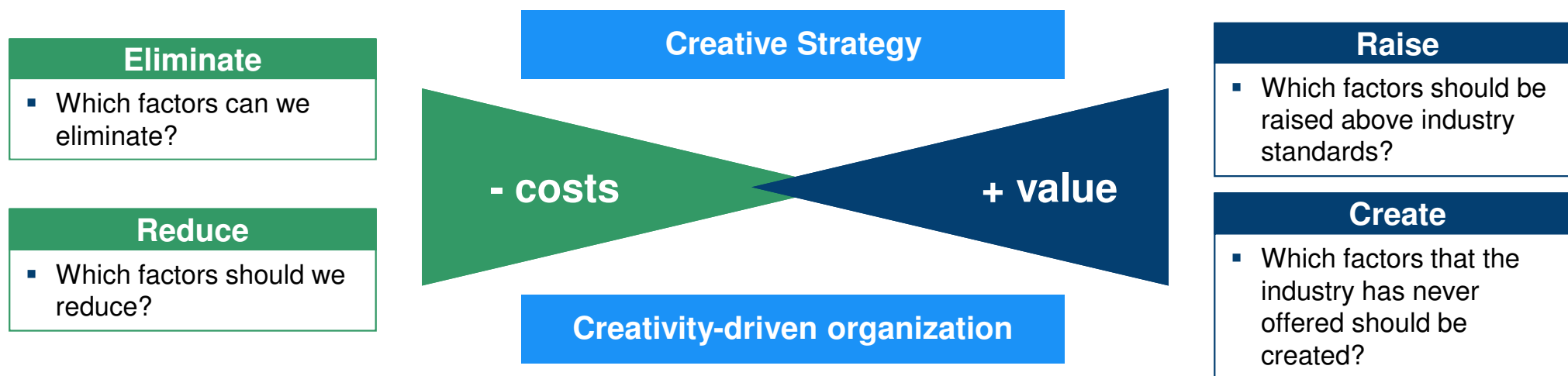
#### Innovation

- Innovation is to make changes in existing products, services, organizations, business models or theories in order to improve them (e.g. long-acting vs. short-acting drugs, calendar packs, etc.)
- These changes may be required to increase efficacy, reduce cost, improve convenience, etc.
- Business innovation intends to improve products, services, organizations, etc., to create more value for stakeholders

**To cope with a deteriorating competitive environment, pharma companies must build a creative business model to reduce costs and/or offer better value to customers**

**New pharma business model**

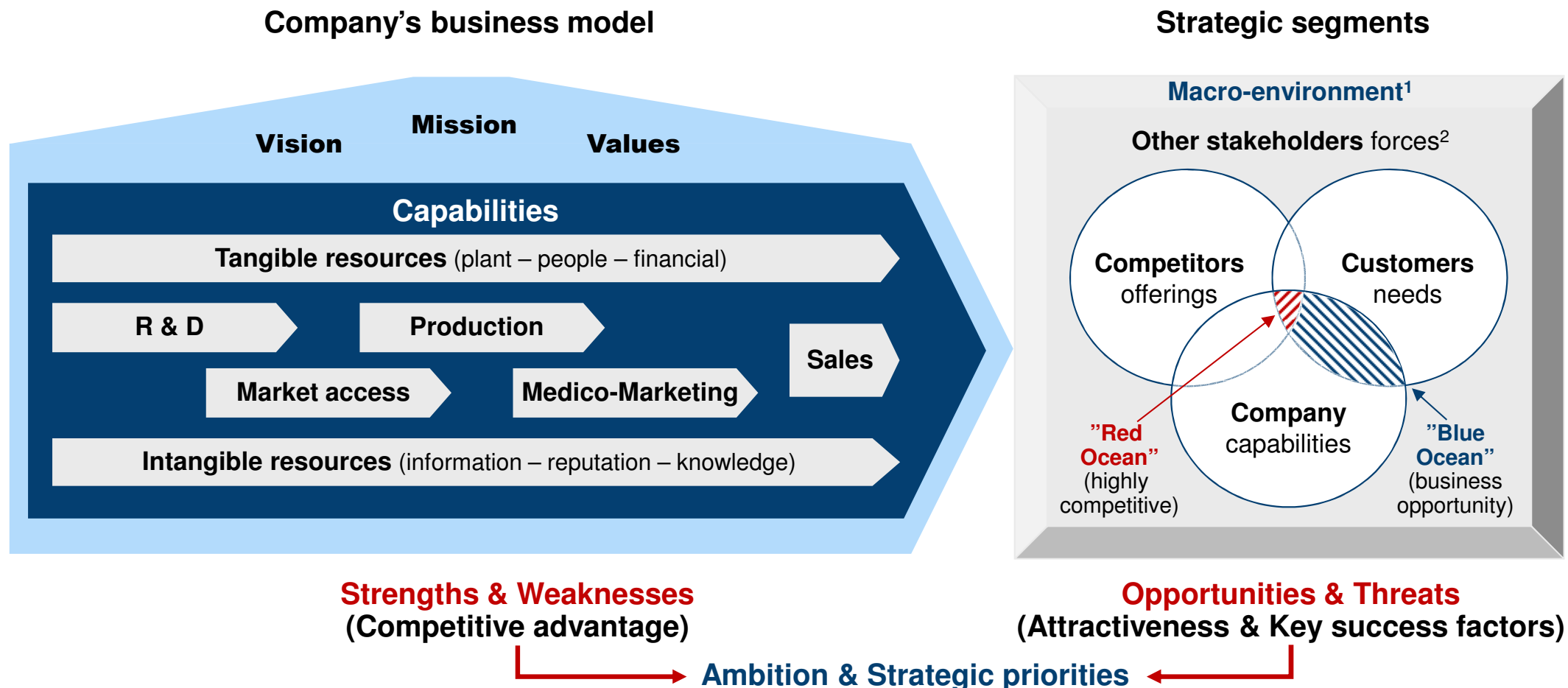
- The **new business model** that pharma companies must craft **should** simultaneously:
  - **Reduce costs** by eliminating less valuable features or services
  - **Increase customer value** (and in return company value) by offering new benefits and services
  - **Rethink the organization** so that functional and operational activities be fully aligned to support the associated strategy



*“New business models consist in doing things differently...  
... while new business strategies consist in doing different things”*

To craft a successful creative strategy, pharma companies must identify the business opportunities where they could have the strongest competitive advantage

**Creative strategy crafting (1/3)**



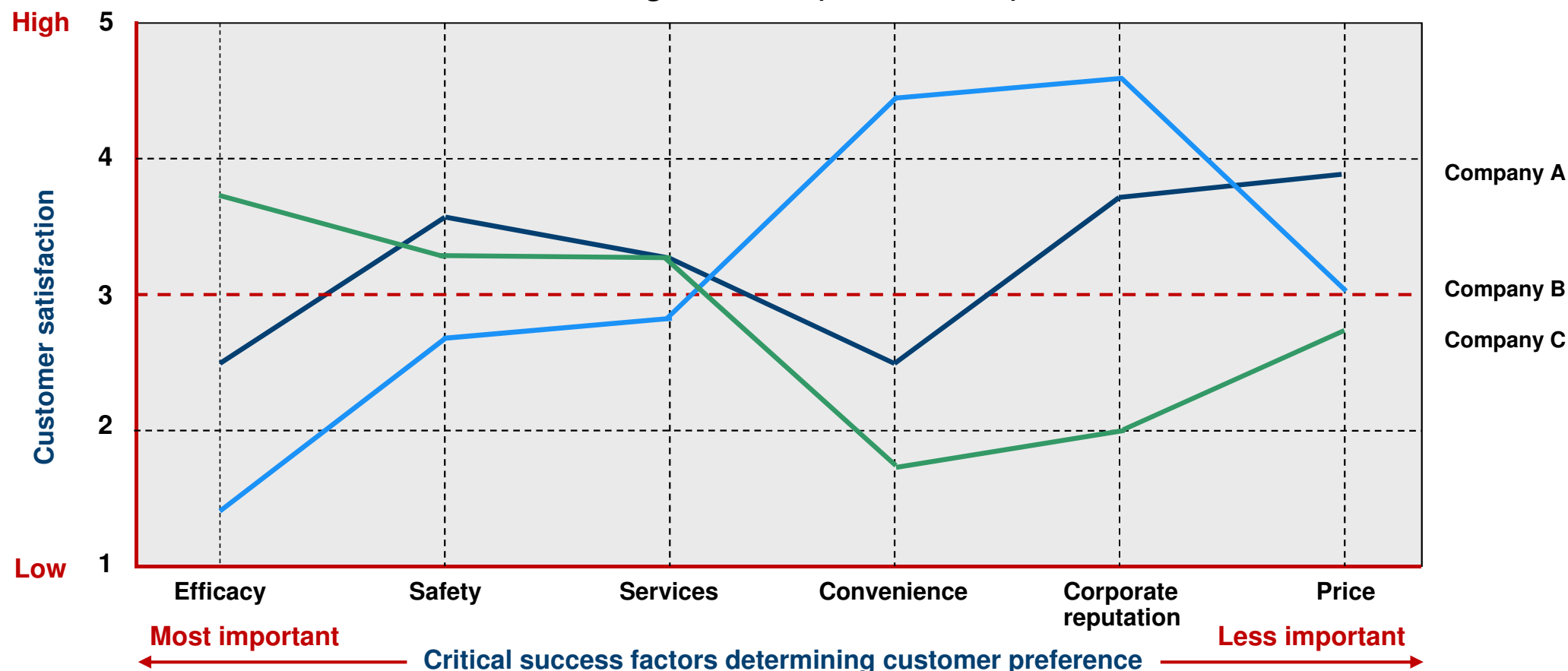
Sources: Adapted after C. Kim et R. Mauborgne 2005 - D.J. Collis, HBR April 2008, M. Porter 1985 - Smart Pharma Consulting

<sup>1</sup> Political / legal, economic, socio-demographic and technological factors –  
<sup>2</sup> Including suppliers, new entrants, substitutes, complements

The Strategic Canvas is both a diagnostic tool to identify gaps not fully exploited by competition and a decision-aid to select which ones to fill up, to meet customer needs

**Creative strategy crafting (2/3)**

Strategic Canvas (Value curves)



Sources: Adapted after C. Kim et R. Mauborgne 2005



“Blue Ocean” strategies, based on value innovation, consist in creating new market spaces, making the competition either “irrelevant” or weak

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**Creative strategy crafting (3/3)**

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**New market space conception****Red Ocean Strategy**

1. Compete in the existing market space
2. Beat the competition
3. Exploit the existing demand
4. Make the value-cost trade off
5. Align the organization with its differentiation or low cost strategy

**Structuralist approach****Blue Ocean Strategy**

1. Create an uncontested market space
2. Make the competition irrelevant
3. Create & capture new demand
4. Break the value-cost trade off
5. Align the organization with its differentiation and low cost strategy

**Reconstructionist approach**

*“Develop a strategy that structures the market and not a strategy that adjusts to the market structure”*

**To exploit new business opportunities, companies must develop new strategies consisting in doing different things that will be highly valued by customers**

**“Blue Ocean” strategic examples**

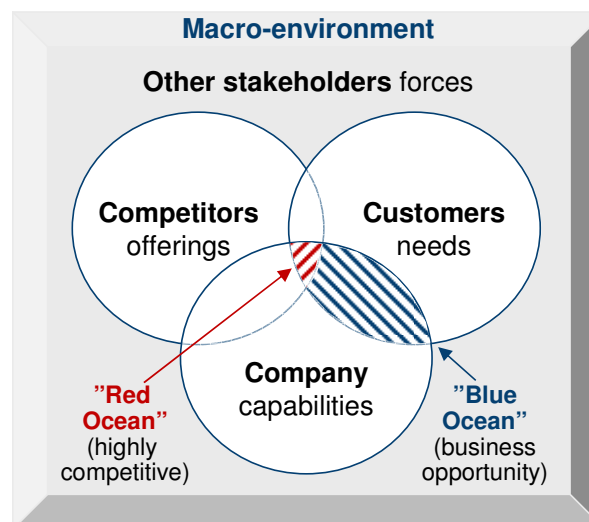
**Price & Performance**



Since 2009, GSK is committed to reinvest 20%<sup>1</sup> of profits made in LDCs<sup>2</sup> and to heavily lower drug prices<sup>3</sup> to increase patient access and then grow on a strategic segment disregarded by most of big pharma companies

**Around-the-pill services**

In 2014, Merck launched a device to inject Rebif, for patients with MS<sup>4</sup>, which collects and stores data that can then be sent to a secure server. The system can prompt patients to a better adherence to treatment



**Functional vs. Emotional focus**

Viagra was not positioned by Pfizer as a treatment of erectile dysfunction but as a solution to enhance patients' life style, putting the emphasis on emotional appeal



**Physicians vs. Patients focus**

NovoPen, the first insulin pen injector, was introduced in 1985 by Novo Nordisk, to make injection more convenient and easier for patients, improving their quality of life and their adherence to treatment



Sources: Adapted after C. Kim et R. Mauborgne 2005, companies websites

<sup>1</sup> Representing a total amount of € 25.4 million reinvested in training 40,000 health workers and building infrastructures, having contributed to improve healthcare access to 11 million people over the 2009-2015 period – <sup>2</sup> Least developed countries – <sup>3</sup> Prices of patented products are capped at no more than 25% of their UK or French price and as low as their manufacturing cost – <sup>4</sup> Multiple Sclerosis

**The creative power of individuals is based on four key dimensions that vary significantly according to innate and acquired personality of individuals**

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**Key traits of creative individuals**

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**Originality**

- They are able to spot underlying patterns in events
- They produce unique, novel, new, creative or innovative and unusual ideas

**Flexibility**

- They are able to shift from one approach to another when addressing issues
- They see relationships between seemingly disconnected elements
- They produce a large variety of ideas

**Fluency**

- They are able to produce many ideas
- They cope with paradoxes
- They challenge status quo
- They can mix viewpoints or perspectives

**Proactivity**

- They are curious
- They look beyond the first “right idea”
- They are not afraid to make mistakes
- They take risks

*“Chance favors only the prepared mind” – Louis Pasteur*

## The mental attitude of individuals can be modified to stimulate the generation of new ideas by applying simple rules

### Creativity stimulation: Practical rules (1/2)

#### Connect unrelated ideas or things

*(e.g. In the 17<sup>th</sup> century, the German astronomer Johannes Kepler drew attention to the fact that tides are somehow linked to the movement of the Moon<sup>1</sup>)*

#### Search for new applications

*(e.g. A visual analogue scale designed to assess the pain of patients may as well be used to assess patients' well-being)*

#### See things in different ways

One thing may be seen in different ways as shown by this picture



#### Use metaphors

The metaphor which connects two different universes of meaning through similarities helps understand one idea by another one  
*(e.g. Thinking of how to catch a fish in order to find new ideas to attract more customers)*

#### Cultivate a sense of humor

Both Albert Einstein and Leonardo da Vinci cultivated the humorous perspective  
*(e.g. How deep is the ocean?  
Just a stone's throw)*

*“The metaphor is probably the most fertile power possessed by man” – José Ortega y Gasset*

## The mental attitude of individuals can be modified to stimulate the generation of new ideas by applying simple rules

### Creativity stimulation: Practical rules (2/2)

#### Get rid of excuses

It takes more creativity to get rid of excuses than it does to come up with new ideas

(e.g. When the Spanish conquistador Hernan Cortés, arrived at Veracruz in Mexico, he burned his ships and told his men “Now you can either fight or die”. Thus, removing the possibility to give up and return to Spain)

#### Reverse viewpoints

By turning conventional logic upside down, we may generate new ideas, and thus open up our thinking

(e.g. Noting that milkmaids were generally immune to smallpox, Edward A. Jenner postulated that the pus in the blisters that milkmaids received from cowpox - a disease similar to smallpox, but much less virulent - protected them from smallpox. Then Jenner tested his hypothesis by inoculating people and proved that they were immune to smallpox). Jenner developed and generalized the vaccination technique)

#### Be persistent

It is important to be persistent when attacking creatively a problem and to keep on searching even when you feel like giving up

#### Think ambiguously

If ambiguity causes confusion and communication problems, it can also be a powerful stimulant to imagination

#### Search for alternatives

(Knight’s move thinking)

Replace the “either/or” statement by “How to” to find additional options  
(e.g. Either you drop your price or lose your customer. The question: “How to retain the customer?” can help find new options)

**“Creativity is contagious.  
Pass it on” – Albert Einstein**


**Creativity-spurring checklists help open minds and explore new areas to find creative ideas by stimulating imagination**

**Creativity stimulation: Idea-generating techniques (1/4)**

SCAMPER		
<b>S</b>	<b>Substitute</b>	<i>What could be substituted to make an improvement?</i>
<b>C</b>	<b>Combine</b>	<i>What could be combined to make something more useful?</i>
<b>A</b>	<b>Adapt</b>	<i>How could the product or service be adjusted for a better output?</i>
<b>M</b>	<b>Modify</b>	<i>What could be modified, minified or magnified?</i>
<b>P</b>	<b>Put to other uses</b>	<i>Could the product or service be used in another market?</i>
<b>E</b>	<b>Eliminate</b>	<i>What would happen if a component was removed?</i>
<b>R</b>	<b>Rearrange</b>	<i>Is there something that could be reversed or done in a different order?</i>

**Kipling's Questions**

The Kipling method is one of the most basic way to explore any idea or problem consisting of a list of 6 fundamental questions



*“Questions are the creative acts of intelligence” – Francis Kingdon-Ward*

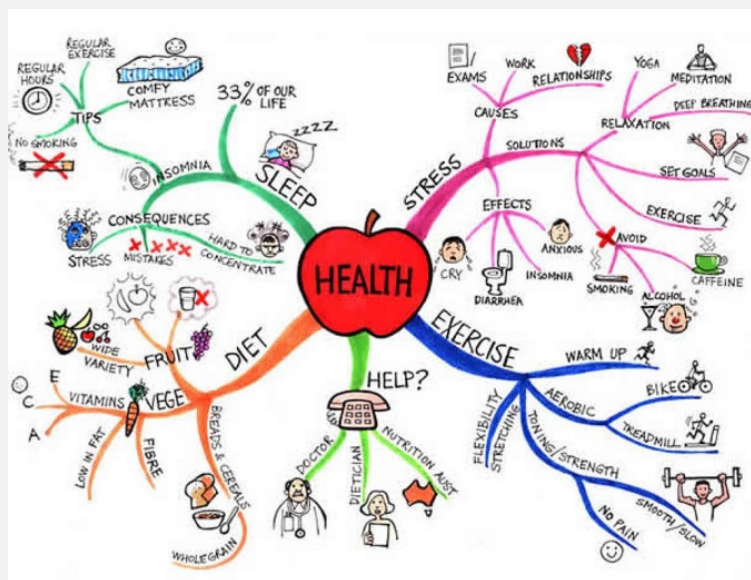


The mind mapping and the relevance tree enable to link thoughts without squeezing them into less natural listing or step-by-step sequence

**Creativity stimulation: Idea-generating techniques (2/4)**

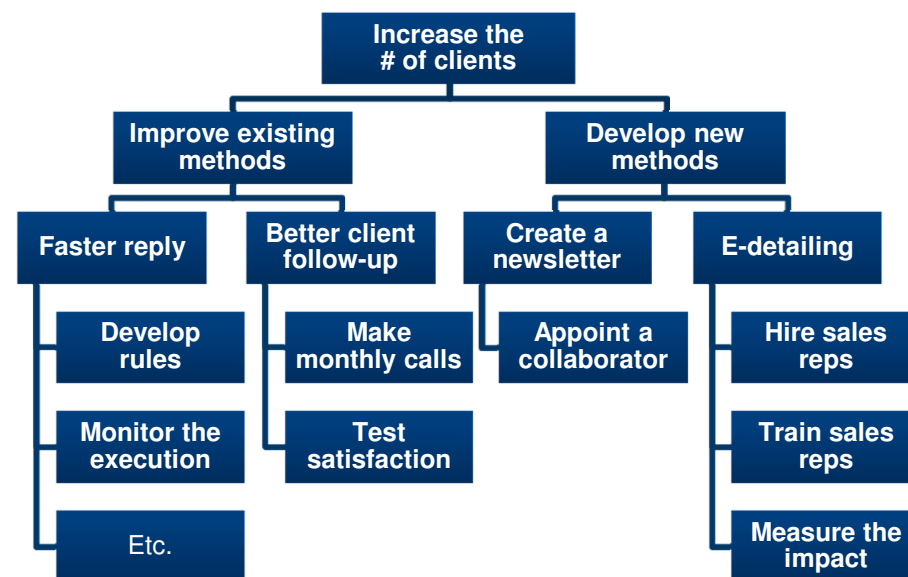
**Description**

A mind map is basically a diagram that connects information around a central subject



**The relevance tree**

The relevance tree serves as visual illustration to help understanding and to stimulate ideas




*“Creativity is the power to connect the seemingly unconnected” – William Plomer*

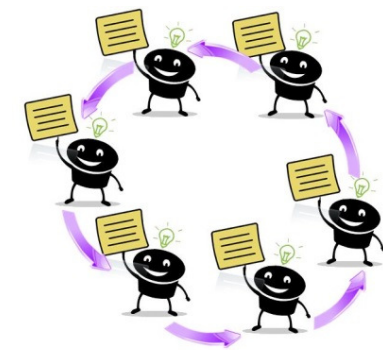
The Brainstorming and the brainwriting are intuitive techniques that stimulate the generation of many creative ideas in a short period of time by a group of participants

**Creativity stimulation: Idea-generating techniques (3/4)**

**Brainstorming**

- 1 **State** and **restate** the **problem** (How to do something?)
  - 2 Brainstorm (idea generation stage)
- 
- 3 Select the **wildest** and **most foolish idea** and turn it round into some **more useful ideas**
  - 4 **Evaluate the ideas** generated, **later on** by the brainstormers and/or a team of people deeply involved with the problem

**Brainwriting**

- 1 After the **first idea** has been **written** by one of the participants and **passed on** to another, every one **reacts** – still **through writing** – to the last idea proposed **until no more idea comes out**
- 
- 2 Then, a **list of all the ideas** is given out to each of the participants

*“The fusion of knowledge is the most creative act of the human mind” – Elwood Murray*



The creativity is stimulated by “synectics” through metaphors and analogies while the “six thinking hats” approach is based on participants role playing

**Creativity stimulation: Idea-generating techniques (4/4)**

**Synectics**

“Synectics” combines elements apparently irrelevant by using **metaphors** and drawing **analogies**







The process includes 3 steps:

- **Referring:** Specific problem definition
- **Reflecting:** Imaginative manipulation of the problem, exploring alternatives, possible solutions and translations of various types
- **Reconstruction:** Reinventing or transforming with synectic trigger mechanisms

Add	Transfer	Substitute	Analogize
Subtract	Emphasize	Fragment	Hybridize
Repeat	Animate	Isolate	Disguise
Combine	Parody	Distort	Fantasize

**Six thinking hats**

**Each participant** (Thinking Hat) of the creative session has a **specific** color representing an **attitude** (role play) leading to **parallel thinking**:

-  Neutral, objective (facts and figures)
-  Emotional (intuitions, impressions, feelings)
-  Objective, negative (critical, pessimism)
-  Objective positive (optimism, exploration)
-  New ideas (creativity, lateral thinking)
-  Moderator (control, organization, facilitation)

The problem is introduced at the beginning of the meeting and then **everyone** should use **all the hats**

This method provides a **comprehensive understanding** of the **issue** but is time consuming

*“You see things; and you say, ‘Why?’ But I dream things that never were; and I say, ‘Why not?’” – George Bernard Shaw*

**While the creative thinking enables the generation of many ideas, the latter should then be evaluated and selected through an analytical thinking process**

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**Combination of creative and analytical processes**

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**Creative thinking**

- Creative thinking (also called lateral thinking) is:
  - Imaginative
  - Divergent
  - Giving many ideas (including those that could be viewed as wild or foolish, and those that appear not to be linked with the problem)

**Analytical thinking**

- Analytical thinking (also called vertical thinking) is:
  - Logical
  - Convergent
  - Giving a unique or small number of ideas
- This approach requires deep and narrow probing to identify all aspects



Analytical and creative thinking processes  
are complement and equally important



**Many ideas generated**



**Few solutions selected**

*“The creative process is any thinking process which solves a problem in an original and useful way” – H. Herbert Fox*

## The creativity at various levels of the company can be fostered by the following key recommendations

### Key drivers to develop a culture of creativity

#### 1. Provide objective

- Collaborators must have a purpose and direction for their creativity
- Guidelines and reasonable constraints will enable to ensure some control over time and cost

#### 2. Permit more interactions

- Creative climate is stimulated if individuals take part in project and working groups
- Such interactions encourage exchange of information, flow of ideas and fresh perspectives

#### 3. Encourage new ideas

- Throughout the company, new ideas should be encouraged
- Thus managers should be willing to listen to suggestions, and organize whenever relevant idea generation meetings

#### 4. Tolerate failure

- Most of new ideas will prove to be impractical or useless
- It is however important to invest in experimenting with these new ideas to identify the ones which will be effective

#### 5. Acceptance of change

- Collaborators should ideally participate in making decisions
- Issues like job security should be carefully handled when changes are planned and implemented

#### 6. Offer recognition

- Creative individuals are most often self-motivated
- However, a monetary and/or non-monetary reward should be granted to demonstrate that creative behavior is valued

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**Creative companies foresee needs that customers have not yet realized and seize opportunities that competitors have not yet seen or have overlooked**

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**Key learnings**

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- Creativity is a **powerful engine** to **discover**, **invent** and **innovate** in products, services, processes, concepts, etc., that **can** potentially **boost** the **performance** of companies
- **In a deleterious environment**, in which innovation is more and more costly, competition intensifies and payers keep on increasing their pressure on price, **pharma companies** should **put creativity at the top of their agenda** to simultaneously:
  - **Reduce** their **costs** and **increase** their **value proposition** to **optimize** the **performance** of their **current business**
  - **Craft innovative** “Blue Ocean” **strategies** to **create** and **develop market spaces** in which **competition** does **not yet exist** or is **still weak**
- For so doing, pharma companies should **put in place** a **creativity-driven organization** in which:
  - **Individual creativity** is **encouraged** and **rewarded**
  - **Group creativity** is **favored** through the introduction of a **formal creative thinking process**

*“Creativity is inventing, experimenting, growing, taking risks, breaking rules, making mistakes, and having fun” – Mary Lou Cook*

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

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**Context & Objective**

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- **Partnerships with KOLs (Key Opinion Leaders)<sup>1</sup>, also called TLs (Thought Leaders) are part of the armamentarium used by pharmaceutical companies to:**
    - Develop their products through pre-clinical and clinical trials
    - Raise the awareness and the preference of HCPs (Health Care Professionals) but also of health authorities, PAGs (Patient Advocacy Groups), individual patients, etc., for their marketed brands
  - **In this position paper, Smart Pharma Consulting proposes:**
    - A simple but rigorous process and...
    - A set of tools...
- ... to recruit and manage KOLs in a more efficient and effective way**

*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 international, national and local levels**

**KOLs definition**

**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 are able to **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**



Sources: Smart Pharma Consulting analysis

Other stakeholders than physicians likely to have an influence on medical practices and physicians preference for a product



The relationships between pharmaceutical companies<sup>1</sup> and healthcare professionals are increasingly regulated and potential conflicts of interest must be disclosed

### Regulatory framework<sup>2</sup> 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 medicines



#### 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** in all circumstances, 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)

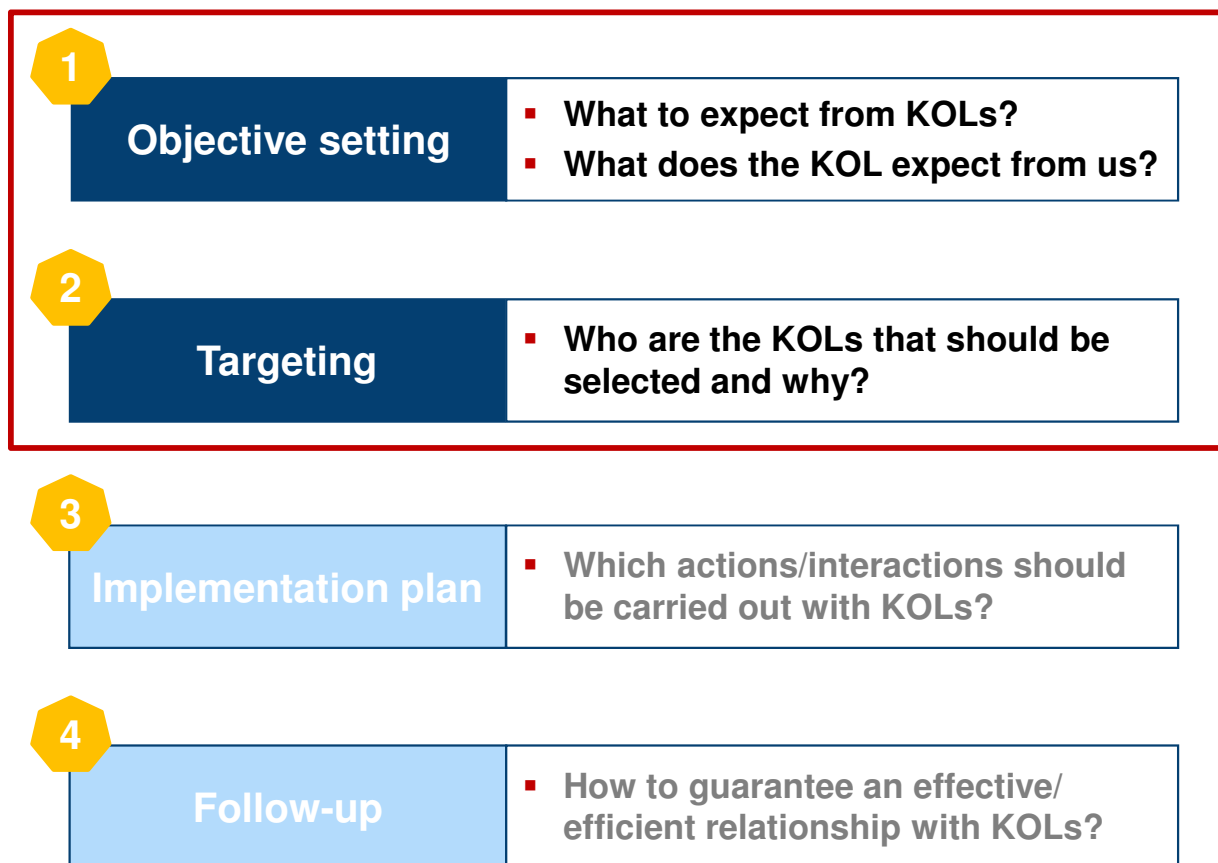
Sources: <http://eur-lex.europa.eu/> – Leem – The ABPI Code of Practice for the Pharmaceutical Industry – Code of conduct farmindustria – Farmaindustria Code of practice – Compliance issues for pharmaceutical companies in Germany

<sup>1</sup> Including biotechnology and medical devices companies – <sup>2</sup> Extracts

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

**Recruitment & Management process of KOLs**

**The 4 key steps**



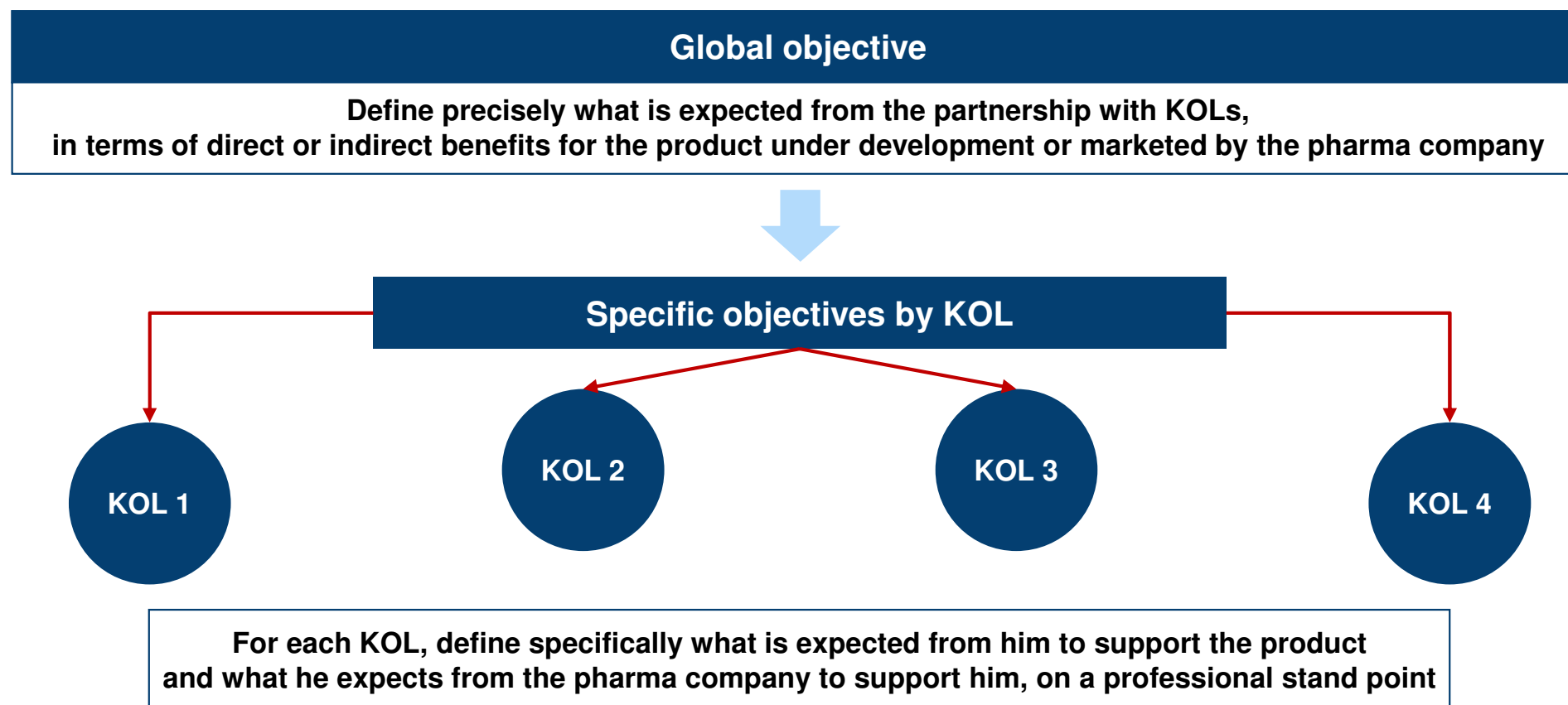
- Relationships with KOLs should be defined according to the set objectives
- Then, the prospective KOLs should be profiled and targeted
- Once the KOLs have been selected, their interactions with the pharma company and the activities they are expected to implement should be defined and formalized in 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, have to be set for each of them

1

## Objective setting

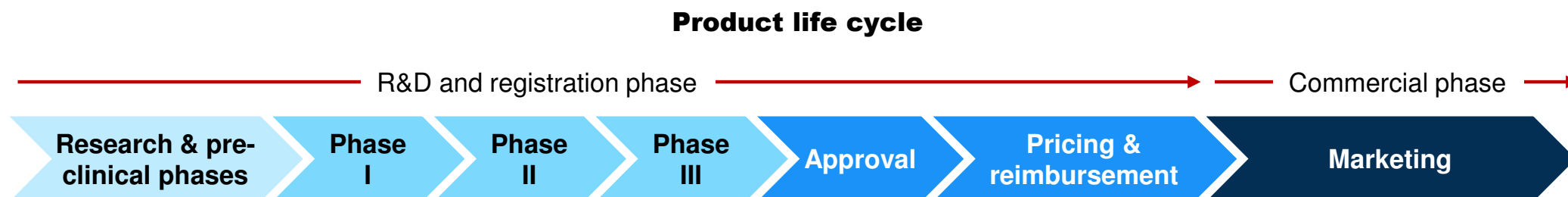
*Partnerships with KOLs should be part of a global strategy, including also market access, medico-marketing and sales initiatives*



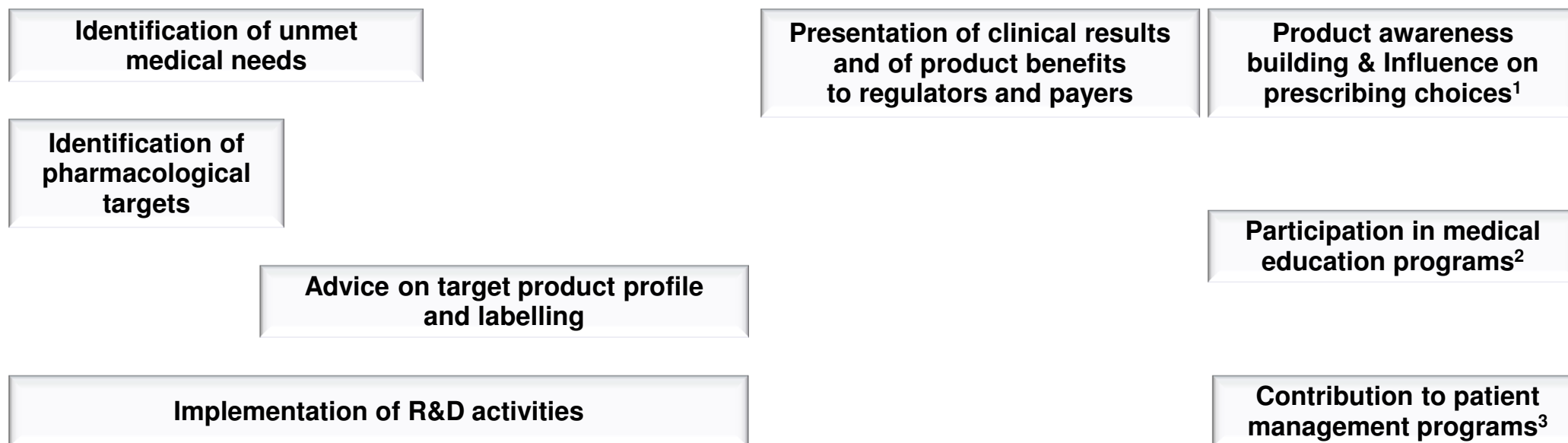
The objective of the KOL partnership and the corresponding activities will depend on where the product is positioned on its life cycle

1

## Examples of KOL roles according to the product life cycle



### Examples of KOL roles



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

2

**KOLs targeting – Methodology (1/2)**
**Key questions**
**What to do**
**Selection criteria**

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

- Review of possible 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 and external databases reviews 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?

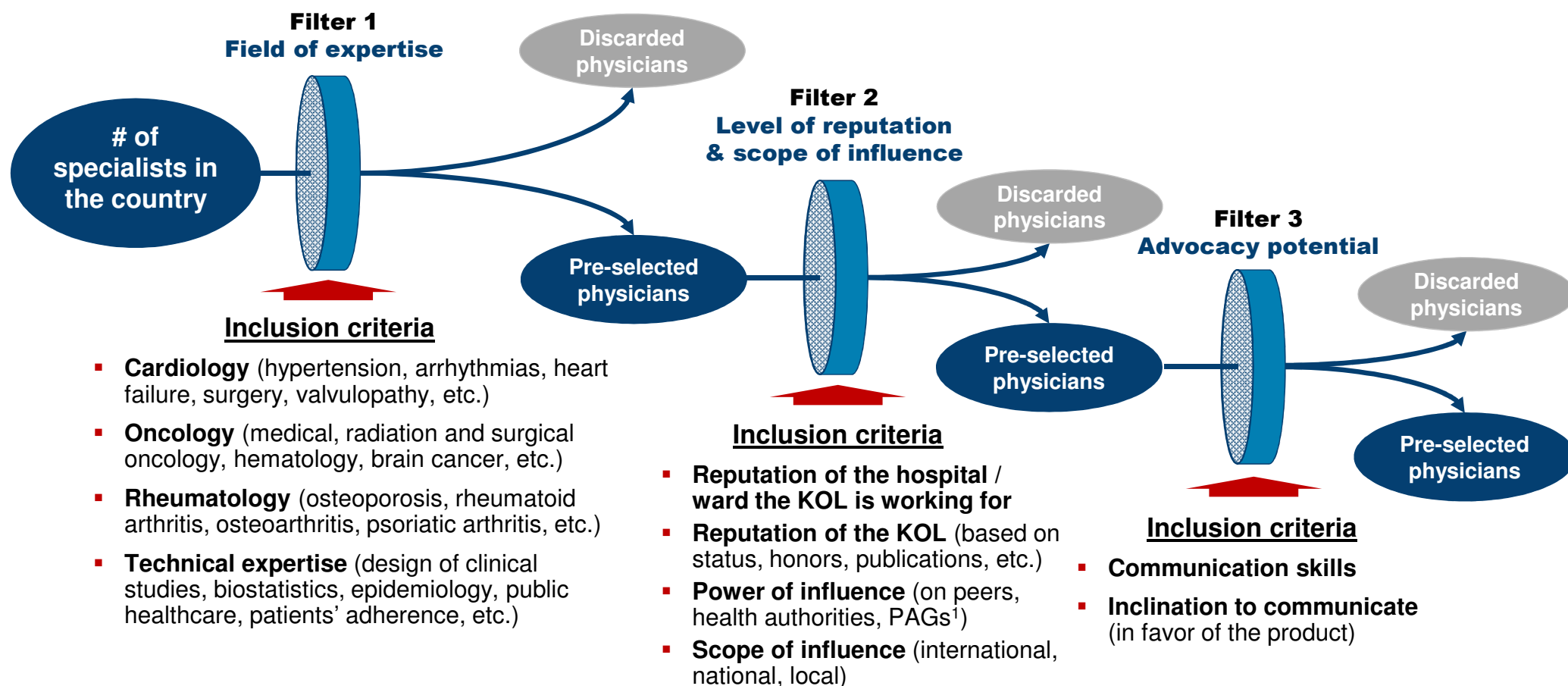
- Selection of the KOLs
- Preliminary definition of the type of partnerships to be carried out with the targeted KOLs

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

2

**KOLs targeting – Methodology (2/2)**

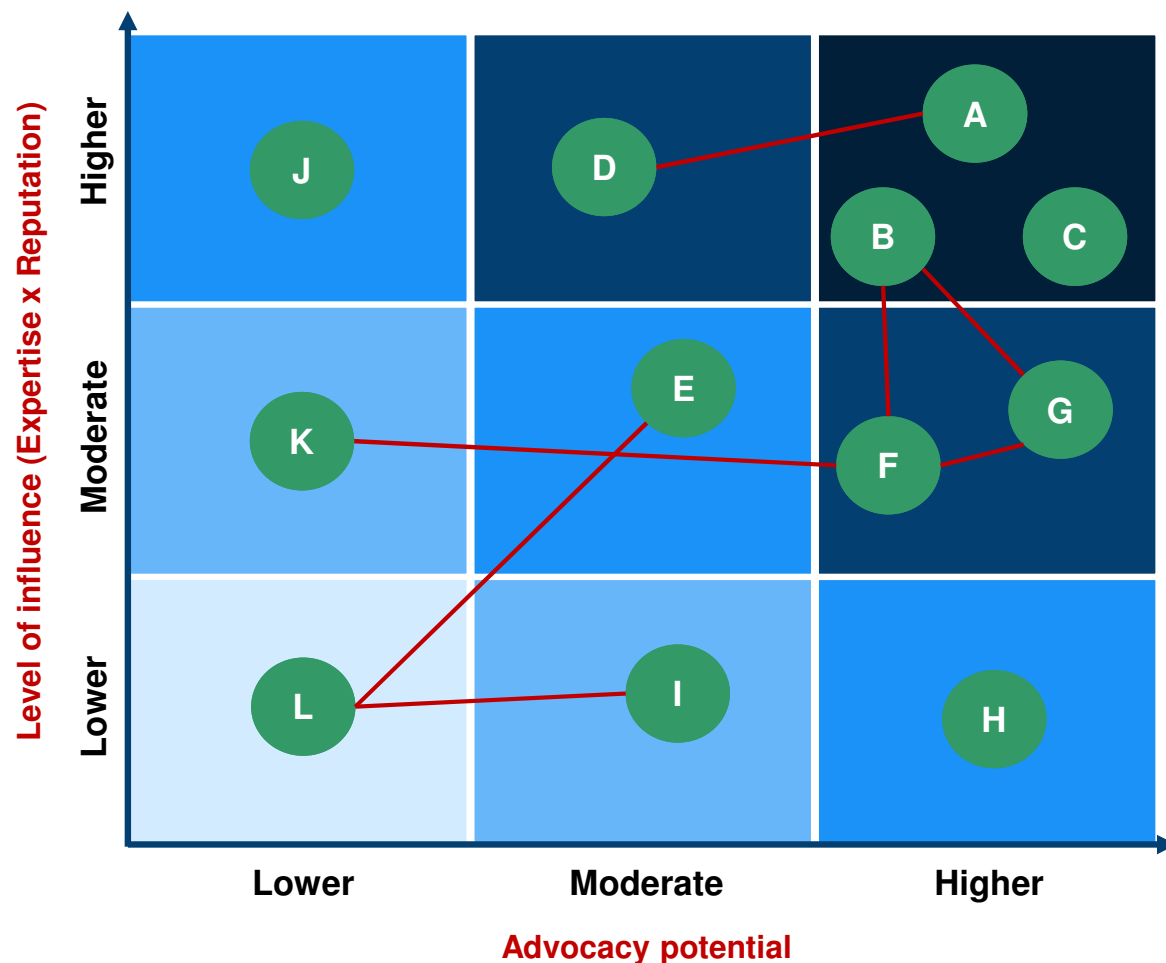
**Screening process (illustrative)**



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

2

**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 take into account:
  - 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)**

2

### How to qualify KOLs?

What data to collect?	How to collect data?	How to analyze data?
<ul style="list-style-type: none"> <li><b>Status</b> (e.g. head of medical department, professor, age, public vs. private practice, place(s) of practice)</li> </ul>	<ul style="list-style-type: none"> <li>Internet, direct search</li> </ul>	<ul style="list-style-type: none"> <li>Being head of hospital and professor is a plus</li> </ul>
<ul style="list-style-type: none"> <li><b>Field of expertise/interest</b> in a therapeutic area, in a technique, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Probing by MSL<sup>1</sup>, medical reps and other collaborators of the pharma company</li> </ul>	<ul style="list-style-type: none"> <li>KOLs should express their field of interest over the long term and their expectations from a partnership with the pharma company</li> </ul>
<ul style="list-style-type: none"> <li><b>Level of reputation &amp; scope of influence</b></li> </ul>	<ul style="list-style-type: none"> <li>Field research (e.g. peers, pharmacists interviews, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Internal or national level is preferable in general to local level (but it depends on the objective)</li> </ul>
<ul style="list-style-type: none"> <li><b>Communication skills</b></li> </ul>	<ul style="list-style-type: none"> <li>Analysis of past performances</li> <li>Interviews of peers</li> </ul>	<ul style="list-style-type: none"> <li>Verbal communication (e.g. lectures, courses)</li> <li>Written communication (e.g. articles, websites)</li> </ul>
<ul style="list-style-type: none"> <li><b>Type &amp; level of communication</b> <ul style="list-style-type: none"> <li># articles published (impact factor<sup>2</sup>, peer-/ non peer reviewed journals, position as an author...)</li> <li># of trainings p.a. (CME<sup>3</sup>)</li> <li>Teaching activity at university</li> <li>Presence on the Internet</li> <li># of lectures (congresses, round tables)</li> <li># of quotes by journalists in current year</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Review of scientific articles published (PubMed/Medline, Google scholar, Expertscape)</li> <li>Probing by collaborators of the pharma company and peers interviews to evaluate trainings, teaching activities and lectures</li> <li>Google searching for presence and quotes on the Internet</li> </ul>	<ul style="list-style-type: none"> <li>The higher the impact factor is, the better</li> <li>KOLs should be ideally positioned as 1<sup>st</sup> or last authors in articles</li> <li>The higher the number of training, teaching and lectures, the better</li> <li>Perceived quality of articles, training, teaching and lectures should be assessed</li> </ul>
<ul style="list-style-type: none"> <li><b>Membership in learned societies</b> <ul style="list-style-type: none"> <li>Title / position / activities</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>On the website of the learned societies or by calling them</li> </ul>	<ul style="list-style-type: none"> <li>Being a member of the management board is a plus</li> </ul>
<ul style="list-style-type: none"> <li><b>Inclination to partner with a pharma company and to support its products</b></li> </ul>	<ul style="list-style-type: none"> <li>Probing by collaborators of the pharma company</li> </ul>	<ul style="list-style-type: none"> <li>They should clearly express their interest in the product and the company...</li> <li>... and in the types of partnerships they are looking for</li> </ul>

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

2

### How to convince KOLs to partner?

#### 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 been qualitatively and quantitatively his level of involvement?
  - What has been his feed-back from previous collaborations?
  - 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 into 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 access to recent information, to high education programs<sup>1</sup>, 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

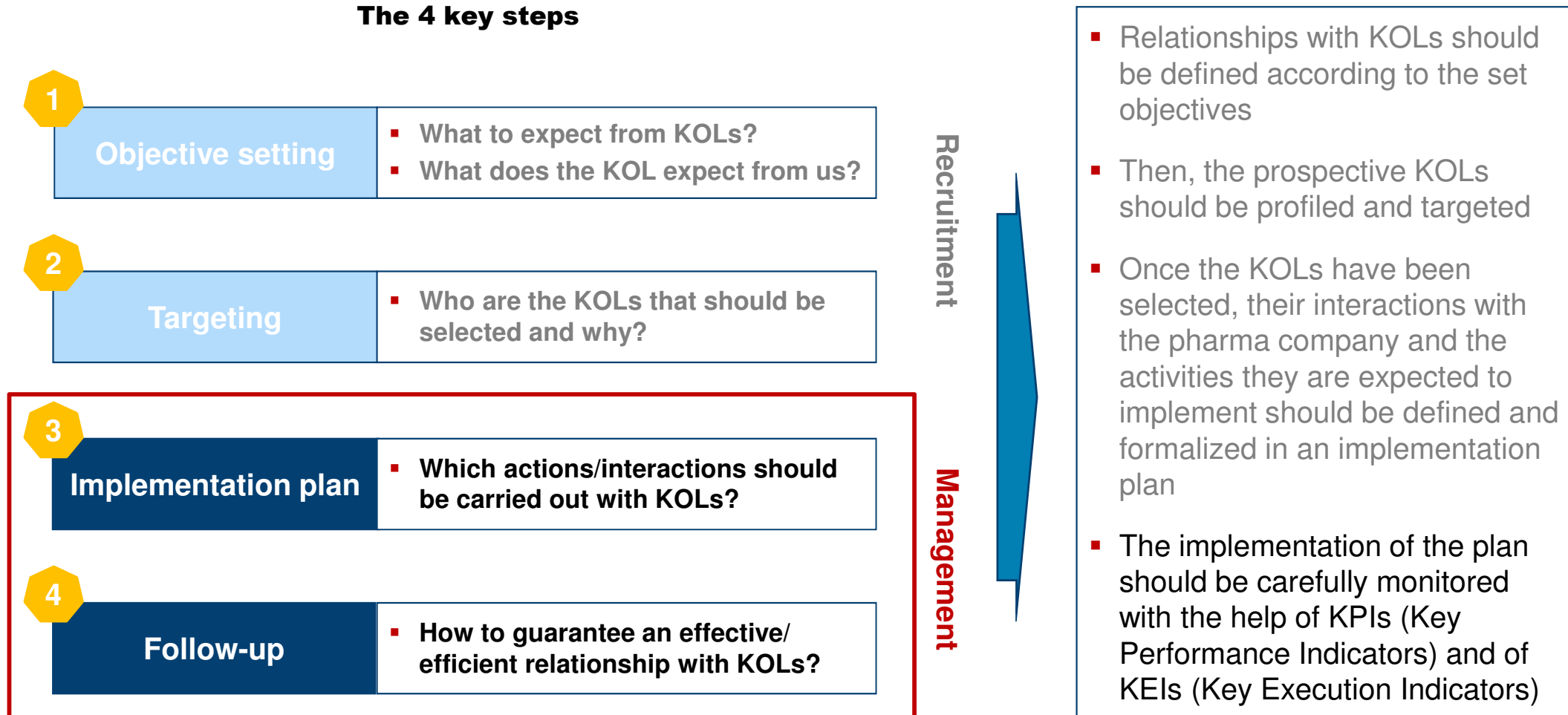
### Tool to facilitate the recruitment process: KOL ID card

<b>KOL name</b>	(First name – surname)	<b>Medical status</b>	MD – head of medical department – professor of medicine, etc.	<b>Location</b>	Address & City
<b>Specialty</b>	(Oncology – cardiology, etc.)	<b>Medical setting</b>	Private hospital – public hospital – teaching hospital – private office	<b>Country</b>	
Specific objectives for the pharma company		•			
Specific benefits for the KOL		•			
<b>Items</b>		<b>Assessment<sup>1</sup></b>		<b>Facts / Rationale</b>	
<b>KOL Profile</b>	Field of expertise/interest in the therapeutic area	<b>International - National - Local</b>	•		
	Level of reputation	<b>Low -Medium-High</b>	•		
	Scope of influence	<b>Low -Medium-High</b>	•		
	Advocacy potential	<b>Low -Medium-High</b>	•		
<b>Recommendations</b>		<b>Priority<sup>1</sup></b>		<b>Rationale</b>	
<b>Medical department</b>		<b>Low -Medium-High</b>		•	
<b>Final decision</b>					
<b>Selection: YES - NO</b>		<b>Rationale:</b>			

**An effective collaboration with KOLs requires to follow a rigorous recruitment process and to develop a precise action plan along with monitoring tools**

**Recruitment & Management process of KOLs**

**The 4 key steps**

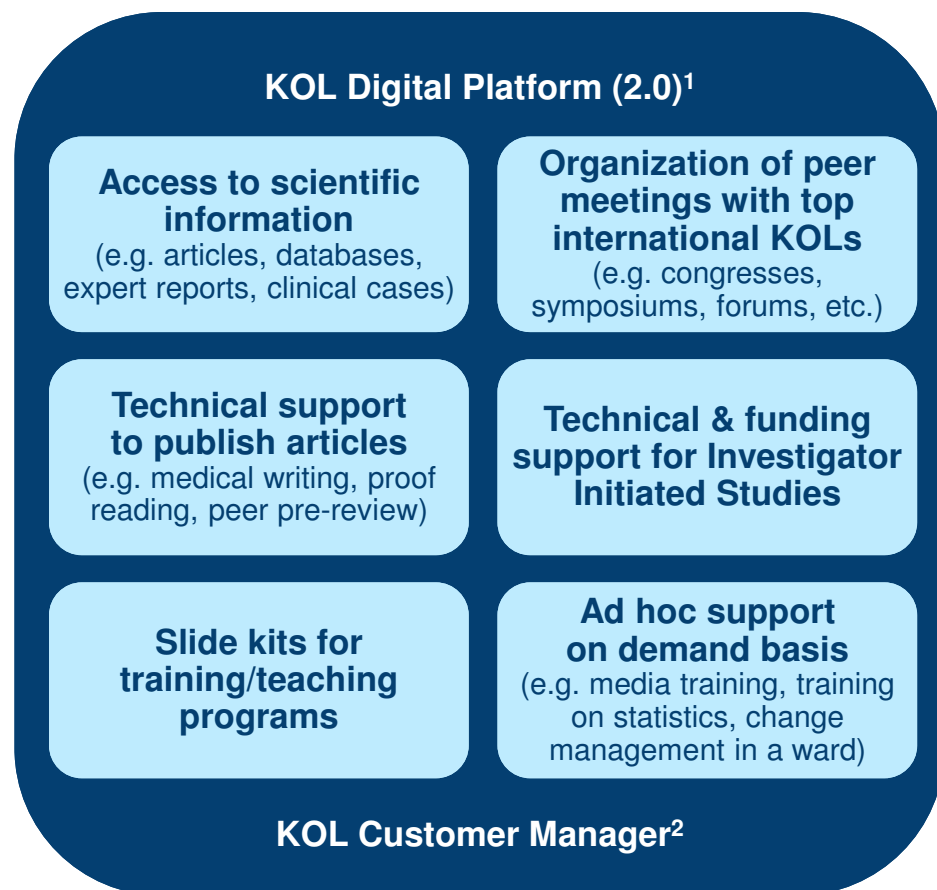


Pharma companies should balance what they expect from KOLs in terms of activities and what they give them in terms of services to ensure a win-win partnership

3

**Services proposed to & activities carried out by KOLs**

**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

3

### Potential value of KOL activities (1/2)

#### Article writing

- KOLs may support the pharmaceutical company priorities by communicating in scientific journals, professional magazines or lay press regarding:
  - New medical approaches, new guidelines, patient management, etc. in a given therapeutic area, etc.)
  - The position of its products in the therapeutic strategy
- Perceived reliability by readers: **H**
- Number of exposed readers: **L** to **H**

#### Lectures during symposia

- While giving lectures, KOLs may accept to cover topics of interest for the company
- ... and/or position their products vs. direct competitors or indirect therapeutic alternatives
- 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: **H**

#### Training of peers / CME<sup>1</sup>

- KOLs may communicate to their peers, to pharmacists, to nurses, etc., during training sessions regarding:
  - Medical topics of interest for the pharma
  - 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, marketing and sales teams of the pharma company**

**3**

### Potential value of KOL activities (2/2)

#### 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, etc.)

#### 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



The development of a “KOL Partnership Plan” or K2P is a centerpiece to maximize the probability of success while partnering with KOLs

**3****KOL Partnership Plan (K2P) – Why?****WHY?**

- The development of a clear – precise – concise and shared implementation plan, called “KOL Partnership Plan” or K2P – between KOLs and pharmaceutical companies – will ensure that:
  - The objectives of the collaboration is well understood and agreed upon
  - The reciprocal expectations are well defined and accepted
  - The respective commitments are fulfilled and in due time
- The preparation of an implementation plan increases the probability of success of the partnership over time...
- ... and minimizes the risks of mutual disappointments
- The KOL Partnership Plan (K2P) will facilitate the coordination and the communication across the pharmaceutical company; and thus optimize synergies across market access, medical, marketing and sales departments

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

**3**

### KOL Partnership Plan (K2P) – How?



- **Step 1:** Design of templates that can be shared with the KOLs and the pharmaceutical company 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 Director<sup>1</sup>
- **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 card<sup>1</sup>, specify the objectives of the partnership, its scope and duration

**3**
**KOL Partnership Plan (K2P) – Model: Introduction**

<b>KOL name</b>	(First name – surname)	<b>Medical status</b>	MD – head of medical department – professor of medicine, etc.	<b>Medical setting</b>	Private clinic – private hospital – public hospital – teaching hospital
<b>Interest/ Expertise</b>	(e.g. Pulmonology, cardiology, etc.)	<b>Reputation/ Influence</b>	Private hospital – public hospital – teaching hospital – private office	<b>Advocacy potential</b>	Address & City & Country
<b>KOL Customer Manager</b>	(First name – surname – position in the company)	<b>Role</b>	(Describe briefly his role vis-à-vis the KOL)	<b>Coordination with...</b>	(Indicates the other collaborators whom to coordinate)
<b>Objectives of the partnership</b>	.				
<b>Specific scope of the partnership<sup>2</sup></b>	.	.	.	.	.
<b>Duration of the partnership</b>	<b>Starting date</b>		<b>Ending date</b>		
	.		.		

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

**3**
**4**
**KOL Partnership Plan (K2P) – Model: Service/Activity Card<sup>1</sup>**

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**

4

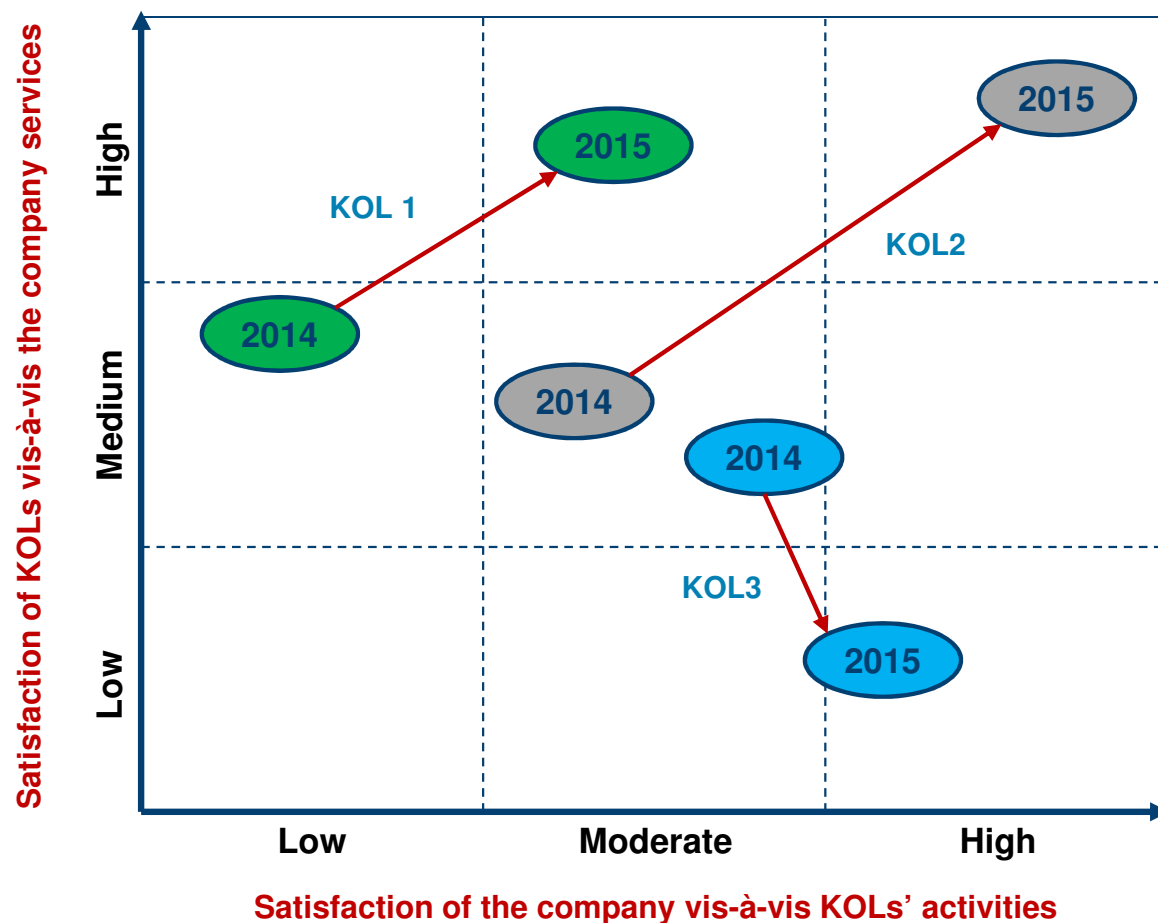
### Example of tool to monitor partnerships with KOLs

Pharma company services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> <li>Access to scientific information</li> <li>Organization of peer meetings with top international KOLs</li> <li>Technical support to publish articles</li> <li>Technical &amp; funding support to IIS<sup>1</sup></li> <li>Slide kits for training/teaching programs</li> <li>Ad hoc support on demand basis</li> </ul>	<ul style="list-style-type: none"> <li>Interest (10-point scale)</li> <li>Utility (10-point scale)</li> <li>Practicality (10-point scale)</li> <li>Implementation<sup>2</sup> (10-point scale)</li> </ul>	<ul style="list-style-type: none"> <li>Global level of satisfaction of KOLs (10-point scale)</li> <li>Inclination of KOLs to support the pharma company products: <ul style="list-style-type: none"> <li>Number of lectures / trainings / publications</li> <li>Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.</li> </ul> </li> <li>Increased level of KOLs awareness and reputation</li> <li>Increased level of products awareness and reputation</li> </ul>
KOLs activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
<ul style="list-style-type: none"> <li>Lecture during symposia</li> <li>Training of peers</li> </ul>	<ul style="list-style-type: none"> <li>Interest (10-point scale)</li> <li>Utility (10-point scale)</li> <li>Practicality (10-point scale)</li> <li>Implementation<sup>2</sup> (10-point scale)</li> </ul>	<ul style="list-style-type: none"> <li>Global level of satisfaction of attendees (10-point scale)</li> <li>Inclination of attendees to support &amp; prescribe the product: <ul style="list-style-type: none"> <li>Number of lectures / trainings / publications</li> <li>Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Writing of article</li> <li>Press conference</li> </ul>	<ul style="list-style-type: none"> <li>Acceptance by recognized journals (scientific, medical, or in lay press, etc.)</li> <li>Post on well-know websites</li> <li>Number of journalists and quality of articles</li> </ul>	<ul style="list-style-type: none"> <li>Impact factor (for scientific/medical journals)</li> <li>Number of broadcasted issues for lay press</li> <li>Number of views / likes on Internet</li> <li>Contribution of content to support the product</li> </ul>
<ul style="list-style-type: none"> <li>Participation in scientific studies</li> </ul>	<ul style="list-style-type: none"> <li>Implementation (number of patients recruited, timing, cost vs. plan)</li> </ul>	<ul style="list-style-type: none"> <li>Publication of an article in a good scientific journal</li> <li>Impact of the publication on product reputation</li> </ul>

This mapping can help visualize the reciprocal assessment of the partnership over time, as perceived by the pharmaceutical company and the KOL

4

**Mapping of KOL involved in partnership – Follow-up tool**



- The matrix helps visualize the opinion of KOLs regarding the services offered by the pharmaceutical company through the partnership...
- ...and the opinion of the pharmaceutical company regarding the activities carried out by the KOL
- It is proposed to evaluate the mutual level of satisfaction on an annual basis, but other periods of time can be used, if more appropriate, such as quarter or semester
- It is suggested to use a three level assessment scale:
  - High (meaning above expectation)
  - Medium (meaning as per expectation)
  - Low (meaning below expectation)

**The recruitment phase requires a painstaking gathering and analysis of information to qualify and evaluate the KOLs with whom the pharma company should partner**

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**Key points to recruit KOLs**

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- The recruitment of KOLs should comply with six key principles:
  1. Define a **specific objective** regarding the recruitment of KOLs, which should be integrated in a global strategy
  2. **Qualify and evaluate** the profile of the **prospective KOLs** by collecting reliable data related to their:
    - Field of expertise (medical and/or technical)
    - Level of reputation & scope of influence
    - Advocacy potential (communication skills and inclination to communicate)
  3. **Segment & pre-select** the KOLs based on their profile
  4. **Inform** the **prospective KOLs** of the pharmaceutical company's intention to partner with them:
    - What is expected from them? (specific objectives of the pharma company)
    - What can be “offered” to them by the pharmaceutical company? (specific benefits for the KOLs)
  5. **Select the KOLs** whose profiles are **in line with** the **specific objectives** of the partnership...
  6. ...and **who value the services** that the pharmaceutical companies is willing to propose



**The optimal management of KOLs requires to agree on a shared objective and on the related services and activities that should be planned and carefully monitored**

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**Key points to manage KOLs**

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- Once the KOLs have accepted, on principle, to partner with the pharma company, the **KOL Customer Manager** who has been assigned should organize an “**alignment meeting**” to:
  - Agree on the **mutual objectives** of the partnership
  - Define the **services to be proposed** by the company
  - Define the **activities to be implemented** by the KOL
  - Specify the **expected outcomes** for each service and activity
  - Set the corresponding **work plan** with timelines
  - Agree on the **approach** to **monitor** and the **indicators** to **measure** the corresponding **outcomes**
- The results of this meeting should be **formalized** in a “**KOL Partnership Plan**” (K2P)
- It is recommended to **maintain** a minimum level of 6 to 7 **services and activities** to ensure **regular contacts** between the KOL and the pharma company
- **After** the **completion** of each **service or activity**, an **assessment of the execution** and of the **impact** should be carried out by the KOL and the KOL Customer Manager of the pharma company

**8 recommendations *to optimize partnerships with KOLs***

1. Define **clear** and **precise objectives**
2. **Communicate**, upfront, on the **mutual benefits** of the partnership, for the KOLs and the pharma company
3. Ensure an **open** and **transparent relationship**
4. **Assign a KOL Customer Manager** who will be the KOLs' preferred contact point and who will ensure alignment and information sharing between all collaborators of the pharma company in contact with him
5. Make sure that the **services** provided by KOLs **contribute to fulfill** his **needs** and **expectations**
6. **Avoid** to ask **KOLs to promote** “**aggressively**” the **products**, which would affect his reputation and the pharma company one, and which may contravene national and international regulations
7. Build the **relationship** on an **exchange of services** rather than a fee-for-service deal
8. Make the **best use** of the **KOLs' limited time** by organizing useful exchanges

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**This section outlines the role of MSLs and proposes strategic and operational recommendations to boost their performance, while also complying with regulations**

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### **Context & Objective**

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- Medical Science Liaisons (MSLs) play a pivotal role to maintain a close relationship with KOLs (Key Opinion Leaders), also called TLs (Thought Leaders) who are instrumental in:
  - Developing new products through their collaboration in pre-clinical and / or clinical trials
  - Raising the awareness and the preference of HCPs (Health Care Professionals) but also of health authorities, PAGs (Patient Advocacy Groups), individual patients, etc., for their products
- **The increasing role of MSLs results mainly from:**
  - New molecular entities that are becoming more and more complex...
  - ... and that are mainly prescribed by specialists who are less and less inclined to meet medical reps
  - Increasing regulatory constraints
- **In this position paper, Smart Pharma Consulting:**
  - Analyzes the current role and responsibilities of MSLs<sup>1</sup>
  - Proposes a process, tools and...
  - Makes strategic recommendations...
  - ... to boost MSLs' performance

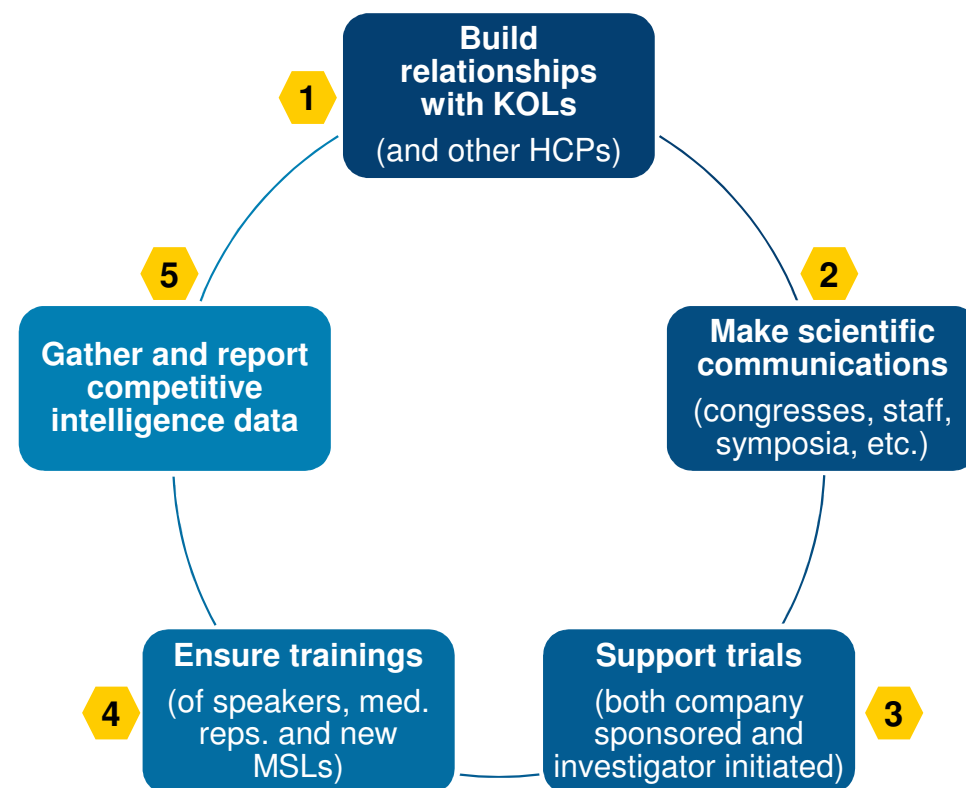
**MSLs are the field team of medical affairs in pharma companies, who are dedicated to the development of relationships with KOLs and to high-level scientific communications**

### Overview

#### MSLs: Medical Science Liaisons<sup>1</sup>

- In the context of science-driven **specialty** and **hospital care**, the industry is increasing its investments towards **partnerships** and **medical information** by implementing MSL teams
- 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** (vs. med reps. affiliated to the sales / marketing department)

#### Core activities<sup>2</sup> 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

<sup>1</sup> 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 – <sup>2</sup> Excluding administrative time

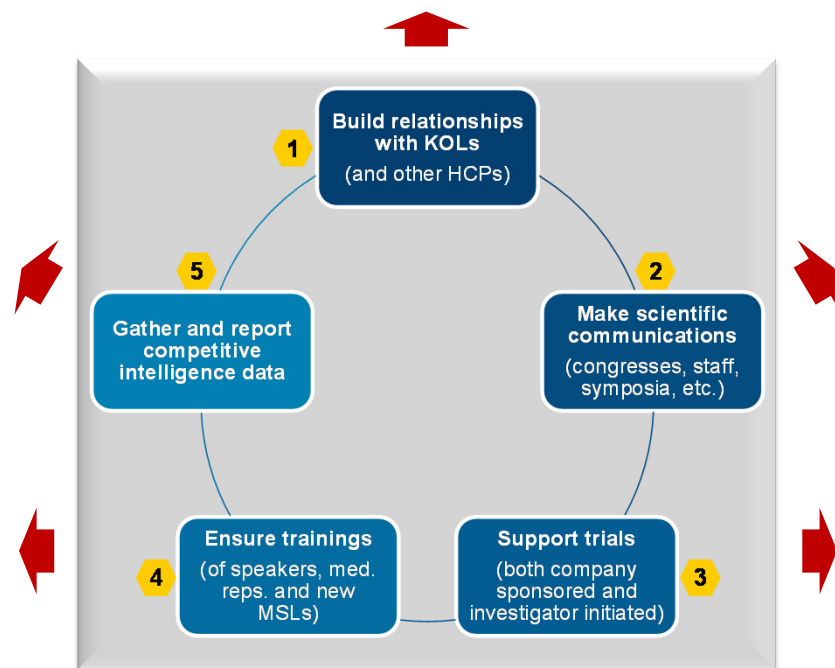
## MSLs are often asked to cover a large scope of activities in collaboration with both internal and external stakeholders

### 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)<sup>1</sup>: 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 and critical review of scientific papers
- Medico-economic research

- Training of med. reps. and certifications
- Training of other functions, such as marketing, in some companies
- Training of speakers communicating on companies' products / therapeutic areas, etc.
- Writing of supports for FAQ&O<sup>2</sup>



- Answers to certain HCPs' medical questions (through med. reps.)
- Participation in scientific information meetings (staffs, face to face, etc.) for on- and off-label indications, therapeutic area and 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 implementation and follow-up jointly with Clinical Research Associates (CRAs)

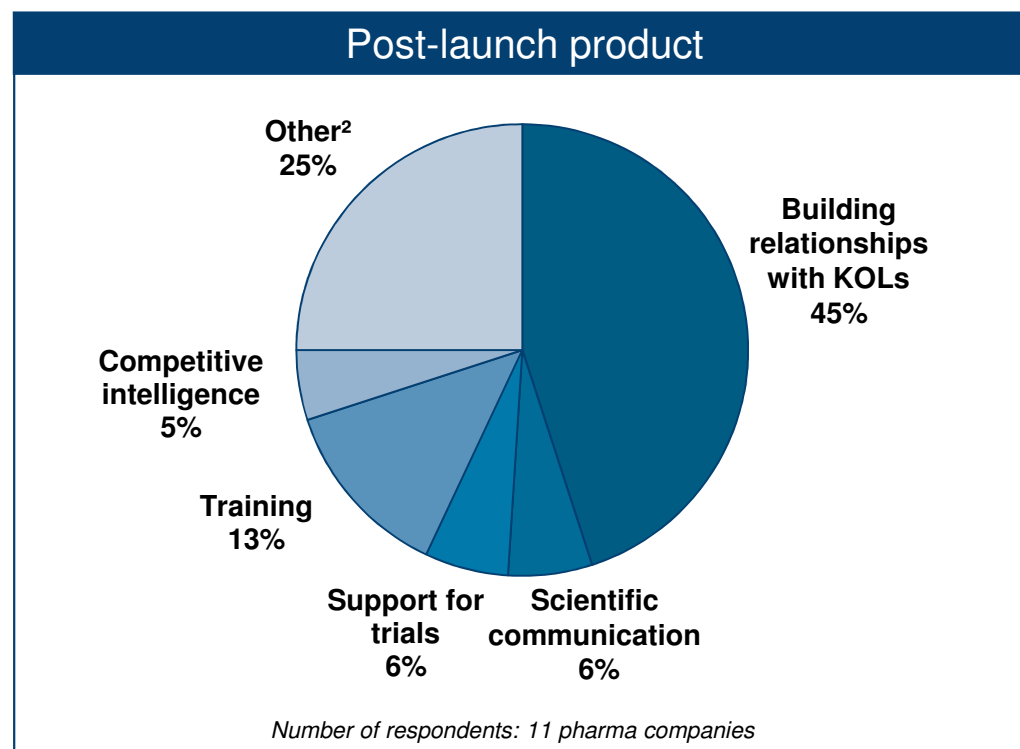
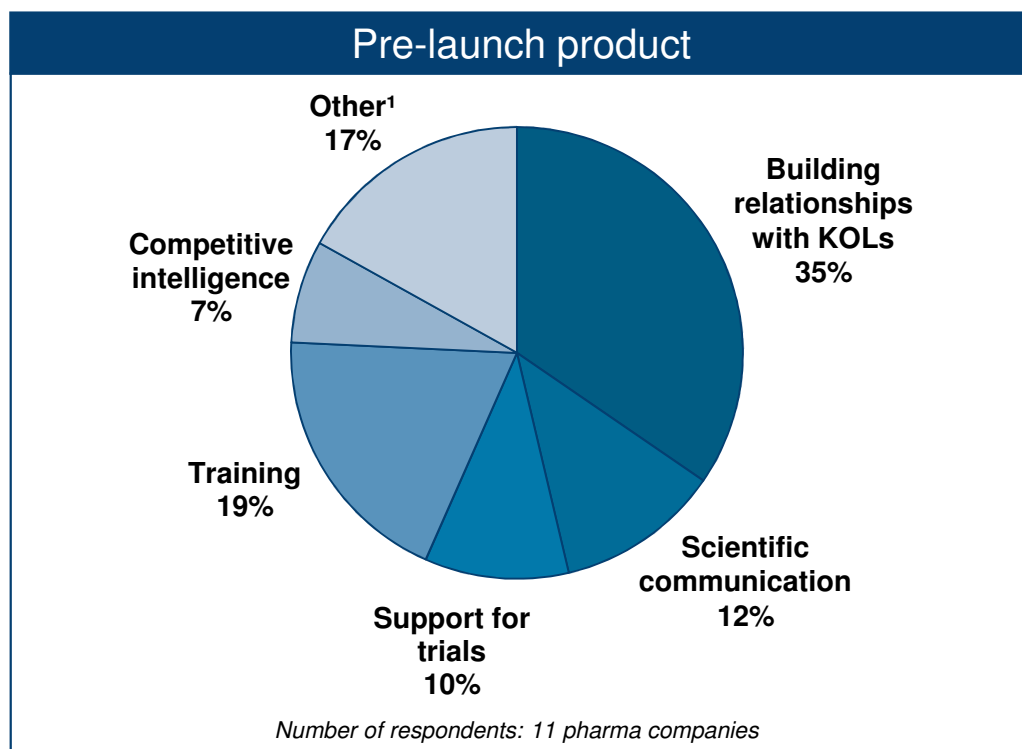
Sources: "An insight into the emerging role of regional medical advisor in the pharmaceutical industry", Perspectives in Clinical Research, 2013 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> Also called: Investigator-Initiated Trials or IIT – <sup>2</sup> 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

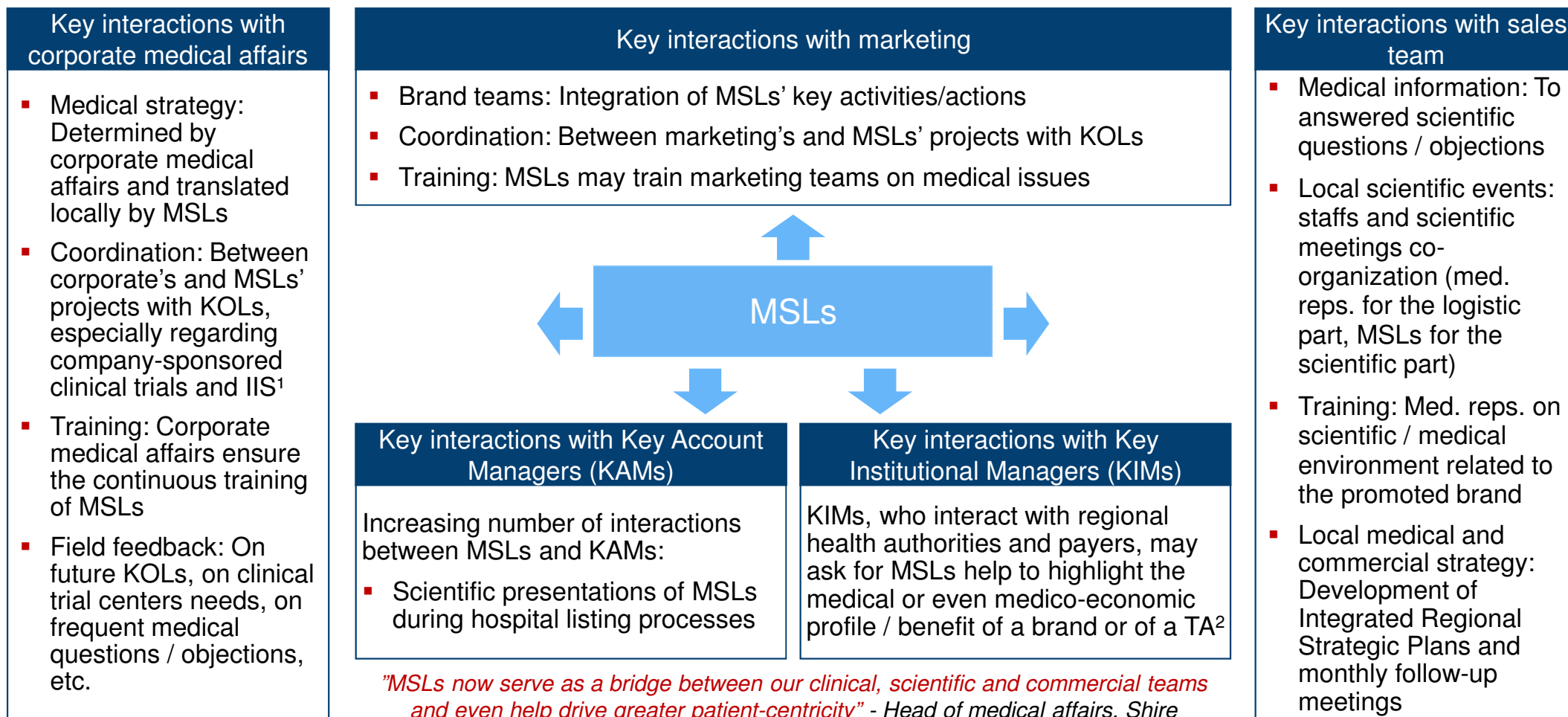


Sources: "Aligning the Activities and Goals of Medical Science Liaison Teams for Strengthened Corporate Sustainability", MSL World – Interviews with 5 MSLs – Smart Pharma Consulting analysis

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

**MSLs must support KIMs who facilitate regional market access of brands, KAMs who ensure their listing 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



**MSLs are not allowed to promote products, however, they can discuss their off-label use from an objective perspective and in response to a demand from HCPs**

### Compliance issues regarding MSLs

#### Current situation analysis

- The main mission of MSLs is **to build collaborative relationships with KOLs** and to facilitate the exchange of unbiased scientific information between them and the company
- Unlike medical representatives, MSLs are **not allowed to promote their company's products...**
- ... but can exchange unrestrictedly unbiased scientific information regarding the products and the related therapeutic areas
- MSLs' activities are not subject to specific laws or regulations
- Like any other employees of the company they belong to, MSLs are supposed to comply with:
  - International and national regulations
  - The industry codes of practice
  - The accepted standards of best practice
  - The company's compliance procedures

#### Focus on off-label prescription

- Off-label prescription is a common practice, particularly in fields where the approved treatments do not provide satisfactory results (e.g. oncology, psychiatry) or for a subset of the patients population, such as children
- Under certain circumstances, and according to more or less well-defined procedures, depending on the country, **it is allowed for physicians to prescribe some products off-label** (e.g. Early Access Programs<sup>1</sup> in Europe or Expanded Access Programs in the USA)
- **Off-label promotion** by pharmaceutical companies **is banned**
- In practice, if KOLs or other HCPs ask questions regarding off-label indications, MSLs should respond factually
- It is not recommended for MSLs to pro-actively communicate about off-label indications, even if the communication is based on scientific evidence, this could be considered as disguised promotion
- To protect their corporate reputation and their own employees and to prevent to be fined, companies such as Bristol-Myers Squibb have written SOPs<sup>2</sup> that clarify the Do's and Don'ts in terms of compliance for employees, including for MSLs

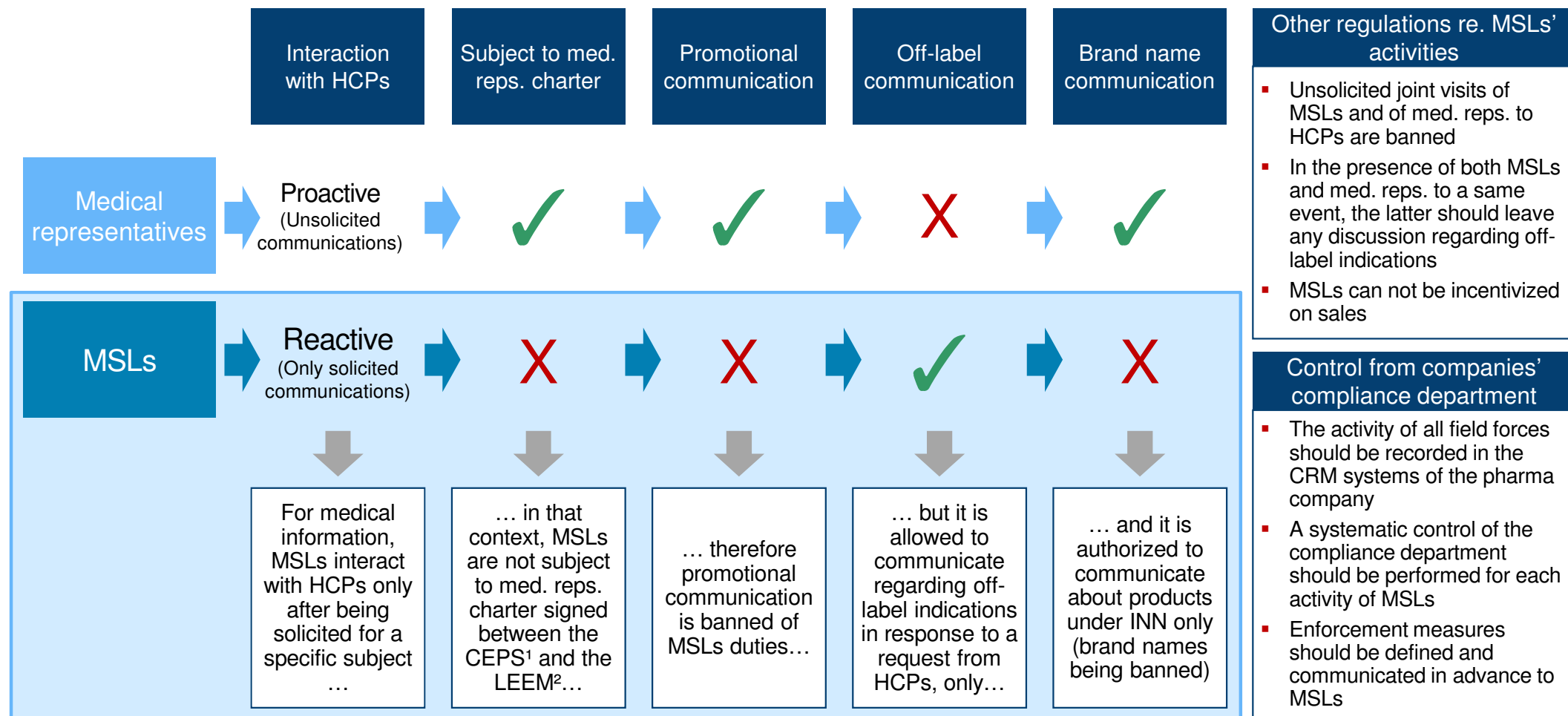
Sources: "MSL-KOL Engagement", FirstWord Dossier June 2011 – MSL Institute – Smart Pharma Consulting analysis

<sup>1</sup> Two types: Compassionate Use Programs (CUPs) or Named-Patient Programs (NPPs) –

<sup>2</sup> Standard Operating Procedures

**In general, MSLs' activity is not regulated by dedicated texts and they are not subject to the same restrictions as medical representatives**

**Regulatory framework relative to MSLs' activities – The French case**



Sources: Charte de la visite médicale, October 2014 – Interviews with 5 MSLs – Smart Pharma Consulting analysis

<sup>1</sup> CEPS: French drugs prices regulation authority – <sup>2</sup> LEEM: French pharma companies association – <sup>3</sup> INN: International Nonproprietary Names

## 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	<b>Distinction from sales / marketing</b>	<ul style="list-style-type: none"> <li>Information campaigns should be implemented to inform stakeholders of the distinctive role of MSLs</li> <li>The information should be provided through calls</li> </ul>
2	<b>Disconnection with corporate initiatives</b>	<ul style="list-style-type: none"> <li>The coordination should be improved by implementing standard communication processes and rules</li> </ul>
3	<b>Distraction from core activities</b>	<ul style="list-style-type: none"> <li>A clear definition of MSLs' responsibilities should be made to all internal stakeholders through information campaigns and the objectives for each of them should be quantified in MSLs' action plans</li> </ul>
4	<b>Extensive geographical zones</b>	<ul style="list-style-type: none"> <li>The use of alternative communication technologies such as web conferencing, e-mailing, teleconferences, etc., should be considered</li> </ul>
5	<b>Complex regulatory environment</b>	<ul style="list-style-type: none"> <li>Pharma companies should focus on MSLs' compliance...</li> <li>... which should be carefully monitored</li> </ul>
6	<b>Trend towards specialization</b>	<ul style="list-style-type: none"> <li>Pharma companies should keep on investing on their MSLs' scientific training</li> </ul>

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

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

**MSLs' activities should be integrated in a Regional Strategic Plan to ensure synergies with marketing, sales, market access and patient adherence departments' activities<sup>1</sup>**

**Integrated Regional Strategic Plan – Principle**



Sources: Smart Pharma Consulting analysis

<sup>1</sup> In compliance with the national regulation and the companies' policies – <sup>2</sup> Patient Advocacy groups

**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 management (e.g. meetings, preparation of staff meetings, invitation to congresses, support of IIS<sup>1</sup> and / or of the company-sponsored clinical trials, etc.)
    - Participation in congresses
    - Training of speakers, of marketing and sales collaborators
    - Support to Key Institutional Managers (KIM) in charge of regional market access and patient adherence programs
    - Competitive intelligence data gathering and analysis
  - Measurement and assessment of activities' impact
  - MSL Advanced SWOT analysis<sup>2</sup>
- Ambition & strategic priorities
  - Ambition setting
  - Strategic priorities to fulfil the ambition (MSL Strategy Card)<sup>2</sup>
  - Key activities to support strategic priorities:
    - Shared activities with other departments (e.g. marketing, sales)
    - 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 (1/6)**

**MSL Advanced SWOT**

<b>Opportunities</b>	<i>Relative importance<sup>1</sup></i>	<b>Threats</b>	<i>Relative importance<sup>1</sup></i>
<p><b>What regional changes are likely to favor the medical environment?</b></p> <p><i>National &amp; regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion &amp; position: re. the company, its services and its products, KOLs' level of influence</i></p> <p><i>Scientific events: regional congresses, other meetings</i></p>		<p><b>What regional changes are likely to disfavor the medical environment?</b></p> <p><i>National &amp; regional regulations: relating to MSLs' activities (e.g. off-label communication, invitation process to congresses, grants, etc.)</i></p> <p><i>KOLs' opinion &amp; position: re. the company, its services and its products, KOLs' level of influence</i></p> <p><i>Scientific events: regional congresses, other meetings</i></p>	
<b>Strengths</b>	<i>Relative importance<sup>1</sup></i>	<b>Weaknesses</b>	<i>Relative importance<sup>1</sup></i>
<p><b>What are the absolute or relative advantages of the company's medical activity at regional level vs. competition?</b></p> <p><b>1</b> <i>Relationships with KOLs: quality and sustainability</i></p> <p><b>2</b> <i>Scientific communications: congresses, staff meetings, symposia, etc.</i></p> <p><b>3</b> <i>Support to trials: company-sponsored trials and IIS<sup>2</sup></i></p> <p><b>4</b> <i>Training: of speakers, med. reps, new MSLs, etc.</i></p> <p><b>5</b> <i>Competitive intelligence: data gathering and analysis</i></p>		<p><b>What are the absolute or relative disadvantages of the company's medical activity at regional level vs competition?</b></p> <p><b>1</b> <i>Relationships with KOLs: quality and sustainability</i></p> <p><b>2</b> <i>Scientific communications: congresses, staff meetings, symposia, etc.</i></p> <p><b>3</b> <i>Support to trials: company-sponsored trials and IIS<sup>2</sup></i></p> <p><b>4</b> <i>Training: of speakers, med. reps, new MSLs, etc.</i></p> <p><b>5</b> <i>Competitive intelligence: data gathering and analysis</i></p>	



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 (2/6)**

**MSL Strategy Card**

Therapeutic area B

Therapeutic area A

Regional Medical Ambition

Strategic levers

Strategic priority #1  
to achieve the ambition

Strategic priority #2  
to achieve the ambition

Strategic priority #3  
to achieve the ambition

Strategic priority #4  
to achieve the ambition

Key activities<sup>1</sup>

Key activities<sup>1</sup>

Key activities<sup>1</sup>

Key activities<sup>1</sup>

The “KOL Partnership Plan” is part of the Integrated Regional Strategic Plan and specifies the objectives of the partnership, its scope and duration

**Integrated Regional Strategic Plan – Specific tools of the Medical Section (3/6)**

**KOL Partnership Plan (K2P) – Model: Introduction**

<b>KOL name</b>	(First name – surname)	<b>Medical status</b>	MD – head of medical department – professor of medicine, etc.	<b>Medical setting</b>	Private clinic – private hospital – public hospital – teaching hospital
<b>Interest/ Expertise</b>	(e.g. Pulmonology, cardiology, etc.)	<b>Reputation/ Influence</b>	Private hospital – public hospital – teaching hospital – private office	<b>Advocacy potential</b>	Address & City
<b>Role</b>	(Describe briefly his role vis-à-vis the KOL)		<b>Coordination with...</b>	(Indicate the other collaborators with whom to coordinate)	
<b>Objectives of the partnership</b>	<div>▪</div>				
<b>Specific scope of the partnership<sup>1</sup></b>	<div>▪</div>	<div>▪</div>	<div>▪</div>	<div>▪</div>	
<b>Duration of the partnership</b>	<b>Starting date</b>			<b>Ending date</b>	
	<div>▪</div>			<div>▪</div>	

Sources: KOL Partnership Model 2016 by Smart Pharma Consulting

<sup>1</sup> Examples: Development of a digital tool to improve patients adherence, Coordination of a multi-centric study, Expert support to estimate the medico-economic value of a new product, Lectures during medical meetings organized with peers, etc.

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

**Integrated Regional Strategic Plan – Specific tools of the Medical Section (4/6)**

**KOL Partnership Plan (K2P) – Model: Service / Activity Card<sup>1</sup>**

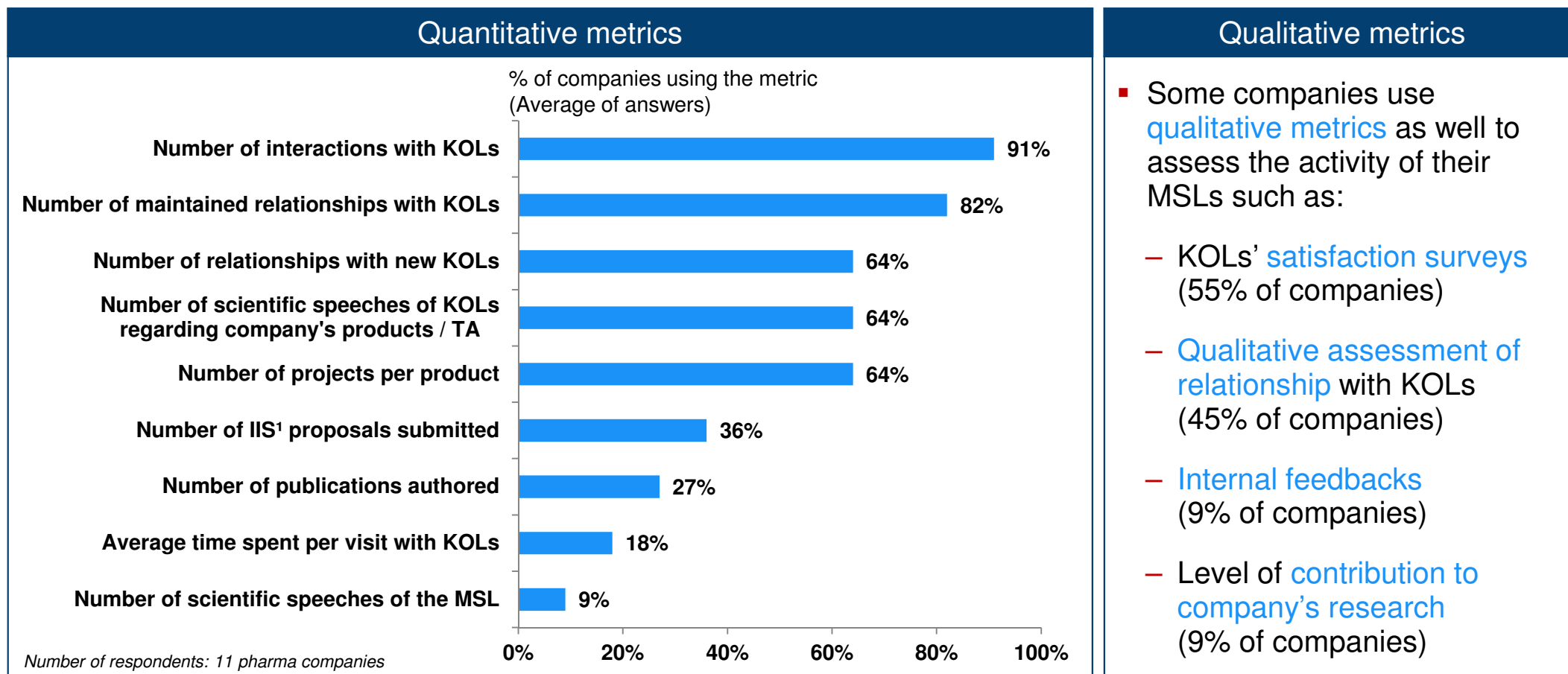
Service or Activity #1	Pharma company objective	KOL objective	Key step description	Timing
■	■	■	■	■

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

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 (5/6)**

**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

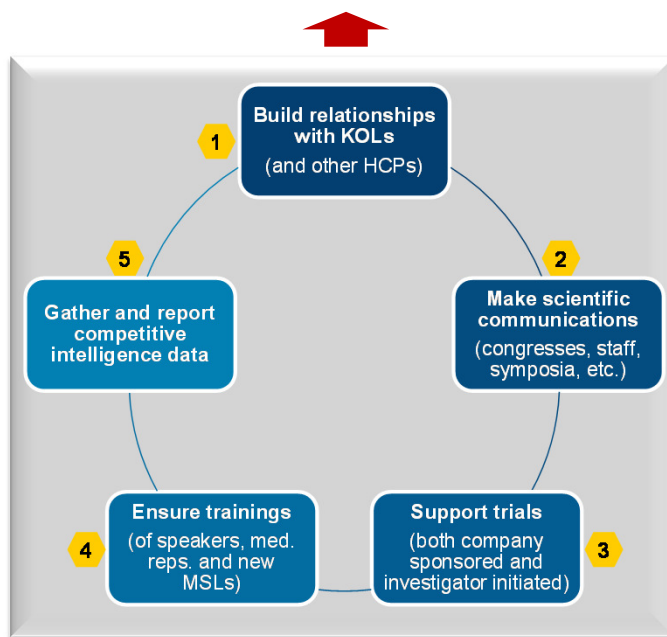
**Integrated Regional Strategic Plan – Specific tools of the Medical Section (6/6)**

**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 IIS<sup>1</sup> and / or company-sponsored clinical trials submitted / completed
- Number of investigators or patients included in company sponsored-clinical trials

## 8 Recommendations *to Boost MSLs' Performance*

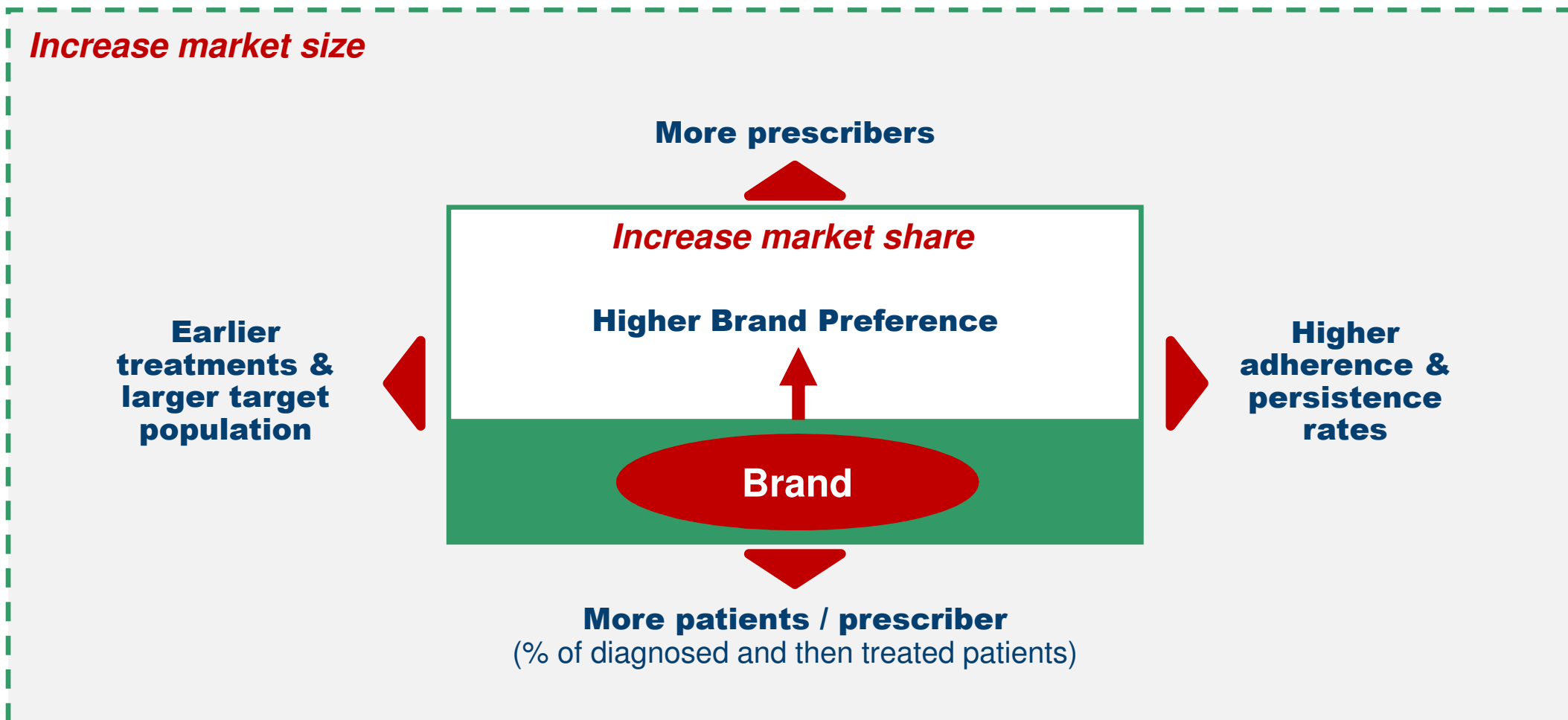
1. Clarify MSLs' roles and responsibilities to HCPs and collaborators of the company to avoid confusion with medical representatives' roles
2. Focus MSLs' activities on KOLs' recruitment and KOL partnership management<sup>1</sup>
3. Maintain a high scientific level of knowledge and of understanding to guarantee highly valued interactions and strong relationships between the MSLs and the KOLs
4. Make sure that MSLs' activities are consistent with their ambition and their strategic priorities, defined both at national and regional levels
5. Develop an Integrated Regional Strategic Plan<sup>2</sup> including a Medical section formalizing MSLs' ambition, strategic priorities and key activities, in accordance 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 to improve MSLs' efficacy and efficiency
7. Make the best use of MSLs' limited time by prioritizing their efforts and promoting the use of new communication technologies
8. Define internal guidelines and a control process to prevent any compliance issues that could damage the corporate reputation

<b>Introduction</b>	<b>p. 2</b>	<b>3. Marketing &amp; Sales</b>	<b>p. 129</b>
<b>1. Strategy</b>	<b>p. 6</b>	Brand Preference	p. 130
Corporate Reputation	p. 7	High Impact Interactions (H2I)	p. 144
Patient Centric Strategy	p. 23	Mature Brand Management	p. 172
Market Access	p. 50	<b>4. Management (Bonus 2017)</b>	<b>p. 193</b>
Creativity & Performance	p. 68	Smart vs. Good Managers	p. 194
<b>2. Medical Affairs</b>	<b>p. 85</b>		
KOL Partnership Model	p. 86		
MSL Best Practices	p. 111		



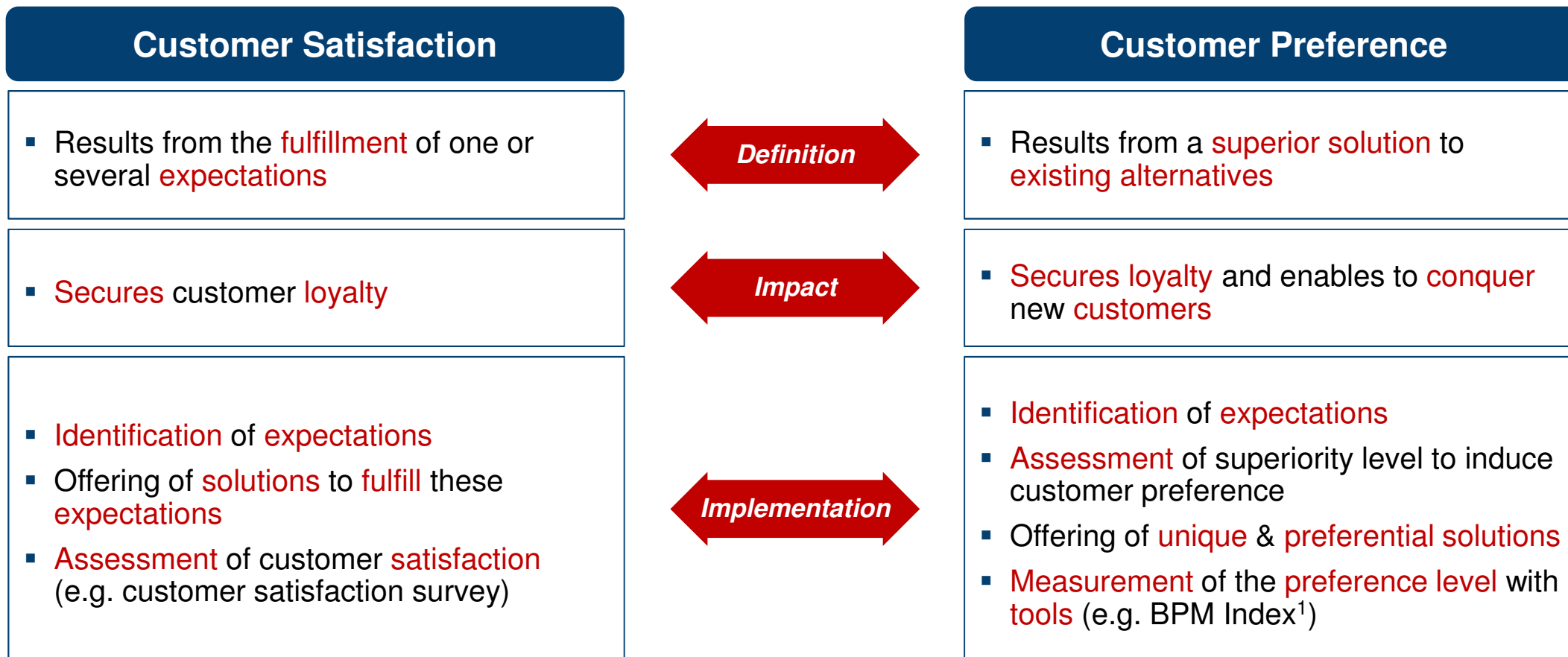
The market share gain, which is directly related to stakeholders' level of preference, is the most important determinant of products performance<sup>1</sup>

**Impact on the performance of pharmaceutical companies**



Unlike customer satisfaction, customer preference enables to gain market share, but for so doing, brands are required to offer benefits perceived as unique and superior

### Why preference should supersede satisfaction?



*“Do not just be liked, try to be preferred!”*

## Consumers' preference for an iPhone vs. a BlackBerry is not only based on products attributes

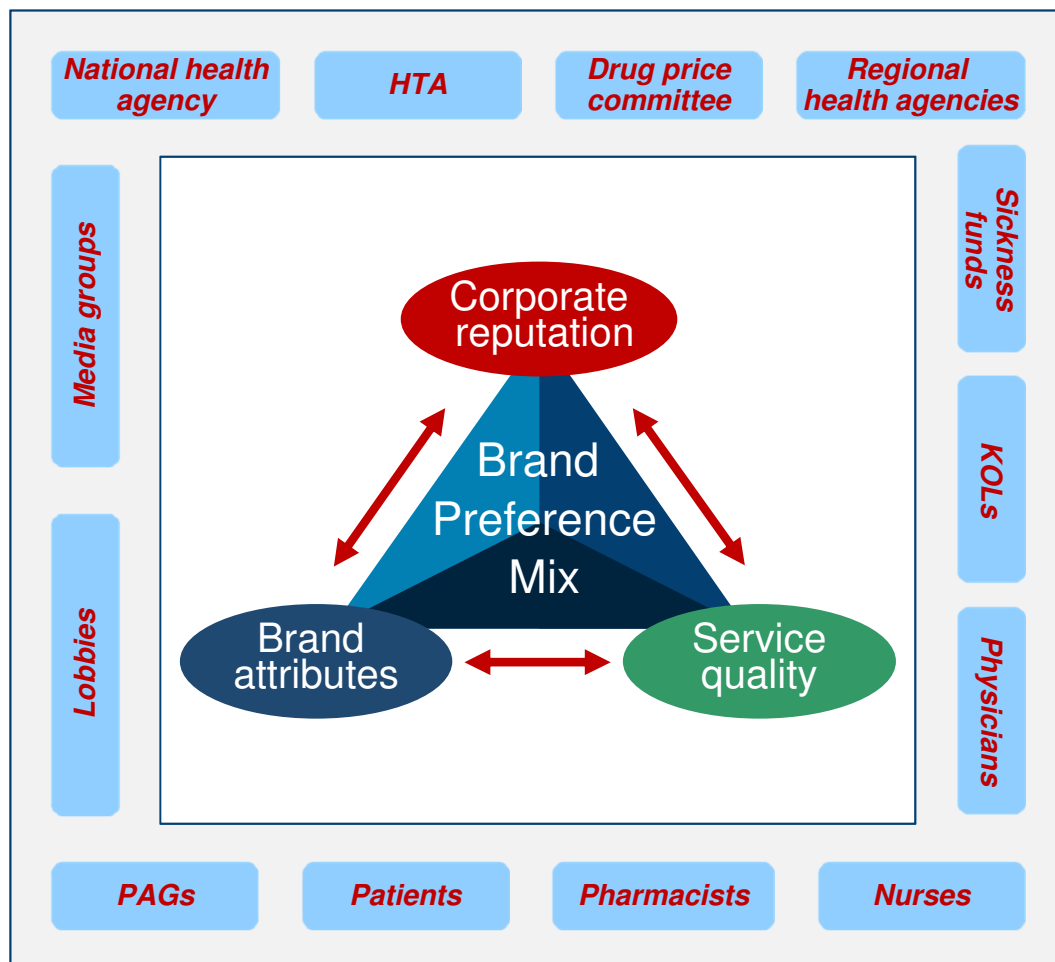
**From difference to preference**



1. What are the main differences between an iPhone & a BlackBerry?
2. Does the corporate reputation (Apple vs. RIM<sup>1</sup>) play a role?
3. Is the service offering attached to each product significantly different<sup>2</sup>?
4. How are these differences transformed into preference?

The Brand Preference Mix is an easy and effective approach to strengthen the preference of stakeholders for brands marketed by pharmaceutical companies

**Brand Preference triangle**

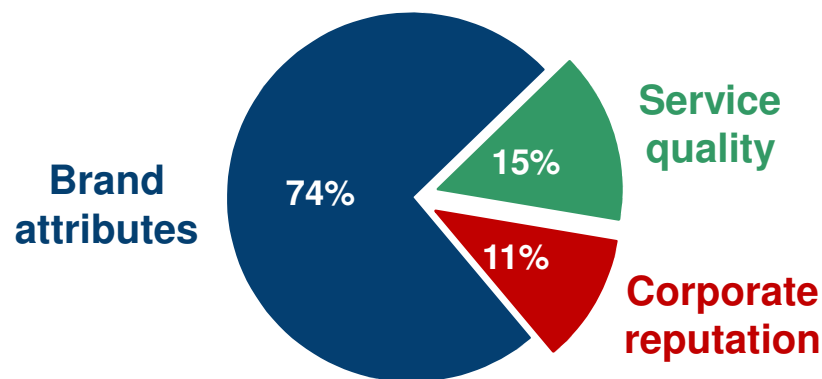


- To change stakeholders' preference:
  - Authorities (National health agency, health technology assessment bodies, drug price committee, regional bodies, etc.)
  - Payers (Insurance system) and buyers
  - KOLs/experts
  - Prescribers and other healthcare professionals
  - Patients
- for a brand, pharmaceutical companies can act on three components:
  - **Corporate** and collaborators reputation
  - The quality of proposed **services**
  - The **image** / the perceived **quality** of **product's attributes**
- These three components are more or less linked between them by stakeholders

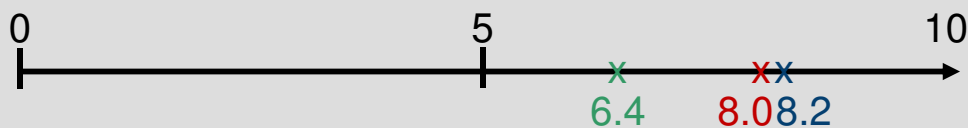
The Brand Preference Mix Index makes it possible to measure the evolution of stakeholders' preference for brands compared to their competitors, overtime

**Brand Preference Mix Index**

Illustrative



Visual Analog Scale



**BPM Index calculation**

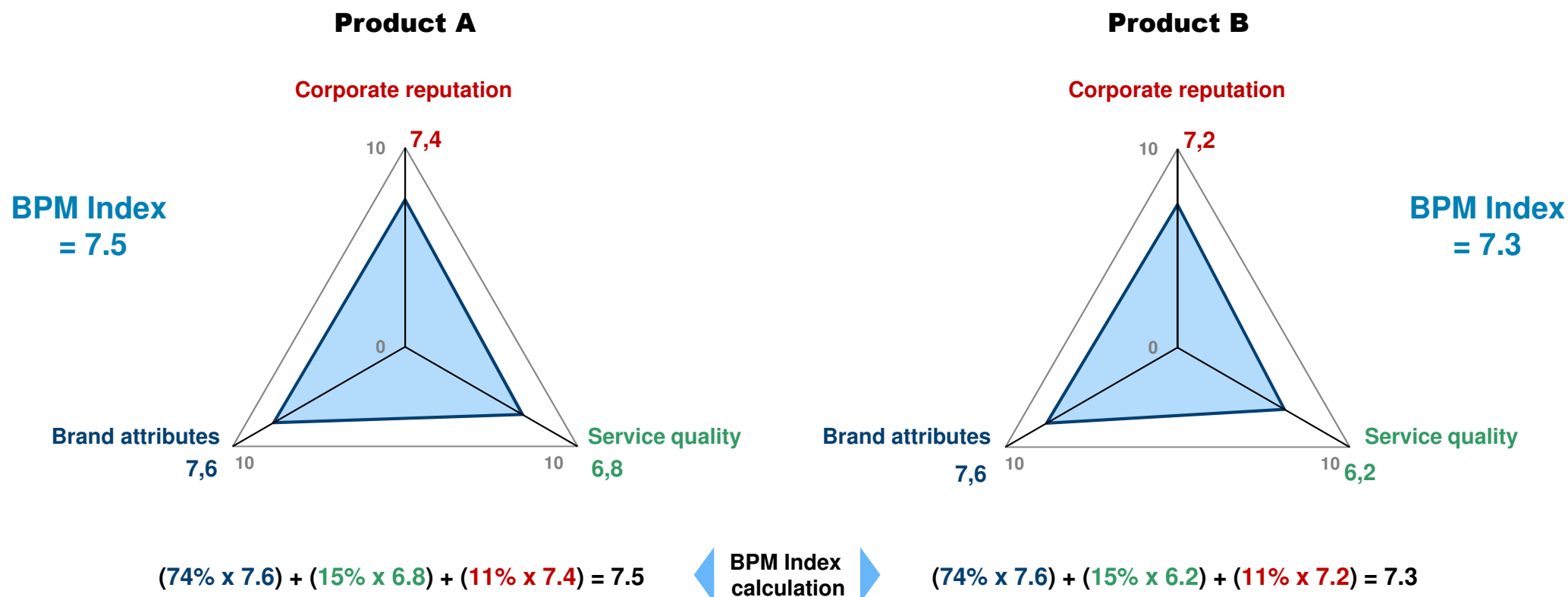
$$(74\% \times 8.2) + (15\% \times 6.4) + (11\% \times 8.0) = 7,9$$

- The Brand Preference Mix Index (BPM Index) can measure, by stakeholder:
  - The importance of the three components of the BPM
  - The perceived image on a scale of 0 to 10
- Thus, the BPM Index measures:
  - Stakeholders' perception at one point
  - Its evolution overtime
  - Its value compared to competitors
- The BPM also enables to:
  - **Understand** the root-causes underlying the commitment of stakeholders to brands...
  - ... define **actions / messages** to modify this attachment to brands

The Brand Preference Mix Index allows to assess the attachment to brands, to define the actions to implement and to manage their impact on preference

**Brand Preference Map**

Illustrative



Few years ago, BMS France communicated on its “commitments” in an attempt to reinforce its corporate reputation

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**Case study: The commitments of BMS France**

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Illustrative

**The 8 commitments for a sustainable partnership with the hospital**

1. “To focus our R&D on **serious diseases** and **market innovative drugs** for the benefit of patients”
2. “To deliver **objective information** for an optimal usage of our drugs”
3. “To be involved in the **management of patients** by **facilitating coordination** between hospital and open care settings”
4. “To **share know-how** between hospital and BMS collaborators”
5. “To propose **innovative trainings** for hospital collaborators”
6. “To **simplify** relationships between BMS and hospital collaborators”
7. “To be involved in **humanitarian projects**”
8. “To participate in the **protection of the environment**”

**The 7 commitments for a sustainable partnership with open care HCPs**

1. “To focus our R&D on **serious diseases** and **market innovative drugs** for the benefit of patients”
2. “To deliver **objective information** for an optimal usage of our drugs”
3. “To be involved in the **management of patients** by **facilitating coordination** between hospital and open care settings”
4. “To develop a **personalized relationship** between healthcare providers and BMS”
5. “To propose **trainings** fulfilling the expectations of healthcare providers”
6. “To be involved in **humanitarian projects**”
7. “To participate in the **protection of the environment**”

Sources: BMS France Internet website – Smart Pharma Consulting



# AbbVie recently launched a global brand called “AbbVie Care” which aims to bring together all the “patient services” of the company

## Case study: AbbVie Care



Illustrative



- By grouping all of its services dedicated to patients under the umbrella brand “AbbVie Care”, AbbVie ensures the correct attachment of the services offered to its brands
- These services, depending on their perceived value and uniqueness, can strengthen the company’s reputation
- A good corporate reputation can then help strengthen the perceived value of its brands and thus, the preference by its “clients”

# The use of “posters” facilitates the presentation of publications by medical representatives or MSL and strengthens their impact on physicians

## Ideas to reinforce physicians' preference



### Illustrative

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

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Vaccine

Vaccine 23 (2005) 4610–4618

[www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)

### Financial requirements of immunisation programmes in developing countries: a 2004–2014 perspective<sup>☆</sup>

Jean-Michel Peny<sup>\*</sup>, Olivier Gleizes, Jean-Pierre Covillard

Smart Pharma Consulting, 1 rue Houdart de Lamotte, 75015 Paris, France

Received 2 April 2005; accepted 18 April 2005  
Available online 9 June 2005

#### Abstract

Vaccines are a key contributor to public health, especially in developing countries. Despite numerous demonstrations of the cost-effectiveness of immunisation, vaccines spending accounted for only 1.7% of the total pharmaceutical market in 2002, when UNICEF estimated that 34 million children were not reached by routine immunisation, most of them in developing countries.

Several international organizations or initiatives, like the Global Alliance for Vaccines and Immunisation (GAVI), have defined a long-term goal of universal immunisation in developing countries. There is an urgent need to estimate the financial resources required to meet this goal.

The objective of this study was to anticipate the funding needs for childhood immunisation in developing countries over the 2004–2014 period. The study scope includes all the 75 countries eligible for support from GAVI, and covers existing vaccines that are considered as a priority for GAVI (DTP (diphtheria, tetanus, pertussis), hepatitis B, *Haemophilus influenzae* type b (as a stand alone presentation or in combination with DTP) and yellow fever) as well as future vaccines (meningitis A and C, rotavirus, human papilloma virus (HPV), malaria, *Streptococcus pneumoniae* and tuberculosis) likely to be available within the 10-year period.

We developed a methodology to estimate the number of doses required, based on disease prevalence and incidence, target populations, introduction dates of new vaccines, coverage dynamics and dosing regimen. The introduction price and price evolution of vaccines over time were modelled, taking into account the type of vaccine, the expected return on investment from vaccine manufacturers and the competitive landscape. Non-vaccine costs (capital costs and non-vaccine recurrent costs) were estimated based on the number of people immunised and number of doses dispensed, using available case studies as a reference.

According to the optimal scenario that would consider the provision of all vaccines to all relevant developing countries as soon as they are available, funding requirements to cover the associated total costs over the 10-year period were estimated to be about US\$ 30 billion.

Vaccines-related costs represent the largest share, with estimated costs of US\$ 21 billion (among which 18 billion for new vaccines), the remaining needs being split between capital costs and other recurrent costs.

Accounting for the main imponderables (such as delay in vaccines launch compared to industry plans) as well as probable phasing of vaccine introduction in countries, the total costs of immunisation would be reduced to US\$ 14–17 billion over the same period. Vaccines-related costs represent the largest share (US\$ 7.1–9.3 billion, among which 4.3–6.5 billion for new vaccines).

This study advocates for the anticipation of the substantial financial resources needed to (a) purchase and introduce these vaccines in the developing countries in order to reduce the time lag between availability in industrialised and developing countries; and (b) stimulate vaccine researchers and manufacturers to continue research and development of much needed vaccines for the developing world.

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**Keywords:** Immunisation; Developing countries; Financial requirements

**Abbreviations:** ADIP, accelerated development and introduction plans; CDC, centre for disease control and prevention; DTP, diphtheria, tetanus, pertussis; GAVI, global alliance for vaccines and immunisation; GNI, gross national income; HepB, hepatitis B; Hib, *Haemophilus influenzae* type b; HPV, human papilloma virus; NGO, non-governmental organisation; PAHO, Pan American Health Organization; UNICEF, United Nations Children's Fund; WHO, The World Health Organization.

<sup>☆</sup> The assumptions and resulting estimates as well as the opinions expressed herein are those of the authors and do not necessarily reflect the views of the organisations or their representatives interviewed.

<sup>\*</sup> Corresponding author. Tel.: +33 6 11 96 33 78; fax: +33 1 45 57 46 59.  
E-mail address: [jpeny@smart-pharma.com](mailto:jpeny@smart-pharma.com) (J.-M. Peny).

### Context & Objective

### Methodology

### Key results

### Conclusion (discussion)

Smart Pharma Consulting

Publication

### Besoins de financement des programmes d'immunisation dans les pays en voie de développement

Une perspective sur la période 2004–2014

#### Contexte et objectif

- Les vaccins jouent un rôle fondamental dans l'amélioration de la santé publique
- Les dépenses de santé font peu de place aux vaccins aujourd'hui qui représentent moins de 2% des dépenses de médicaments au niveau mondial, et dont les besoins sont particulièrement importants dans les pays en voie de développement
- Les objectifs à long terme d'immunisation universelle des pays en voie de développement, tels que définis par nombre d'organisations ou de programmes internationaux, nécessiteront des moyens financiers importants qu'il convient d'anticiper
- Cette étude a pour ambition d'estimer les besoins financiers pour assurer l'immunisation des enfants des pays en voie de développement sur la période 2004–2014, afin de prévoir si nécessaire de nouveaux modes de financement

#### Méthodologie de prévision

- Périmètre géographique: 75 pays éligibles pour le soutien du GAVI (72 pays à bas revenus, plus la Chine, l'Inde et l'Indonésie)
- Vaccins inclus dans l'étude: vaccins actuels (DTP, Hépatite B, *Haemophilus influenzae* B (Meningite bactérienne), Fièvre Jaune) seuls ou en combinaison avec le DTP, ainsi que 6 vaccins à venir qui seront introduits dans les pays en voie de développement sur la période 2004–2014 (Meningite A/C, Rotavirus, Paludisme, Virus du Papillome Humain, Pneumocoque, Tuberculose)
- Les besoins en financement ont été estimés à partir de l'évaluation de 6 variables et 7 constantes:

Variables	Données paramétriques	Constantes	Hypothèses
<b>Population cible</b>	• Nouveaux-nés (0-1) et enfants âgés (1-4 et 10-12 ans d'âge), avec une fonction fixe (gestion par période)		
<b>Dates de lancement</b>	• Dates de lancement attribuées par des fabricants de vaccins		
<b>Dynamique de couverture</b>	• Date de mise à disposition auprès du GAVI		• L'efficacité des vaccins est prise en compte dans la pénétration et le taux de couverture
<b>Nombre de doses</b>	• Taux de couverture au moment de la mise à disposition des vaccins		• Observation des schémas de vaccination
<b>Prix des vaccins</b>	• Coût unitaire par dose (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• Taux de gaspillage moyen fixé à 20%, constant au fil des années
<b>Coûts non vaccinaux</b>	• Coût unitaire par dose (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• A chaque changement d'antigène, 20% de quantités supplémentaires (y compris le gaspillage) sont ajoutées la première année d'introduction du vaccin
	• Coût de transport (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• Plus de constantes sur la période 2004–2014, i.e. la disponibilité et les prix des vaccins ne sont pas impactés par des problèmes potentiels de capacité
	• Coût de stockage (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• Plus de problèmes logistiques considérées, i.e. les vaccins sont supposés disponibles à la fois au moment requis, en temps et quantité appropriée
	• Coût de distribution (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• Taux de perte de vaccins
	• Coût de recyclage (calculé à partir du coût de production du DTP sur les 10 ans suivant son introduction pour les vaccins futurs)		• Taux maintenu constant à 0%, i.e. la probabilité que les vaccins aient une durée de vie de 100%

#### Résultats

##### Nombre de personnes immunisées par segment de population

##### Estimation des coûts totaux d'immunisation des personnes dans les pays éligibles pour le soutien du GAVI (2004–2014)

#### Conclusion

- Pour atteindre l'objectif d'immunisation universelle des enfants (et adolescentes) dans tous les pays du GAVI avec ces 12 antigènes sur la période 2004–2014, les besoins de financement cumulés sont estimés à 30 Mds de \$
- 71% des coûts cumulés correspondent à l'achat des vaccins actuels et futurs en tant que tel (i.e. 20.9 Mds de \$), 26% aux autres coûts récurrents (i.e. 7.6 Mds de \$) et 3% aux investissements (1 Mds de \$)
- En absence de cet effort international, au moins 1 milliard d'enfants (et d'adolescentes) ne seront pas vaccinés par ces 12 antigènes sur la période 2004–2014
- Il semble donc urgent pour les organisations internationales de repenser leurs stratégies de financement pour espérer atteindre leur objectif à long terme d'immunisation universelle

Pour de plus amples renseignements, merci de contacter Jean-Michel PENY: Smart Pharma Consulting 1, rue Houdart de Lamotte - 75015 Paris - France  
Tel.: +33 6 11 96 33 78 - Fax: +33 1 45 57 46 59 - e-mail: [jpeny@smart-pharma.com](mailto:jpeny@smart-pharma.com)

To generate preference for brands, associated services must be highly valued, unique if possible; and linked by stakeholders to the corresponding brands

**Definition of the “preferential power” of a service**



The “preferential power” of a service is even more important when it is...

**... highly valued**

The valuation of a service is based on the assessment by the targeted stakeholders of four key factors:

1. The interest in the service
2. Its usefulness
3. Its convenience
4. Its quality of execution



**... unique**

- The more unique a service is, the more it will contribute to reinforce preference, provided that it is highly valued
- The (perceived) uniqueness is either:
  - Total
  - Partial
  - Non-existent



**... linked to the product**

- A highly valued service, even if it is unique, will only help to strengthen the preference for a product brand:
  - If it is properly linked with the corresponding product...
  - ... and that this link is sustainable

Perform qualitative reps calls, with high scientific content, able to positively differentiate the company and its products from competitors

#### Example of innovative reps call



Illustrative

#### Commitments for a quality detailing

##### Objectives

- Increase the perception of a **superior quality of detailing**, vis-à-vis competitors

##### Principles

- **Commitments** are **formalized** and **proactively communicated** to physicians
- Sales Reps must **systematically comply** with those commitments
- Commitments may be as follows:
  1. **Exhaustive information** will be presented, incl. side effects (as per the current regulation)
  2. **Detailing** will be adapted to physicians availability/convenience
  3. **Physicians' questions/requests** will be addressed within 5 working days
  4. **Competitive information** will always be supported by scientific proofs (evidence-based medicine)




##### Benefits



- **Perceived efforts** by physicians of the **company attempts** to **improve** detailing **quality / value** for them
- **Referential** to **measure** Sales Representatives **performance**

##### Complexity of change



- **Organization** 
- **Tools** 
- **Processes:** 
  - **Clear and rigid enough** to fulfill commitments (e.g. Reprint delivery within 5 days)
  - Compliant with the content of “Medical call charter” but **Reps behavior needs to be adapted**

##### Risk



- **Over promises** leading to physicians disappointment
- **Non strict respect of commitments** by Sales Representatives

It is key to make sure that the proposed services will significantly contribute to reinforce the brand preference with the help of specifically designed tools

***A priori* tool to evaluate contribution of services to brand preference**



Illustrative

Description		Objective		Target (HCPs, patients, etc.)				
Expected Value by the Target			Exclusivity			Expected Link to the Brand		
Evaluation*		Rationale	Evaluation		Rationale	Evaluation		Rationale
Interest	1 2 <b>3</b> 4 5	•	Total	✓		Magnitude		•
Usefulness	1 2 3 <b>4</b> 5		Partial	✓				
Convenience	1 <b>2</b> 3 4 5					None	✓	
Execution	1 2 <b>3</b> 4 5							
Total	1 2 <b>3</b> 4 5							

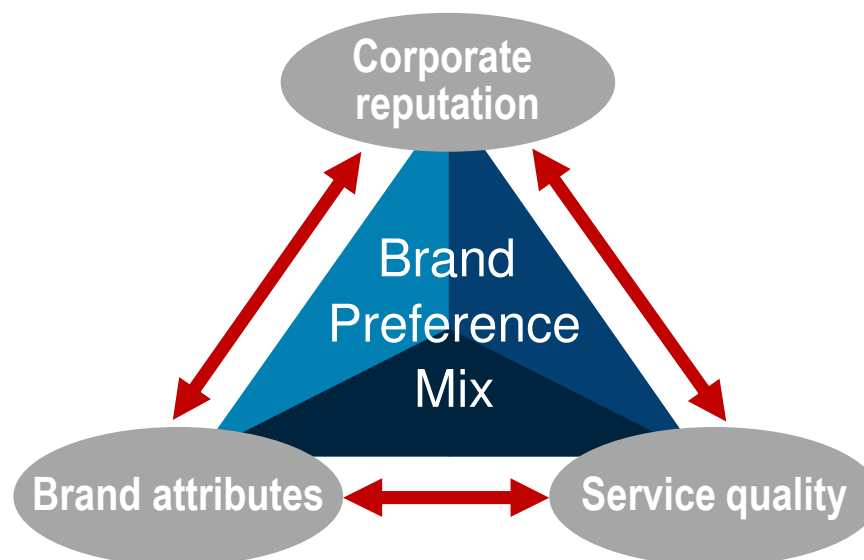
Barriers		Rationale	KPIs (Key performance indicators)	KEIs (Key execution indicators)	Decision	
Technical		• Implementation	•	•	GO	
Regulatory		• Compliance				
Economic		• Estimated cost and return				

It is essential that stakeholders correctly connect the company and the proposed services to its products in order to enhance the preference for the latter

**Link between the three components of the Brand Preference Mix**



→ Reinforce the links between the BPM components



*“Pharma companies must always ensure that their actions to strengthen their reputation and the services they propose contribute to improve the perceived value of their products, which are their only source of income”*



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## Smart Pharma Consulting, which developed the « Brand Preference Mix », can help pharma companies effectively deploy this innovative approach

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### Key takeaways

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- The **BPM** (Brand Preference Mix) approach, which strengthens the preference to brands, can be applied to all pharma companies' stakeholders:
  - Health authorities and payers
  - Healthcare professionals
  - Patients and PAGs<sup>1</sup>
- The BPM requires an excellent **knowledge** and **understanding** of **stakeholders** by the **employees** of the pharma company to define **actions** to be implemented to **positively impact** their **opinions** and **decisions**
- The **implementation** of this **approach** and of the **brand preference concept** requires:
  - Their **adoption** by all **employees**, whether they are directly in contact with customers or in support
  - **Systematizing** their **application**
  - **Creating practical tools** to **facilitate** their **use** and the **estimate** of their **impact**
- Smart Pharma Consulting, which developed the **Brand Preference Mix**, has an extensive experience in helping pharma companies effectively deploy this innovative approach



**Smart Pharma Consulting presents a new approach, called the H2I Program, to help Med Reps create High Impact Interactions with the physicians they are in charge of**

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**Create High Impact Interactions with Physicians: Context & Objective**

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- Against all odds, a survey carried out in 2014 in the USA has shown that 62% of GPs and 91% of specialists want more Med Reps calling on them provided they are highly trained, experienced, and able to engage discussions based on clinical studies and evidence-based medicine (EBM)
- Thus, physicians view Med Reps as a key source of information adding value to their practice
- There is a lot of debate regarding the role of Med Reps with an increasing number of stakeholders considering that the information delivered to physicians should be limited to the SmPc<sup>1</sup> of the brand
- Pharmaceutical companies have a different opinion and consider that Med Reps are also an important means to raise their brand awareness and reinforce the physicians preference
- Smart Pharma Consulting which has developed the Brand Preference Mix approach<sup>2</sup> in which Med Reps are instrumental, proposes the H2I (High Impact Interactions) Program to help them...
- ... create high impact interactions, that physicians will remember as exceptional experiences

*Smart Pharma Consulting assumes that promoting a brand is legal and does not pose any ethical problem, provided the information conveyed by the Med Reps to the physicians is unbiased, in line with local regulations and not likely to influence their decisions at the expense of their patients*

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**The decreasing value of Med Reps calls, as perceived by physicians, represents an opportunity and a challenge for pharma companies to differentiate themselves**

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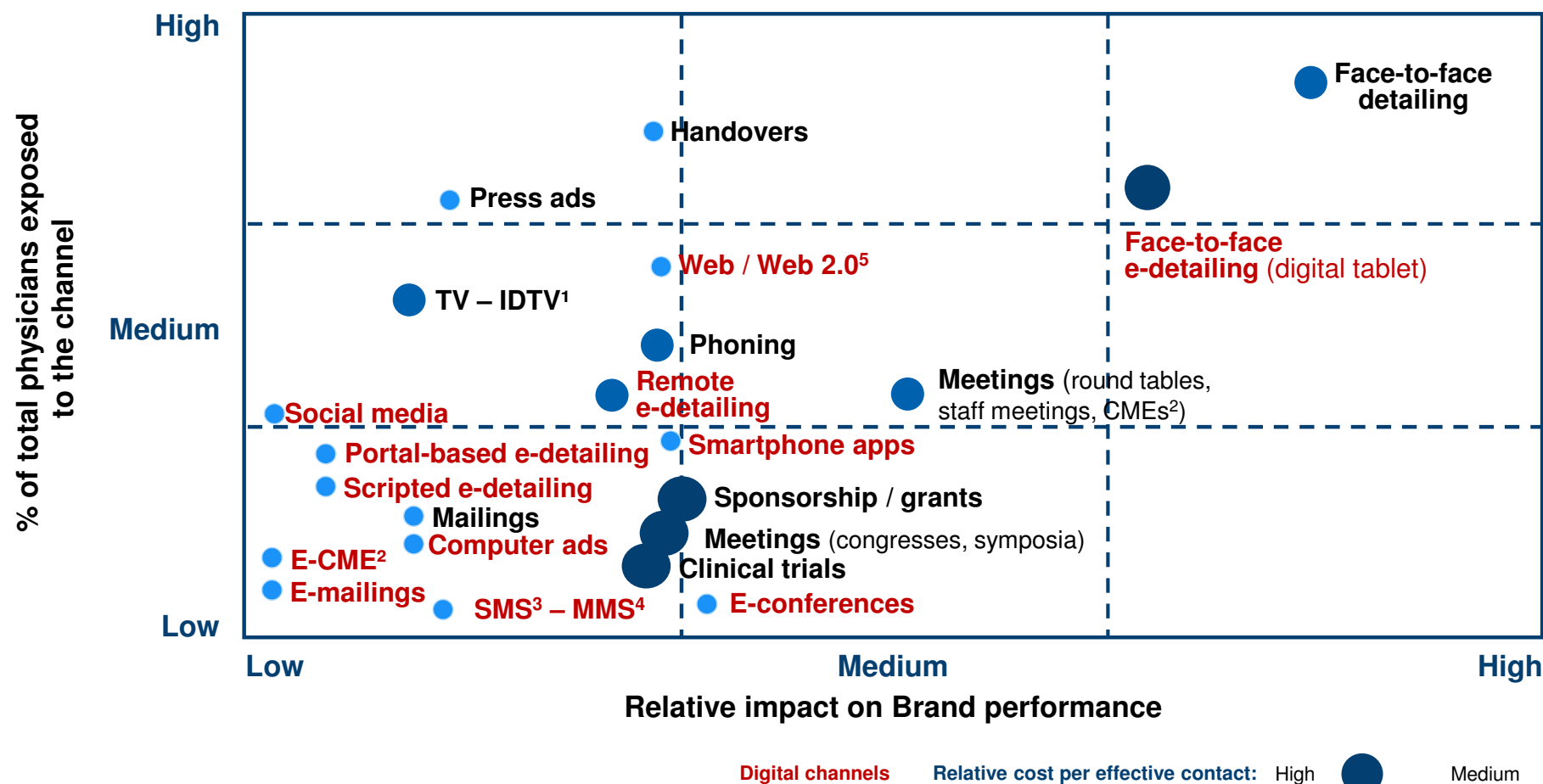
### **Med Reps & Physicians Interactions**

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- Pharmaceutical companies were estimated to employ ~750,000 medical representatives in the world in 2015, showing an average of -2% decrease per annum since 2012
- In 2015, sales forces expenditure accounted for ~60% of total marketing & sales investment, compared to less than 3% for digital expenditure
- The reduction in the number of Med Reps is mainly due to:
  1. The increased share of secondary care products - which require smaller reps lines - at the expense of primary care products
  2. The M&As between big pharma companies, leading to sales force streamlining
  3. The increasing number of physicians (>70-75%) imposing access limitations to Med Reps
- Access restrictions imposed by physicians are mainly driven by:
  1. The development of Internet which offers convenient, free, reliable and up-to-date information
  2. The regulatory and compliance constraints making in-person contacts by Med Reps of lower usefulness
- Despite this challenging environment, Med Reps calls remain an effective promotional means

Face-to-face detailing is still the most effective promotional means because it enables to cover a much larger number of physicians than any alternative options

**Relative efficacy of promotional activities by channel**



Sources: Smart Pharma Consulting analysis

<sup>1</sup> Interactive digital television – <sup>2</sup> Continuous medical education – <sup>3</sup> Short message service – <sup>4</sup> Multimedia message service – <sup>5</sup> Including websites and blogs

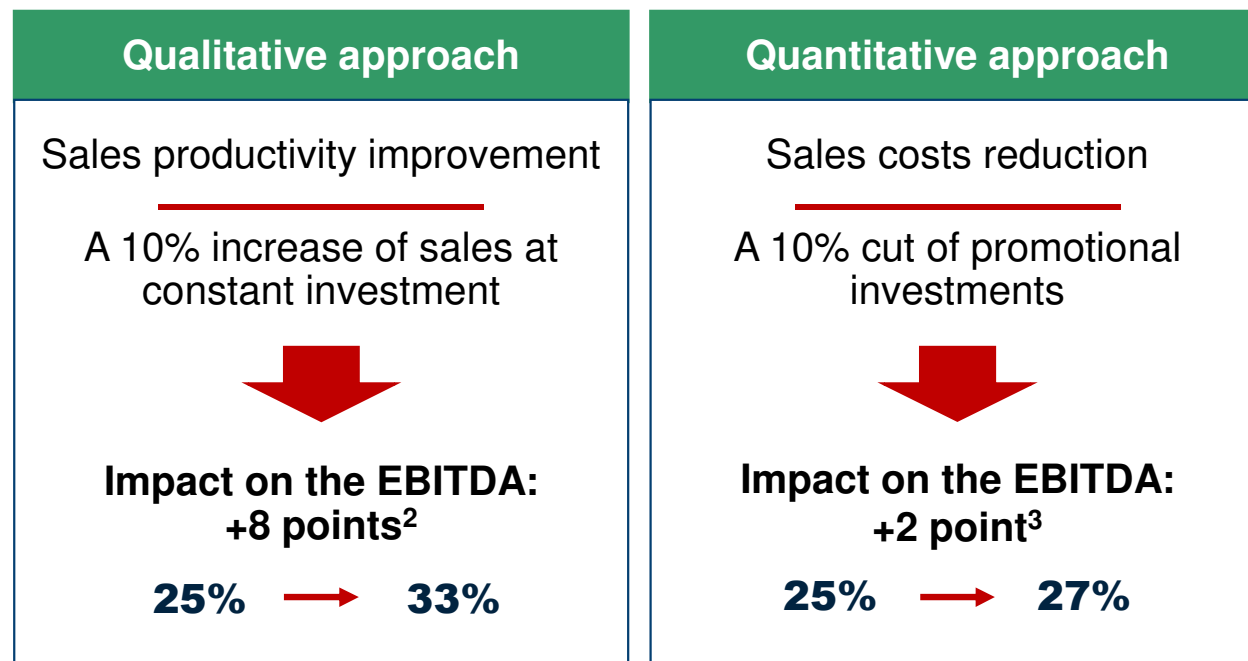
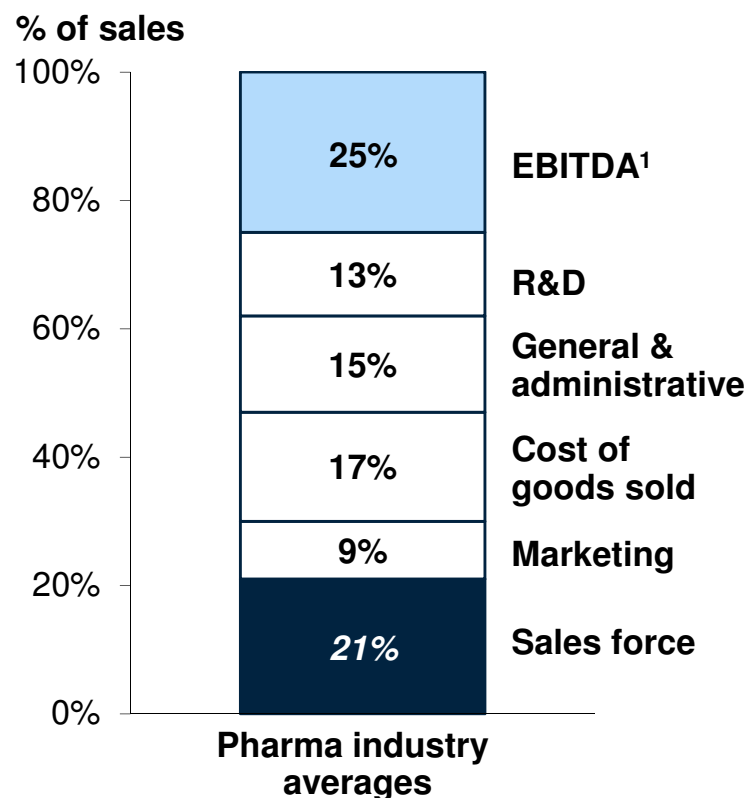
Improving sales force effectiveness has a significant impact on pharmaceutical companies' sales and profit growth

**Impact of improving sales force effectiveness**

*Illustrative*

**Cost structure**

**Effectiveness improvement of sales investment**



Sources: Smart Pharma Consulting analysis

<sup>1</sup> Earnings before interest, tax, depreciation and amortization – <sup>2</sup> Additional manufacturing costs while all other costs are assumed constant – <sup>3</sup> Assuming marketing and sales force performance is maintained

**Med Reps should rethink the way they interact with physicians to boost their image and thus increase the impact of their interactions on the brands they promote**

**Why should Med Reps rethink their interactions with physicians? (1/2)**

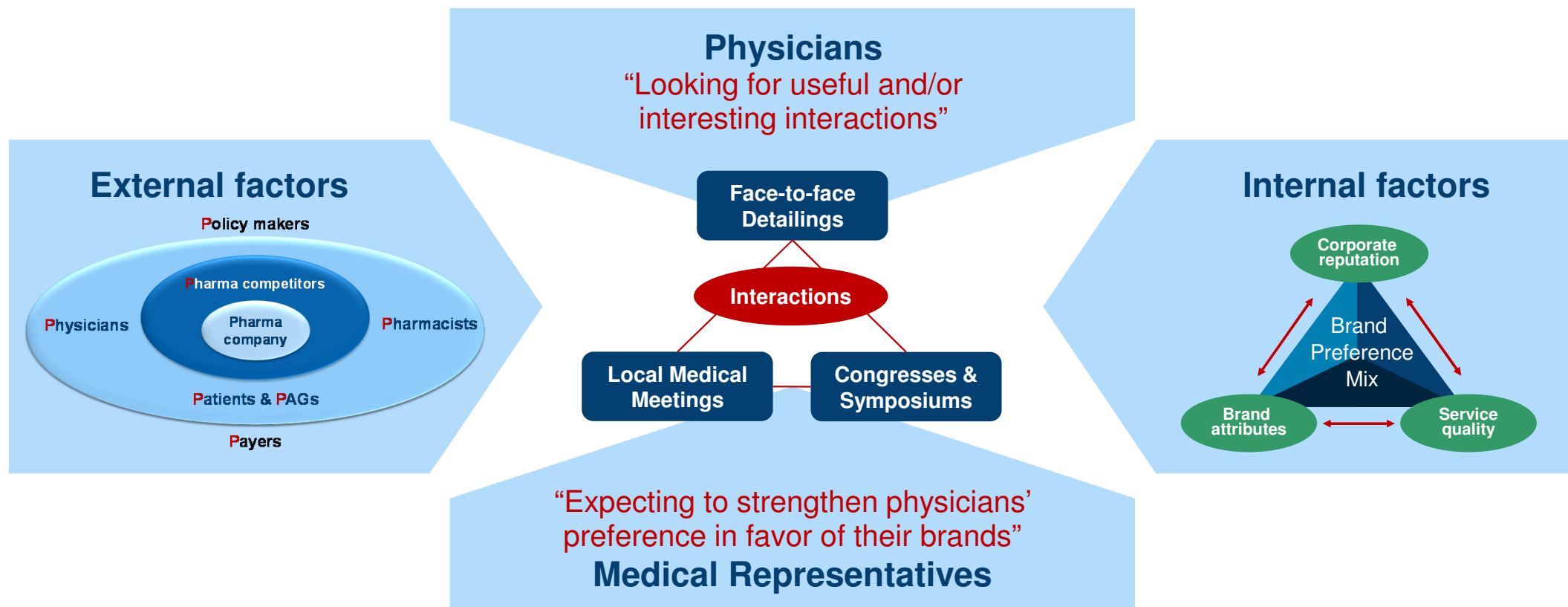
- Med Reps interactions with physicians are of three kinds:



- These Med Reps activities are instrumental to influence the opinion and the behavior of physicians
- However, physicians' opinion and behavior are also strongly influenced by other external and internal factors that are not under the direct and/or the indirect control of Med Reps:
  - External factors:** market stakeholders (7 Ps: policy makers, payers, pharmacists, other physicians, patients, patient advocacy groups, pharma competitors)
  - Internal factors:** corporate reputation<sup>1</sup>, quality of services offered, perceived value of products
- This position paper objective is to help Med Reps **“create High Impact Interactions with physicians”**

When brand attributes are not significantly differentiated from competitors' ones, physicians' preference may be influenced by their interactions with Med Reps

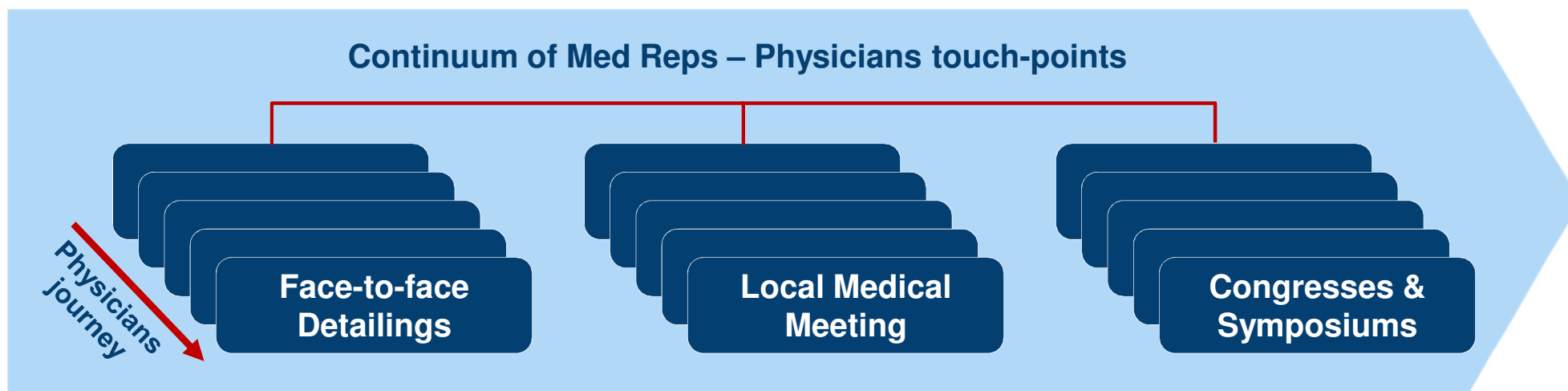
**Why should Med Reps rethink their interactions with physicians? (2/2)**



**By offering physicians exceptional experiences while interacting with them, Med Reps access will be eased and the preference to the brands they promote increased**

### **H2I Program Objective**

- Smart Pharma Consulting has developed the “H2I Program” (High Impact Interactions Program) to help Med Reps<sup>1</sup> create a continuous series of exceptional interactions with physicians so that they:
  - Accept (or even ask for) more regular contacts with the Med Reps
  - Increase their preference for the brands promoted by the Med Reps

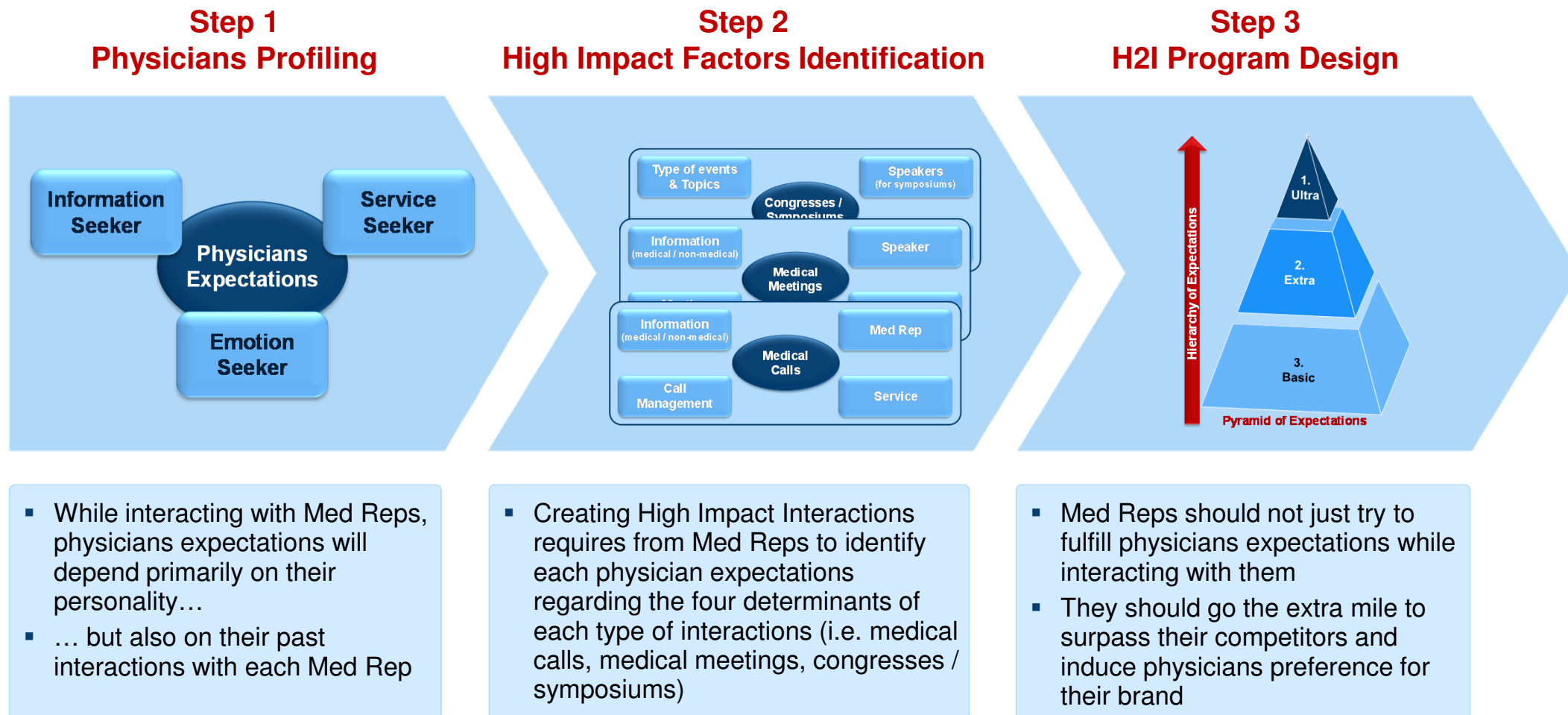


*“Each physician should feel that he is unique to you”*



The H2I Program follows a straightforward approach but each of the three steps should be well understood by the Med Reps and perfectly carried out

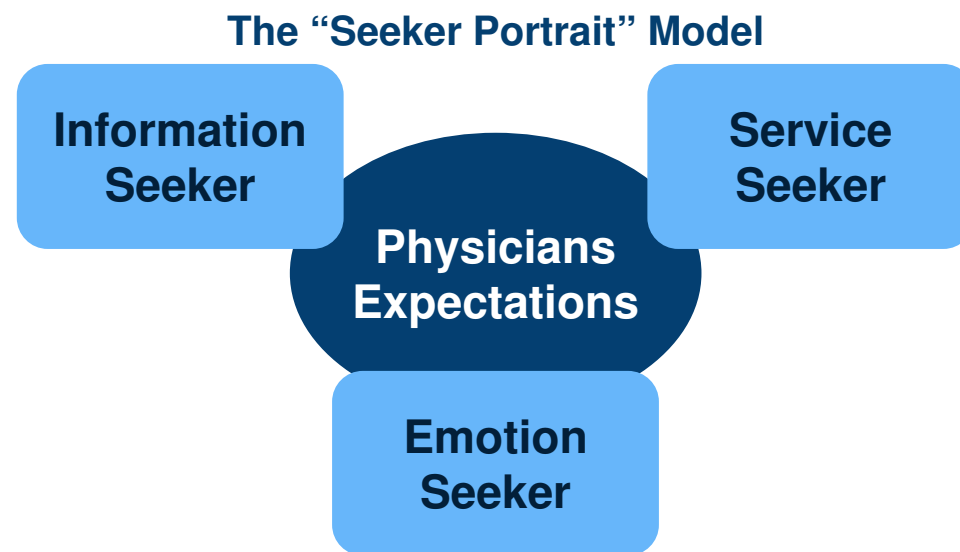
## H2I Program Framework



**While interacting with Med Reps, physicians will be looking for: information, service, an/or emotion, knowing that one of them is in general predominant, at a point of time**

## **Step 1 – Physicians Profiling: Introduction of the Model**

- Physicians expectations vis-à-vis Med Reps are strongly influenced by their personality
- We propose the “Seeker Portrait” model to help Med Reps characterize what physicians will predominantly expect while interacting with them
- We can consider that, while interacting with Med Reps, physicians will be seeking for:
  - Information
  - Services
  - Emotion
- If physicians expectations are in fact a mix of the three types, one will be dominant, reflecting his personality and his specific needs at a point of time
- Physician dominant expectations may vary:
  - Over time
  - With the promoted brand (innovative or me-too)
  - With Med Reps (based on their past interactions)



**To increase the probability of generating High Impact Interactions, Med Reps must define, physician by physician, their dominant type of expectations vis-à-vis them**

## **Step 1 – Physicians Profiling: Description of the Model**

### The “Seeker Portrait” Model



- **“Information-Seekers”** expect from Med Reps information based on clinical studies and evidence-based medicines (EBM)
- Physicians want to be kept informed about the latest disease-related news (*i.e. new clinical studies about the promoted product and its competitors, new medical guidelines, scientific events, new regulations from health authorities, or new conditions of co-payment by payers, etc.*)

- **“Emotion-Seekers”** expect from interactions with Med Reps to have a good time, a pleasant exchange (e.g. about its medical practice, its hobbies, the Med Reps experience, the company he works for, etc. )
- They expect Med Reps to be trusted advisors, delivering unbiased information, demonstrating empathy, respect, etc.

- **“Service-Seekers”** expect from Med Reps service delivery such as:
  - Invitation to enroll their patients in adherence programs to help them stay on their medications
  - Completion of patient registries
  - Compilation of scientific information
  - Invitations to CME (continuous medical education) programs
  - Invitations to congresses / symposiums
  - Etc.

**The different types of dominant expectations require from Med Reps different sets of skills and an adjustment of their behavior while interacting with physicians**

**Step 1 – Physicians Profiling: Implications for Med Reps**

**The “Seeker Portrait” Model**



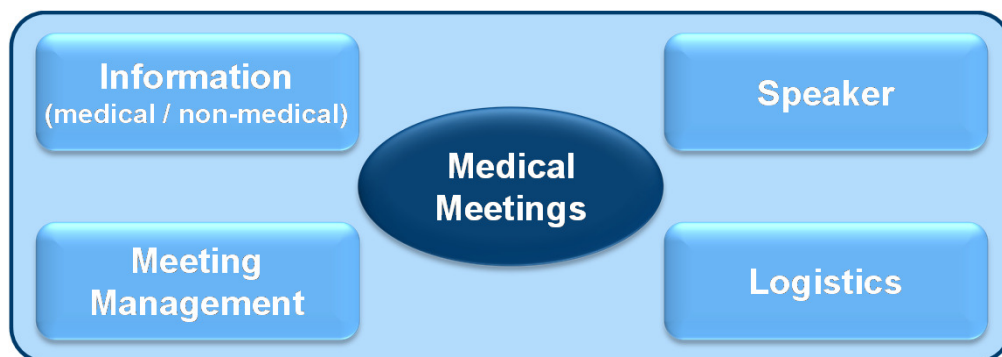
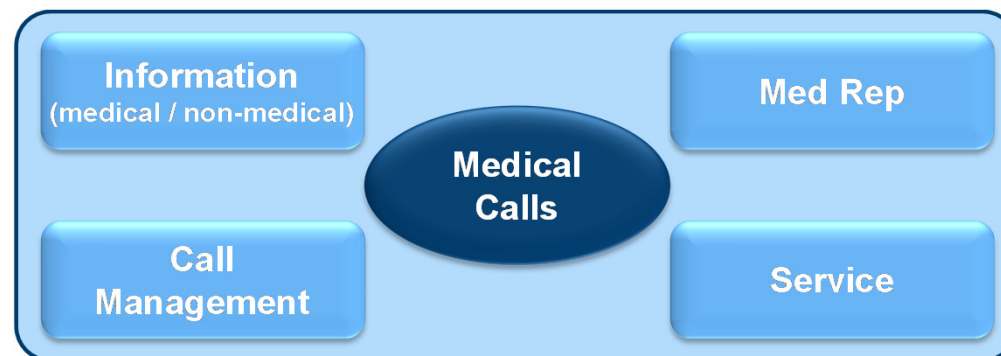
- Med Reps must have a solid expertise in analyzing and presenting clinical studies
- They should have a strong understanding of the science, including disease state, therapeutic options, etc.
- They should deliver up-to-date information that will help physicians make better decisions for their patients
- They should also be well-trained regarding the healthcare environment (system, regulations, etc.)

- Med Reps should benefit from a high emotional intelligence to be able to perceive and analyze physicians emotions and adapt their interactions accordingly
- Thus, they will have to add emotions to the brand attributes (efficacy, safety, convenience)
- The brand should not be considered as just another me-too but as a specific brand with its own personality that will match physicians expectations and will stimulate their preference

- To fulfil ‘Service-Seekers’ expectations, Med Reps should be clear about what they can deliver or not to avoid physicians disappointments
- They should make sure that the service they propose is valued by the physicians and then...
- ... ensure its perfect execution
- It is easier to differentiate from competitors through a higher quality of execution than through the service itself, because companies provide similar services

Physicians experience while interacting with Med Reps will depend on their assessment of the four determinants of the three following types of interactions

**Step 2 – High Impact Factors Identification per Interaction**

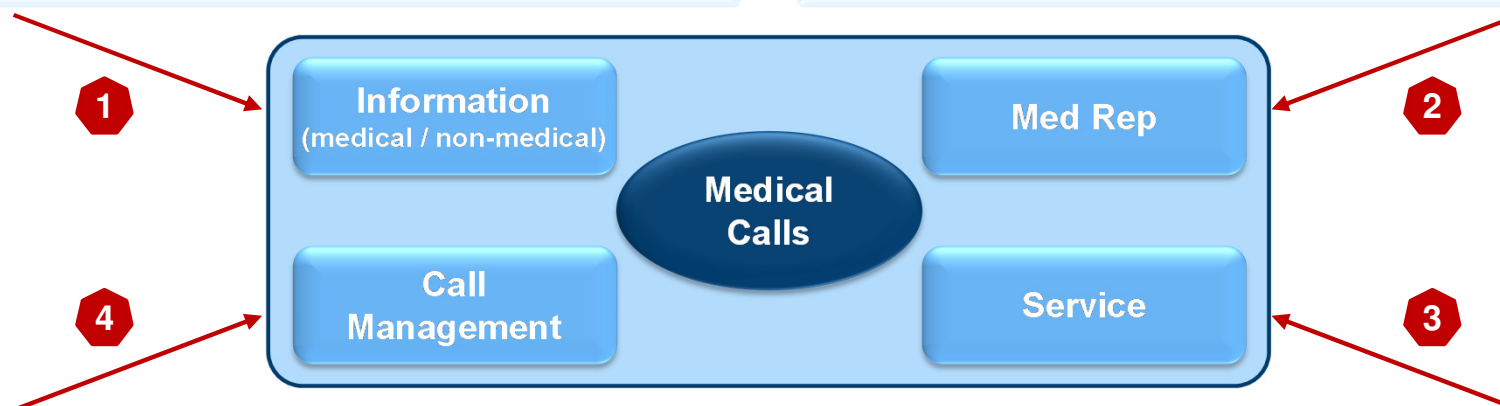


**To carry out an impactful visit that physicians will remember as a positive experience, Med Reps should carefully and specifically activate the following determinants**

**Step 2 – High Impact Factors Identification: Medical Calls**

- Delivery of up-to-date and reliable Information<sup>1</sup>
- These information should be meaningful for the physicians practice (if medical)...
- ... or at least interesting (if not medical)

- Med Reps should have a perfect knowledge of the brands they promote and of their environment<sup>2</sup>
- Style and behavior should be adjusted to physicians
- They should always demonstrate empathy, be polite, on time, and possibly in a good mood and cheerful



- Calls duration should be short (10-12 minutes) and the place calm enough
- Clear, precise and concise communication style
- Use of visual aids (printed, tablets, iPads) only if it adds value to convey the information

- Med Reps should propose only services that are highly valued by the physicians and for which the quality of execution is likely to be high or very high
- All services should be systematically associated directly or indirectly to the promoted brand

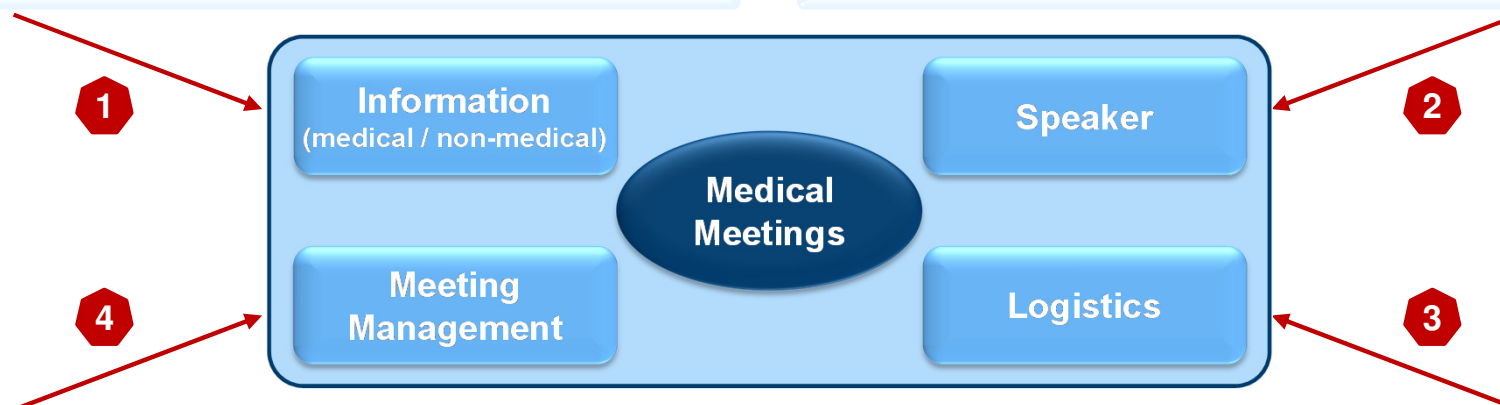


**Most physicians expect from medical meetings practical exchanges with peers, no (or limited) promotional speech, in a pleasant and convenient place**

**Step 2 – High Impact Factors Identification: Medical Meetings**

- Proposed topics should be useful and innovative, with concrete implications for physicians daily practices
- Certain physicians may be interested by specific therapeutic areas<sup>1</sup> or by topics such as: stress management, physician-patient relationship, etc.

- Speakers should be renowned, expert in their field, and able to substantiate their opinion with tangible data based on publications or their own experience
- They should have good communication skills...
- ... and not promote the brands of the Med Reps



- Typically, medical meetings should not last more than one hour (including presentation and Q&A session)<sup>2</sup>
- Med Reps should welcome each physician like a “guest” and make sure he enjoys his participation
- Facilitate exchanges between physicians<sup>3</sup>

- The invitation should be sent at least one month before the “D” day and reminders should be sent
- The location should be attractive and its access easy
- The food does not need to be sophisticated but the quality should be good and it should well presented

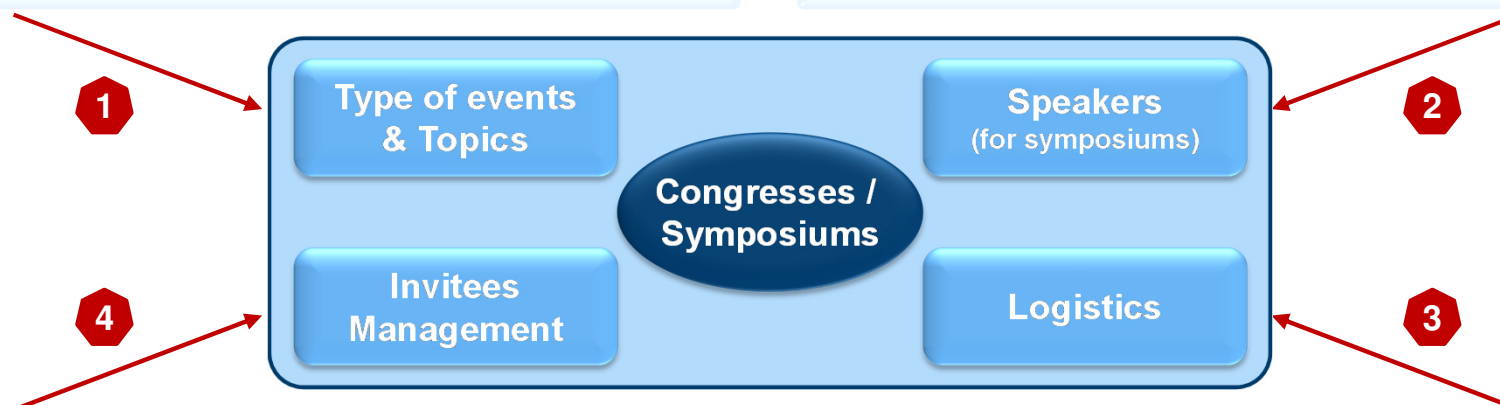


**Invitations of physicians to congresses or symposiums should be carefully planned and implemented to make them live a unique experience they will remember**

**Step 2 – High Impact Factors Identification: Congresses / Symposiums**

- The type of proposed invitations (i.e. international, national or regional congress, symposium) should take into consideration physicians preference
- The topics covered should be highly scientific, with preferably practical clinical implications for attendees

- Speakers should be renowned, expert in their field, and able to substantiate their opinion with tangible data based on publications or their own experience
- They should have good communication skills...
- ... and not promote the brands of the Med Reps

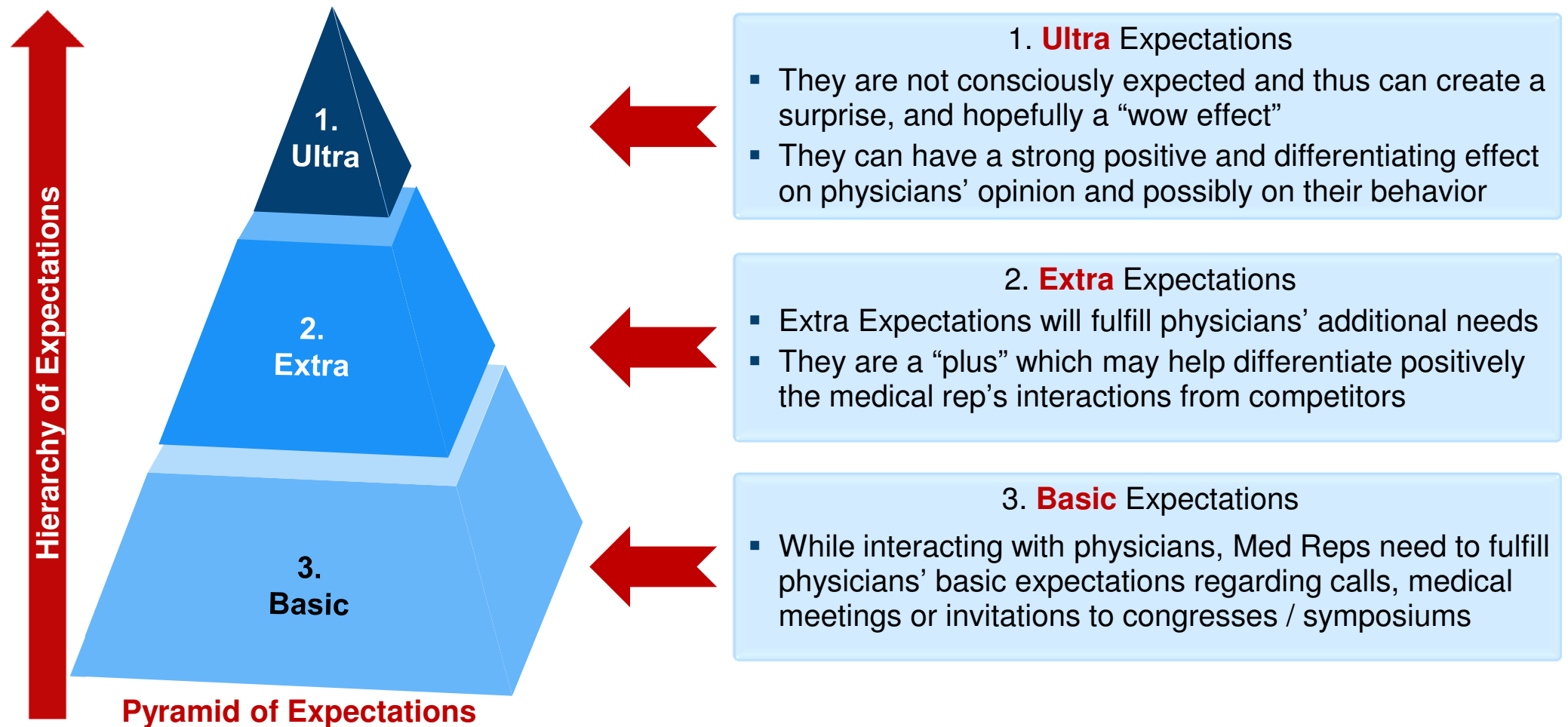


- Send invitations rather than waiting for requests
- Choose a hotel which is close to the place of the event
- Make sure to assist the physicians (by Med Reps or other colleagues) to build a stronger relationship with them and offer them a unique experience

- The invitation should be sent from six months to one year before the event, with regular reminders between
- The country or city where the event will take place is important for most physicians
- Ensure a prompt reimbursement of expenses

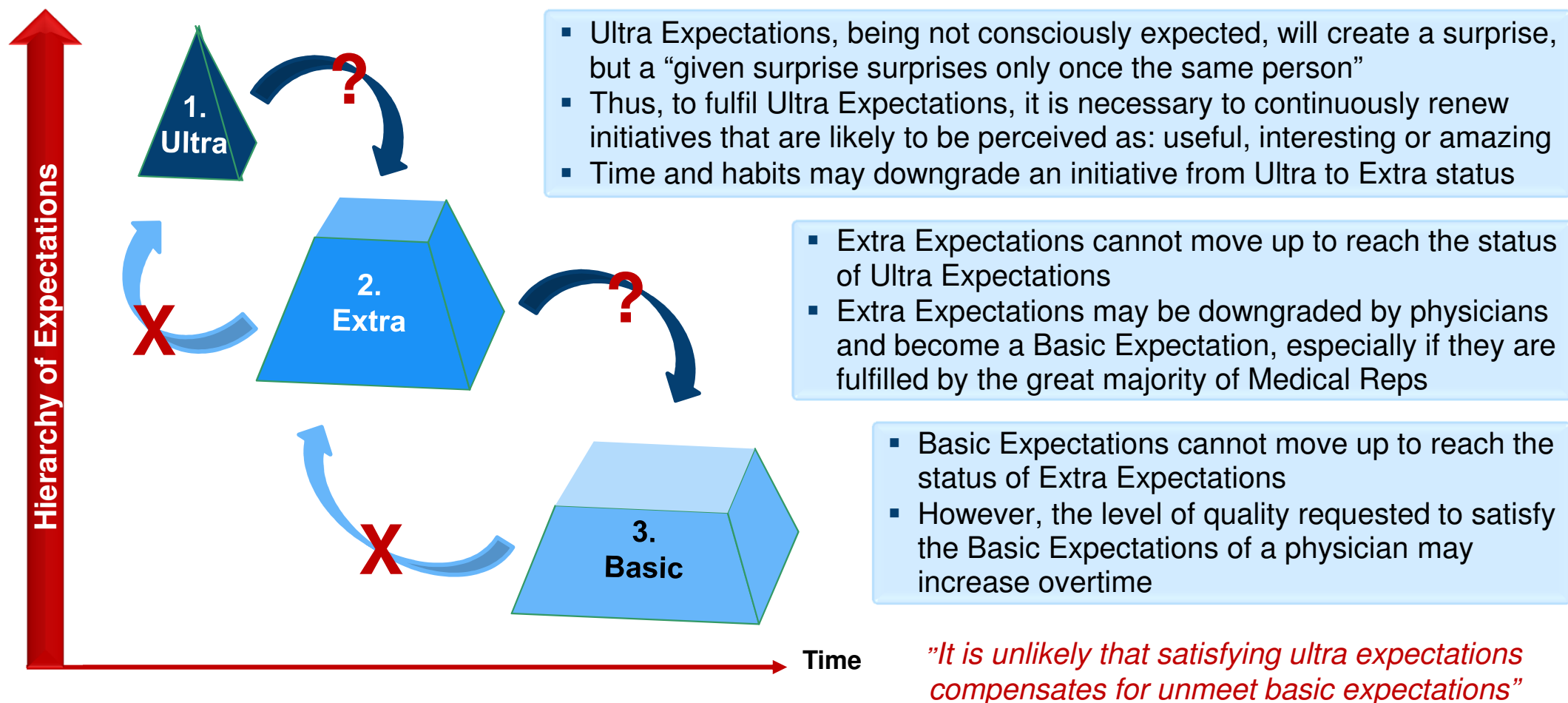
To create High Impact Interactions, Med Reps need to move up the pyramid of expectations in an attempt to offer physicians “a unique experience”

**Step 3 – H2I Program Design: Principles (1/3)**



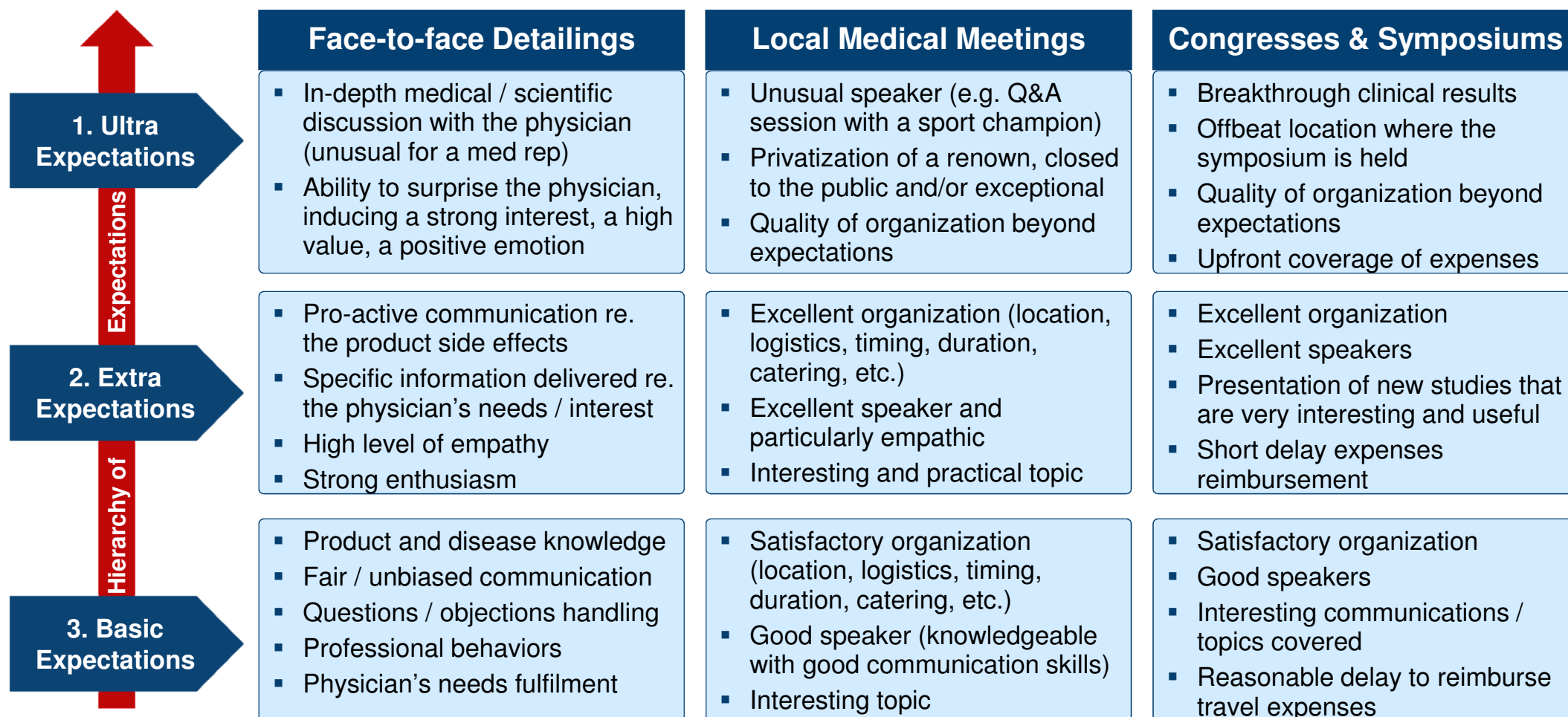
The status of an expectation may be downgraded over time, physicians becoming used to an interaction, initially fulfilling an Ultra or an Extra Expectation

**Step 3 – H2I Program Design: Principles (2/3)**



Meeting a physician Ultra Expectation is rare but it may induce a long-lasting higher impact contributing to reinforce his preference for the brand

## Step 3 – H2I Program Design: Principles (3/3)



Sources: Smart Pharma Consulting analysis

These examples of exceptional physician experience were created intentionally, and not by accident, by Med Reps who managed to reach the level of “Ultra Expectations”

### Step 3 – H2I Program Design: Examples of Interactions

#### Case Study #1: The Teacher

##### The Situation

- A Med Rep promoting a new anti-asthmatic drug with no significant benefits compared to the existing brands which are well-established could not manage to raise a pulmonologist interest who used to limit the number of medical calls to two per year

##### The Solution

- After several months, the Med Rep had the idea to propose the pulmonologist to give a lecture on the health risks associated with tobacco to his son's class
- He accepted the proposition and they prepared together the conference
- Surprisingly the physician enjoyed this experience. Since that date, the Med Rep is allowed to visit him more frequently, and he has also started to treat few patients with his brand

#### Case Study #2: The Pianist

##### The Situation

- A Med Rep realized that most of the physicians he used to invite to medical meetings did not really remember, after few weeks, what had been the content and who had organized it
- Thus, these meetings were unlikely to change the opinion and the prescribing behavior of the attendees

##### The Solution

- In an attempt to address this problem, the Med Rep organized a new medical meeting after having informed the 18 invitees that a “special event” had been prepared, after the scientific presentation of the speaker and the Q&A session
- He also happened to be a good pianist, and he offered the physicians attending the meeting a “mini concert” of 15-20 minutes which created a big surprise and amazed them
- They ignored that the Med Rep had this hidden talent

These case studies show that unique experiences may results from very different triggering factors, for which the number is unlimited

## Step 3 – H2I Program Design: Examples of Interactions

### Case Study #3: The Expert

#### The Situation

- The Med Rep of a big company who promotes the biosimilar of a well-established long-acting insulin, knows that it is going to be difficult to convince diabetologists to adopt his brand
- This Med Rep has a solid academic background (Pharma D) and is passionate by this therapeutic area

#### The Solution

- In agreement with his manager, he decided to reinforce his scientific knowledge, and after a couple of months of article reviews, and of specific trainings organized by his company, he reached a scientific level similar to that of MSLs<sup>1</sup> which is not common for a Med Rep
- This enables him to provide physicians with updated and high quality information likely to be useful for their medical practice and of interest to them, while calling on them

### Case Study #4: The Tour Operator

#### The Situation

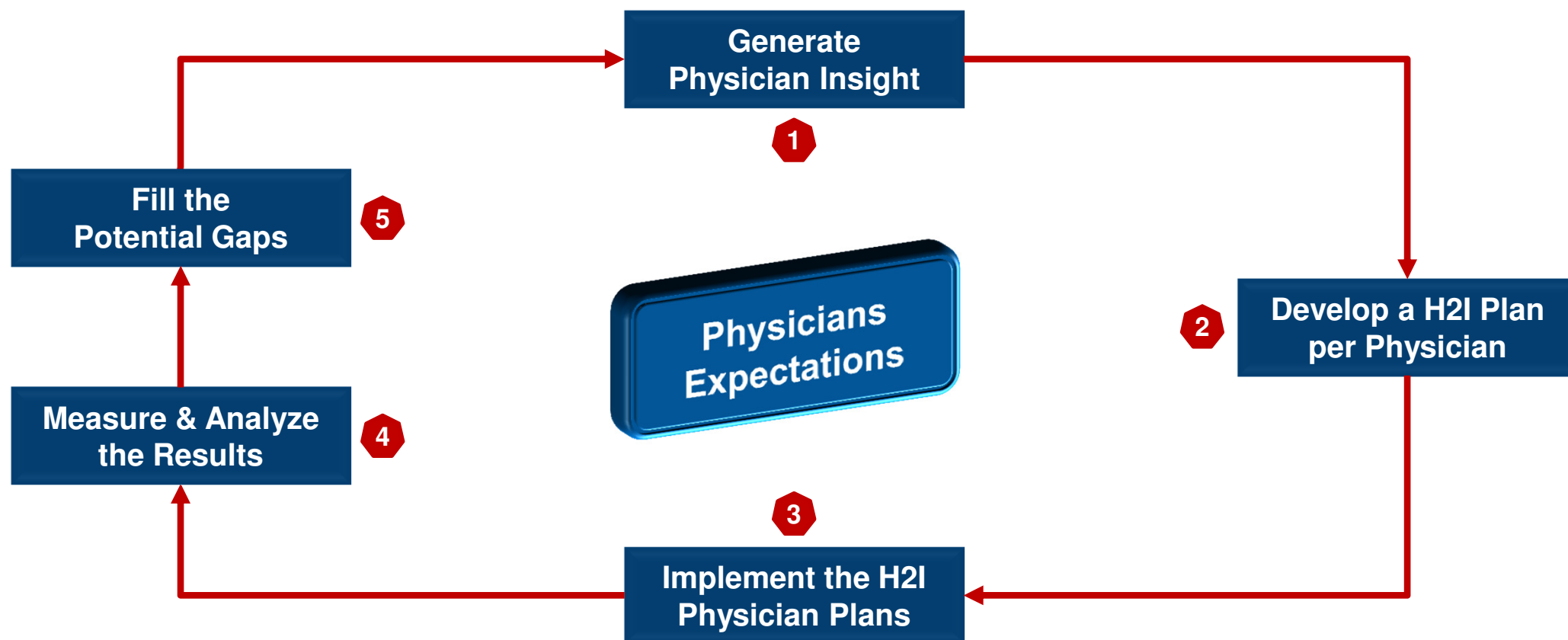
- It not rare to hear physicians, and especially KOLs<sup>2</sup>, saying “*I have been invited by a pharma company to a congress but I can’t remember by which one and for which product*”
- If the physician does not link the invitation to the brand, he will not modify his opinion nor his prescribing behavior as a result

#### The Solution

- To “decommoditize” these invitations and transform them into a powerful preference trigger, a mid-size pharma company decided to stimulate physicians emotion as follows:
  - Each invitee is informed that he has been specifically chosen by the Med Rep and that he will be part of a small group
  - The Med Rep will address all the administrative matters<sup>3</sup>
  - The Med Rep<sup>4</sup> will make sure that “his” physician enjoys his participation to the congress and he will be available 24/24 to address any issue and make this invitation a unique experience

The implementation of the H2I Program follows a 5-step process that will help Med Reps ensure a high quality of execution which is a prerequisite to get good results

### H2I Program Implementation: Framework





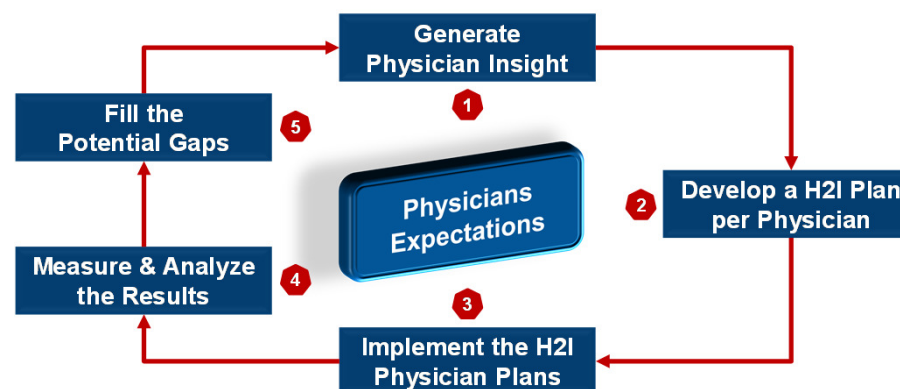
**Med Reps being a “masterpiece” of the H2I Program, they should be well-trained and supported to secure its effective and efficient implementation**

## H2I Program Implementation: Framework – Key Steps

- 5**
- Med Reps, with the support of their company market research experts and their first line sales manager should define priority actions to fill up the most important gaps identified during the previous step, to raise physicians experience
  - Selected solutions should then be tested and implemented

- 1**
- Identifying and understanding the in-depth wants and needs of each physician, is the first step to find out what a “great experience” means for them, while interacting with Med Reps
- By better assessing and addressing customer needs, Amazon and Uber have disrupted the market they compete in*

- 4**
- Med Reps should identify per physician, once or twice a year for medical calls and after each event for medical meetings and invitations to congresses / symposiums:
    - Their level of satisfaction<sup>4</sup> and the reasons
    - What will make them have a better opinion next time
    - The link between what they say and what they do
    - The economic outcomes of their interactions with metrics (e.g. BPM, NPS)<sup>5</sup>

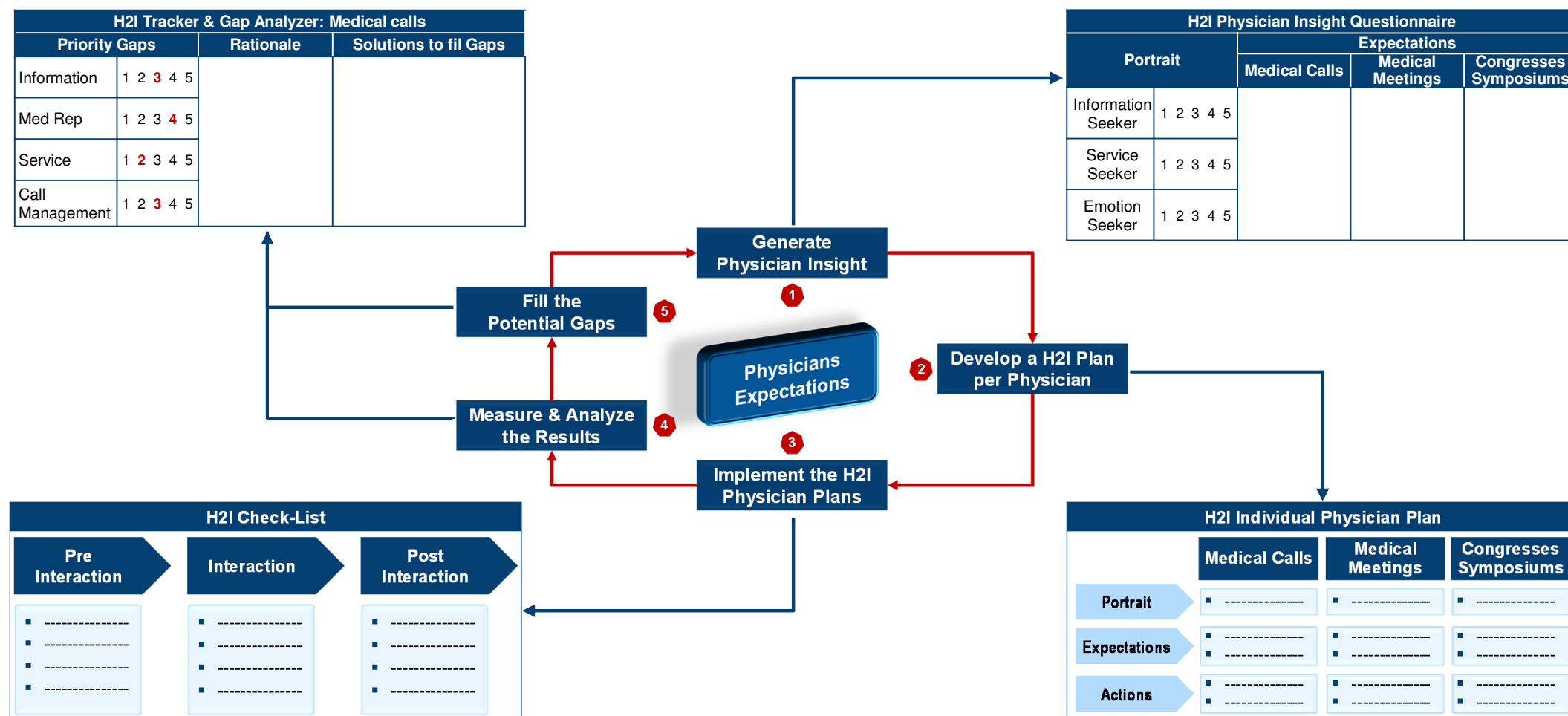


- 3**
- Med Reps should prepare carefully their interactions with physicians to “offer” them an “exceptional moment”
  - They should highlight their brands attributes, propose valuable services<sup>3</sup>, communicate on their company and themselves if relevant, and adopt a behavior likely to trigger positive emotions and thus their desire to prescribe more their brands

- 2**
- Based on each physician profile (“Seeker Portrait” Model) and insights, Med Reps will determine by type of interaction:
    - The most important determinant of satisfaction
    - The best way to fulfill the physicians expectations on these determinants
  - These actions should then be structured and organized in a “H2I Work Plan” and for each of these actions KEIs<sup>1</sup> and KPIs<sup>2</sup> will be set

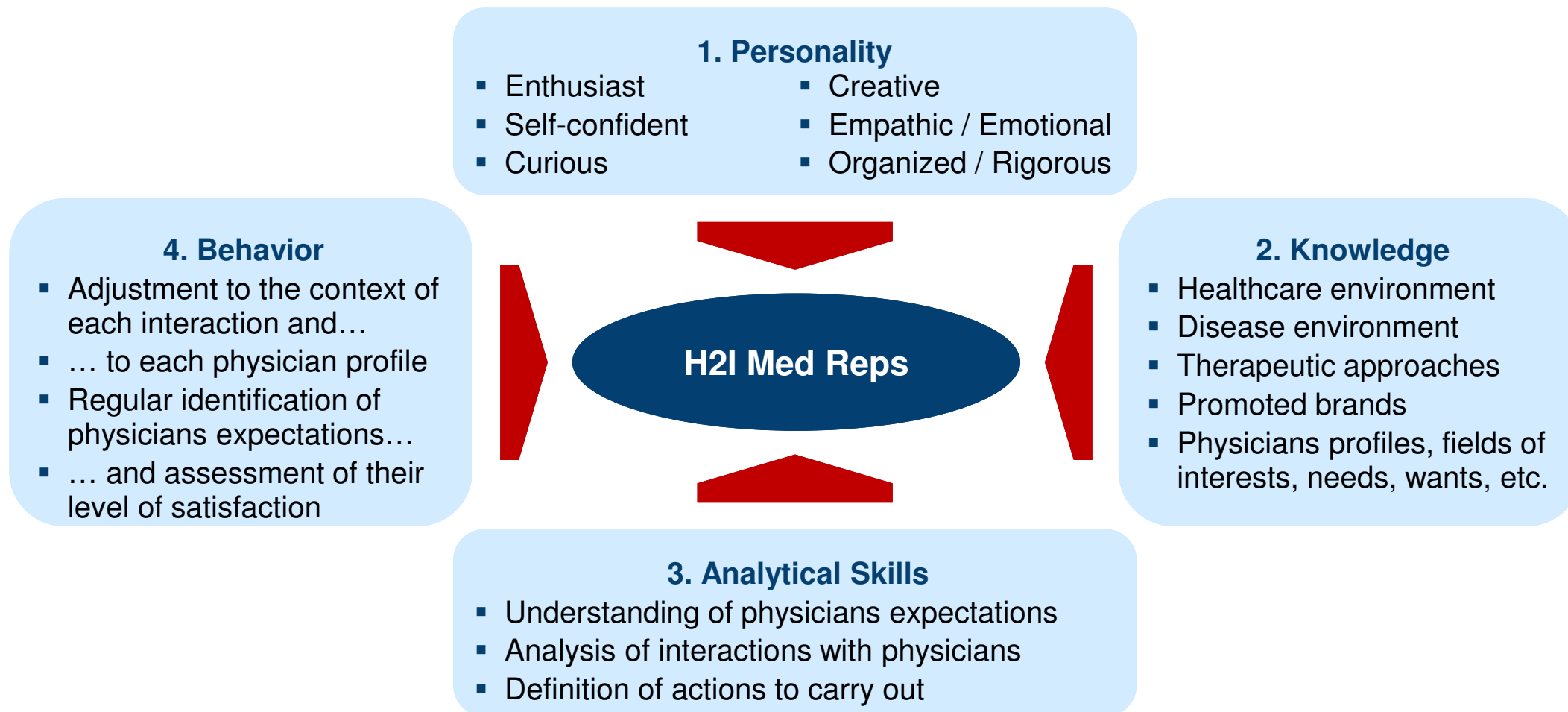
For each of the 5 steps of the H2I Program, enabling tools will be designed to facilitate their execution by the Med Reps and the other collaborators involved

## H2I Program Implementation: Framework – Tools (Illustrative)



To obtain quick and tangible results, “H2I Med Reps” would need to adjust their behavior, certain traits of their personality and improve their technical skills

## H2I Program Implementation: Key Success Factors (1/2)

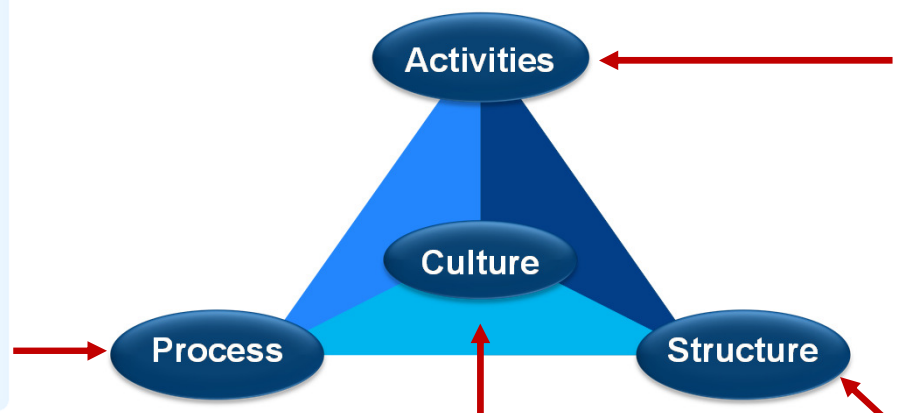


**The H2I Organization should be designed to offer unique experiences that physicians will remember as being particularly useful, interesting and/or even amazing**

## **H2I Program Implementation: Key Success Factors (2/2)**

- Interactions by all collaborators should be coordinated to ensure:
  - High and consistent quality level
  - Leverage of internal synergies
  - Insight- and experience-sharing
- H2Is should be part of Med Reps required competencies
- A planning and monitoring process should be put in place
- Compliance rules should be clear

### **H2I Organization**



- The opportunities to interact with physicians being very limited<sup>1</sup>, Med Reps should be perfectly trained and organized to offer them “exceptional moments”
- Each interaction will be carefully planned and prepared with the help of a “H2I Planner” and then ...
- ... followed up with a specific “H2I Tracker & Gap Analyzer”

- Pharma companies must push their ambition beyond satisfying physicians basic expectations; they must try to fulfil extra- and ultra expectations to increase their preference
- Pharma companies should also take into account physicians emotional needs, knowing that behavior is more easily driven by emotion
- The H2I Program should be designed by pharma companies so that Med Reps<sup>3</sup> are not only the providers of “unique experiences” but also the beneficiaries
- To build internal momentum to develop unique physician experience, the top management should share its conviction and aspiration across the company
- Med Reps should understand the support they will receive from the company, and the personal and professional benefits they will draw from the H2I Program

- Med Reps should be assigned a reasonable number of physicians:
  - ~250 for open care sales forces (incl. GPs + office-based specialists)
  - ~150 for specialists<sup>2</sup> sales forces
 so that they can implement the H2I Program which requires a significant amount of time to ensure the preparation and follow up of each interaction

**The best performing companies are able to develop deeper physicians insights and to create sustainable physicians experiences that stimulate their desire and preference**

### **4 Tips to create High Impact Interactions with physicians**

#### **Develop Insights**

- Use interactions as an opportunity to better know and understand physicians needs...
- ... and to identify to what they are sensitive: *What is likely to please, impress, delight, or positively surprise them?*

#### **Instill a Culture**

- The ambition to create H2I through exceptional experience should come from the top management and disseminate throughout the company to reach in-field collaborators
- Each employee should directly or indirectly understand and adhere to the H2I Program

#### **Define a Strategy**

- The H2I Program should be part of a broader strategy aiming at strengthening physicians preference to the brands promoted by the company
- The H2I Program should be aligned with the brand strategy promise

#### **Design a Process**

- Train Med Reps and design a clear process to ensure a consistently high quality of execution to best support the strategy
- Monitor interactions with specific metrics and fill the gaps; if any, with proper solutions

*“Excellence is doing ordinary things extraordinarily well”* - John W Gardner

The H2I Program significantly contributes to address the key issues related to the 3 components of the Brand Preference Mix and thus to boost physicians preference

## Link between the H2I Program and the Brand Preference Mix (BPM)

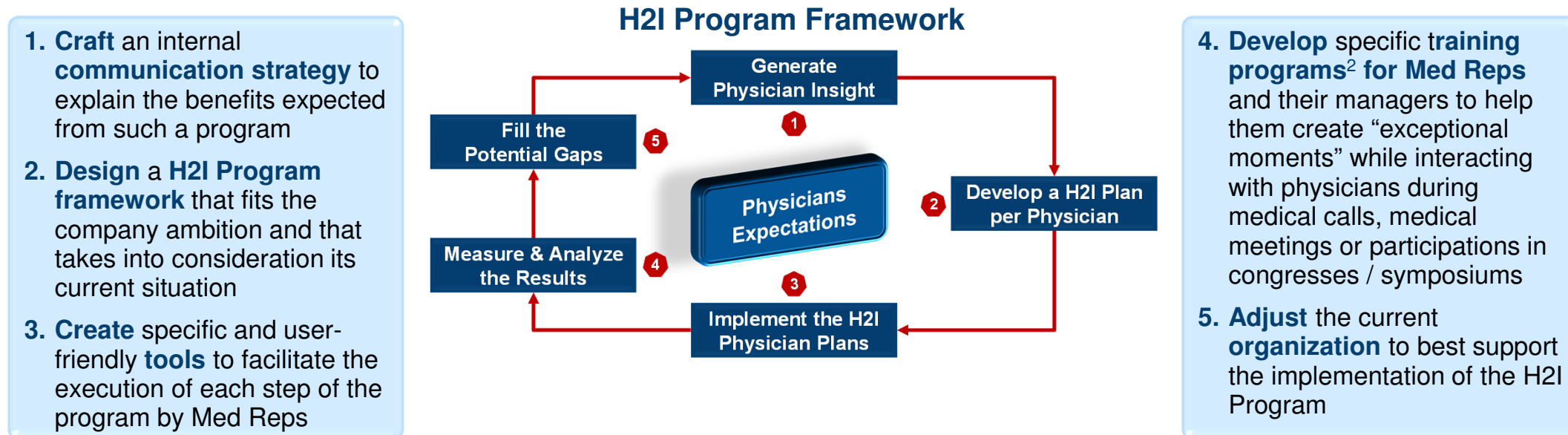




**Based on its strong expertise and practical consulting approach, Smart Pharma can help companies deploy, smoothly and efficiently, initiatives such as the H2I Program**

### How can Smart Pharma Consulting help you?

- Smart Pharma Consulting has an in-depth expertise in improving marketing and sales efficacy, shared with 72 pharma companies since 2001, both in France and abroad
- The H2I Program is a new building block in our Brand Preference Mix approach that will help Med Reps and other in-field collaborators such as MSLs<sup>1</sup> offer physicians unique experiences
- Smart Pharma consultants can help you implement the H2I Program Framework as follows:





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Smart Pharma Consulting has developed its methodology based on desk research, benchmarking studies and own experience to optimize mature brands management

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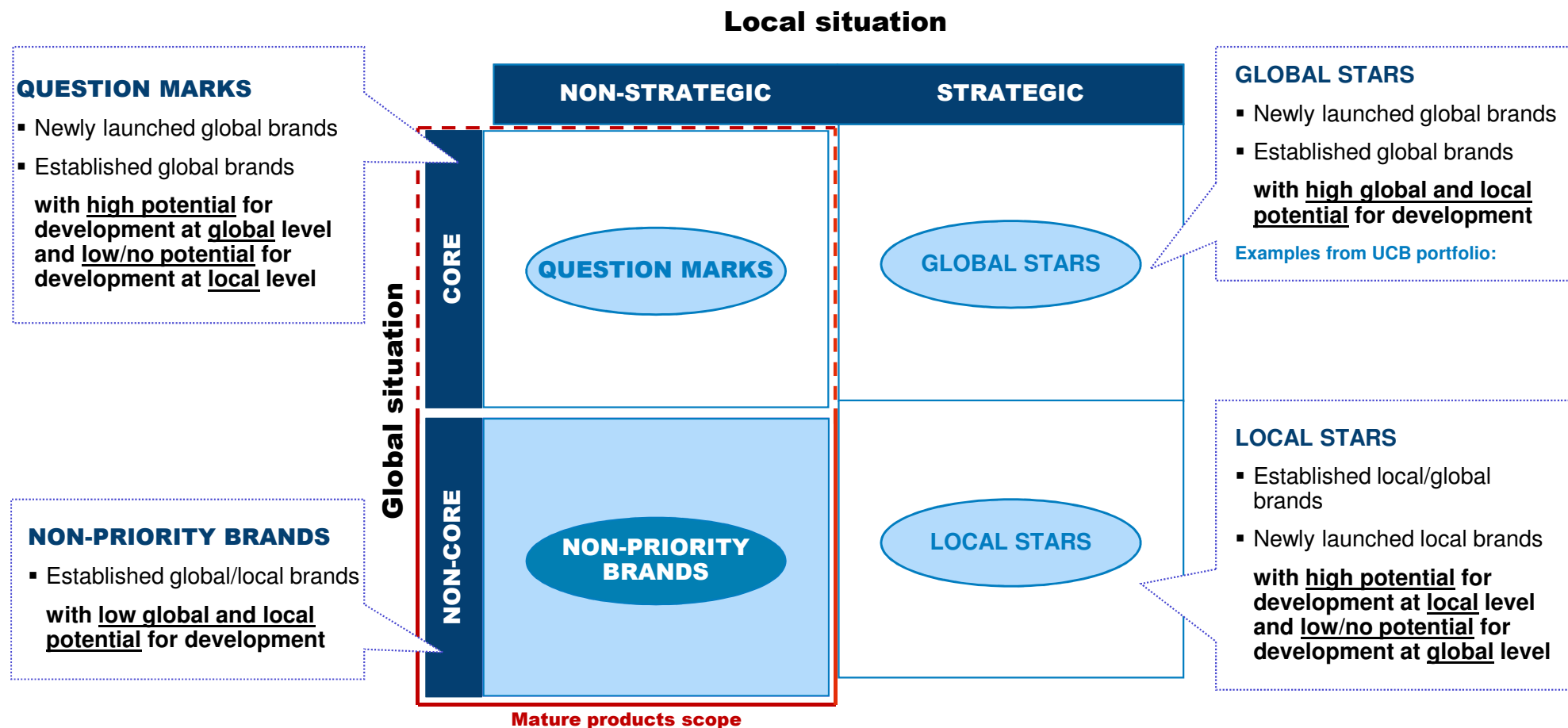
### **Objective & Approach**

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- **Mature brands** play an ambiguous role within the portfolio of pharma companies:
  - They show in general **low or negative growths** while...
  - ... providing **high profit contribution**
- **Performance optimization** of mature brands requires to answer the two following questions:
  - What is the **sensitivity** of the brands **to promotional investments**?
  - If sensitive, what are the **optimal investment level** and **mix**?
- To help pharma companies optimize the performance of their mature brands, Smart Pharma Consulting has formalized a **methodology** based on:
  1. Review of **expert reports**, **articles**, **position papers** on mature brands management
  2. **Benchmarking** studies
  3. Its own consulting **expertise** and **experience**

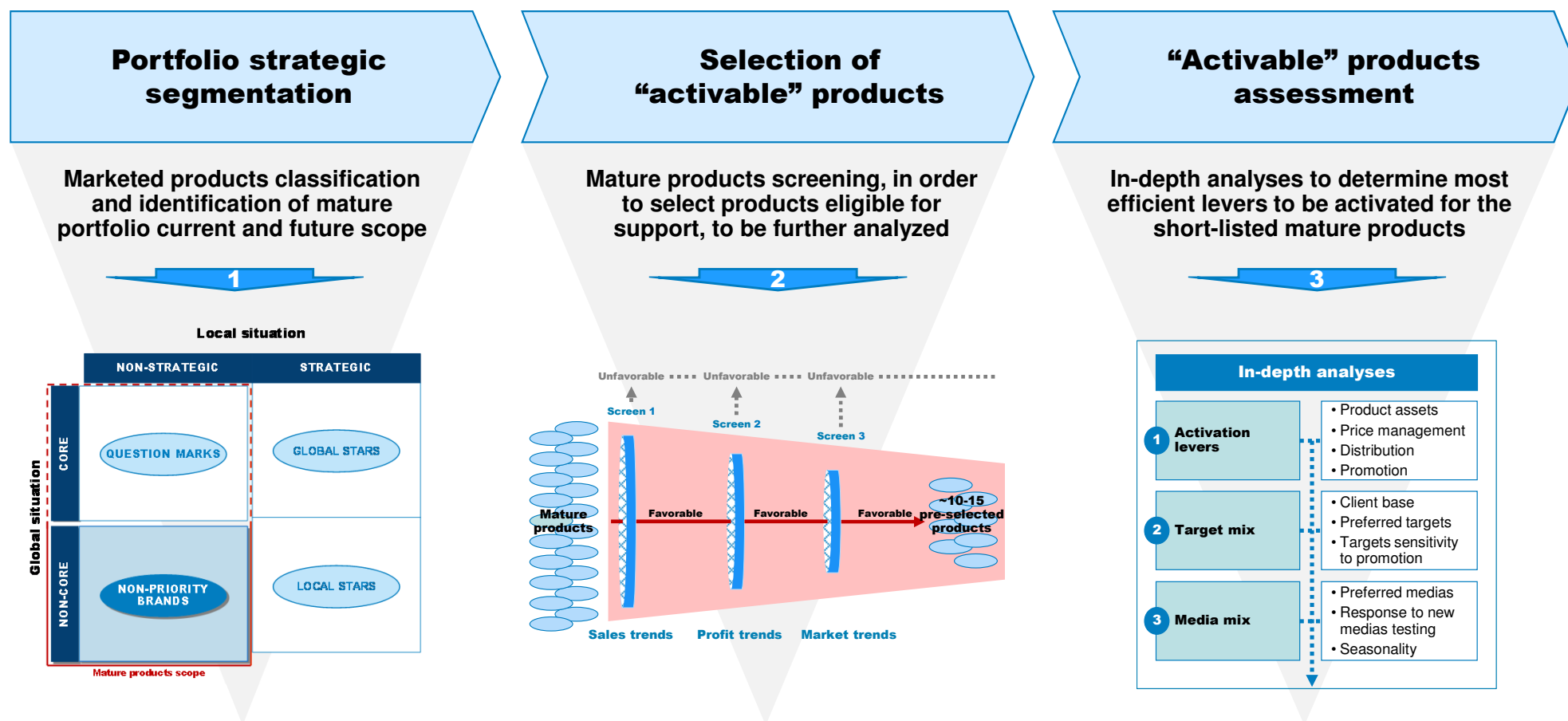
Most companies currently limit strategic thinking on mature products to brands with limited local potential, with a special focus on corporate non-core brands

**Portfolio strategic matrix**



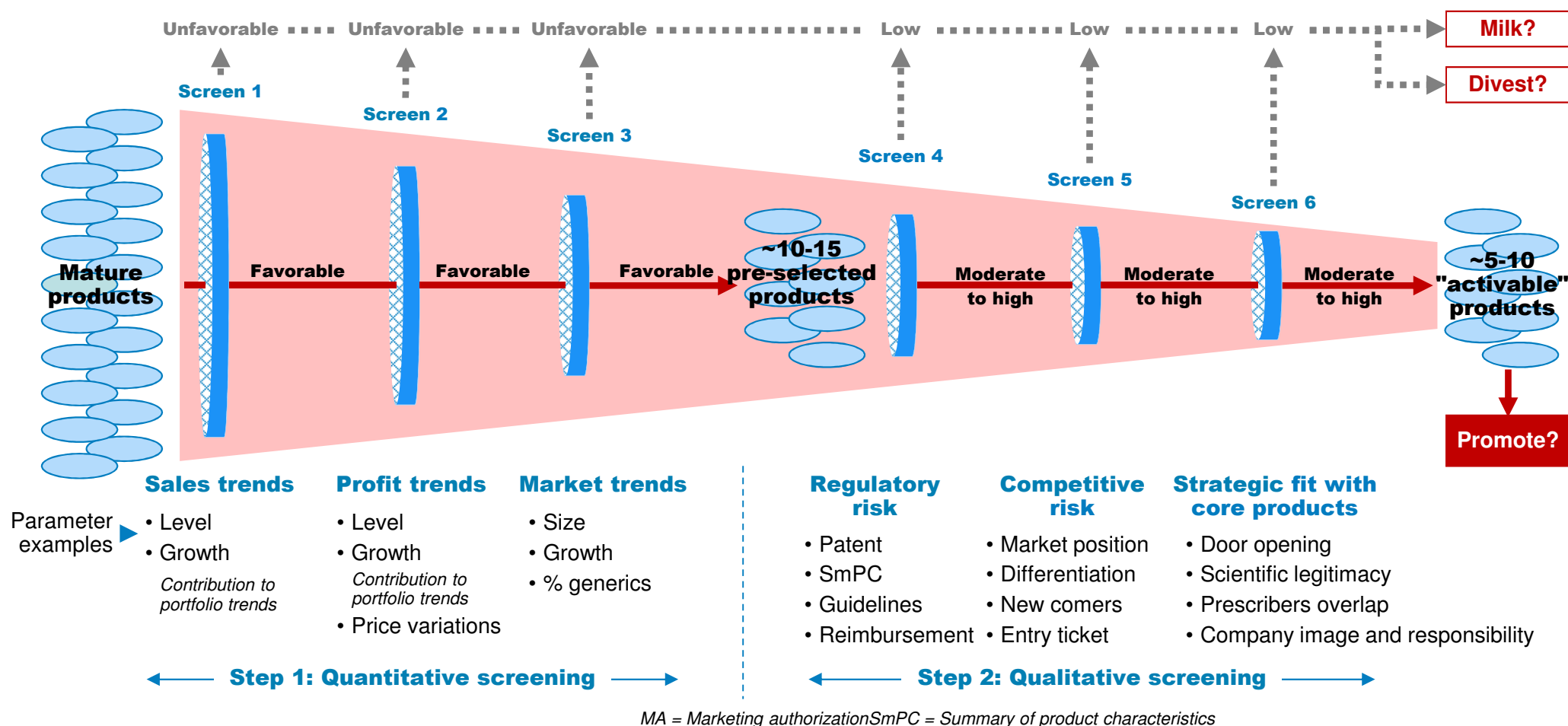
Before selecting “activable” products within mature products portfolio, the screening scope needs to be clearly defined through portfolio segmentation

**Portfolio analysis & mature brands optimization process**



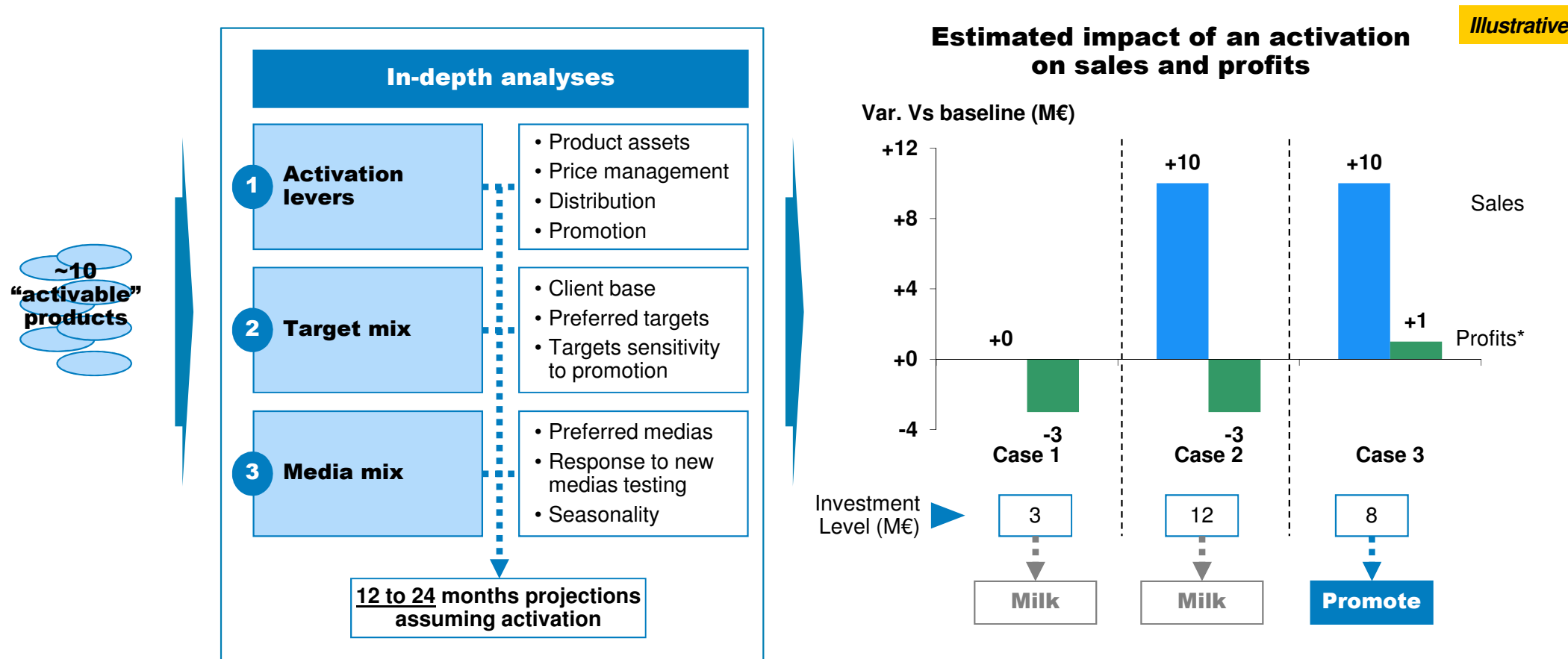
The selection of "activable" mature products within marketed MAs and "sleeping" MAs of interest can be made through a 2-step screening process

## Selection of "activable" mature products



An in-depth analysis of "activable" mature products is then required to determine most efficient levers to activate selected products

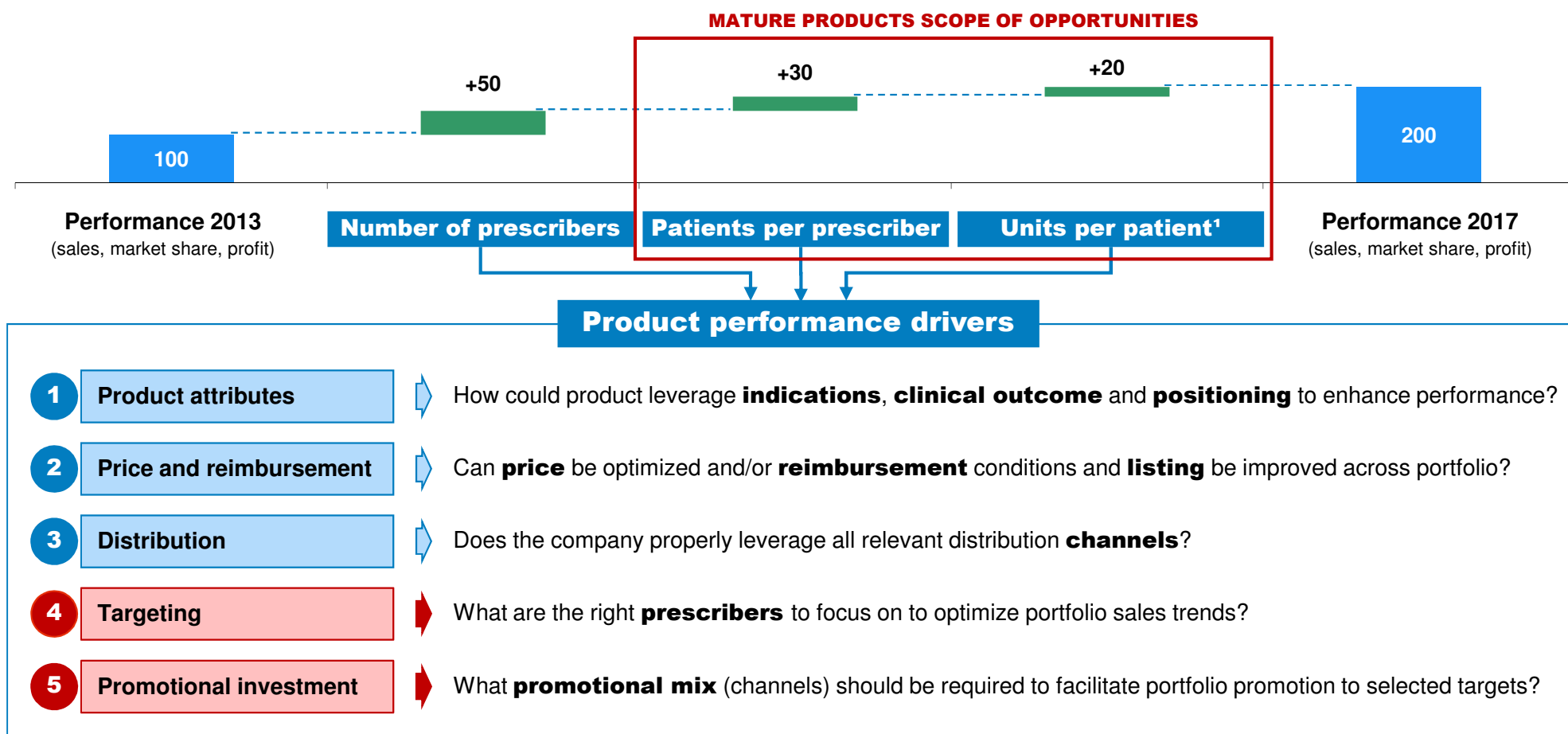
## “Activable” products assessment



\* Assumption: gross profit = 90% of sales. Thus, +€ 10M for an investment of € 8M will lead to a profit variation of: (€ 10M x 90%) – € 8M = +€ 1M)

Opportunities usually considered to enhance sales trends at mature products level merely consist in maximizing the prescriptions per prescriber ratio

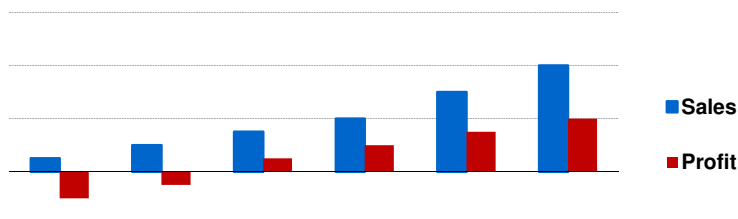
## Product growth levers



The primary goal of mature products management is to maximize profits, also sales optimization may come as an immediate second-line objective

## Portfolio management objectives

### Growing products



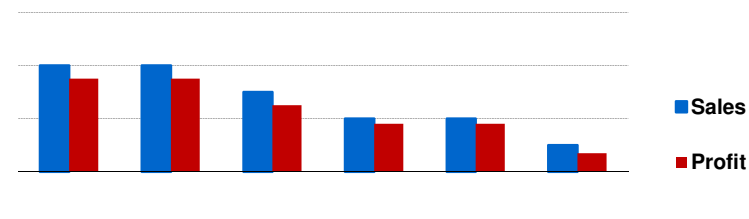
#### Objectives

- 1 Maximize sales
- 2 Develop profits

**Maximizing investment**  
may be the obvious response  
However,  
some products sales may not soar  
with an excessive promotional support,  
thus inducing a rapid drop in profits

Investment should be regarded first in the  
light of **sales enhancement magnitude**

### Mature products



#### Objectives

- 1 Maximize profits<sup>1</sup>
- 2 Optimize sales

**Milking**  
may be the obvious response  
However,  
some products sales may slump dramatically  
in the absence of promotional support,  
thus inducing a rapid drop in profits

Investment should be regarded first in the  
light of **profit erosion magnitude**



Preferred product strategies currently range from limiting generics penetration to developing product prescriptions

### Mature portfolio strategies

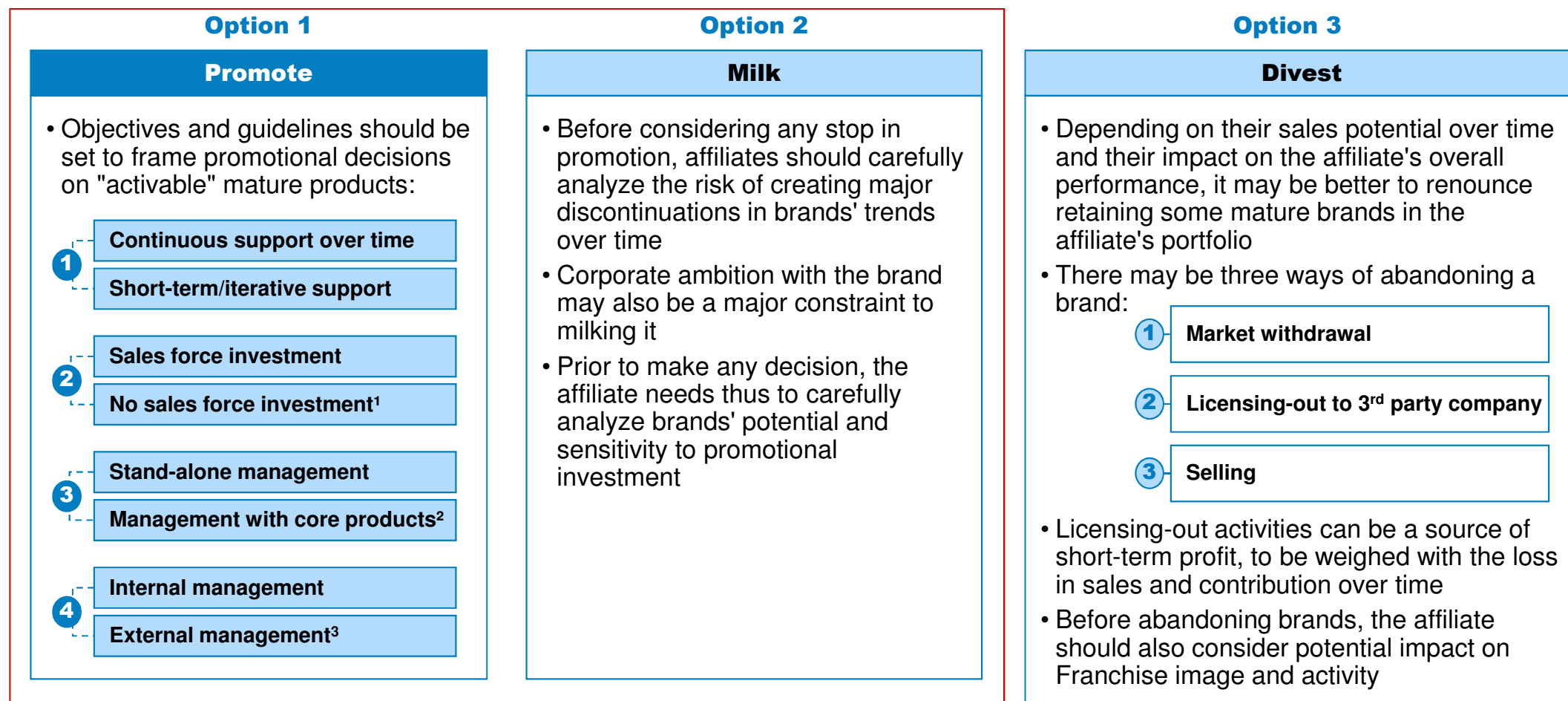
	Challenges		Eligible actions
<b>Genericized products</b>	<ul style="list-style-type: none"> <li>Limit generics penetration</li> <li>Minimize sales eligible for substitution</li> </ul>	➔	<ol style="list-style-type: none"> <li>1. Immediately align prices if a reference price is enforced</li> <li>2. Convince pharmacists not to increase product substitution<sup>1</sup></li> <li>3. Foster prescriptions transfer to non-genericized forms</li> </ol>
<b>De-reimbursed products</b>	<ul style="list-style-type: none"> <li>Preserve product prescriptions</li> <li>Ensure product is properly delivered in pharmacies</li> </ul>	➔	<ol style="list-style-type: none"> <li>1. Foster prescriptions transfer to non-genericized forms</li> <li>2. Maintain prescriptions of de-reimbursed forms with valid MA</li> <li>3. Prevent delivery switch to high-margin non-listed products</li> </ol>
<b>Other products</b>	<ul style="list-style-type: none"> <li>Limit sales erosion</li> <li>Develop sales of positive-trend forms</li> </ul>	➔	<ol style="list-style-type: none"> <li>1. Control and/or enlarge prescriber basis</li> <li>2. Control and/or develop prescriptions per prescriber</li> <li>3. Maximize spill-over effect</li> </ol>

Sources: Smart Pharma Consulting Analyses

<sup>1</sup> In certain countries such a practice may be considered as illegal

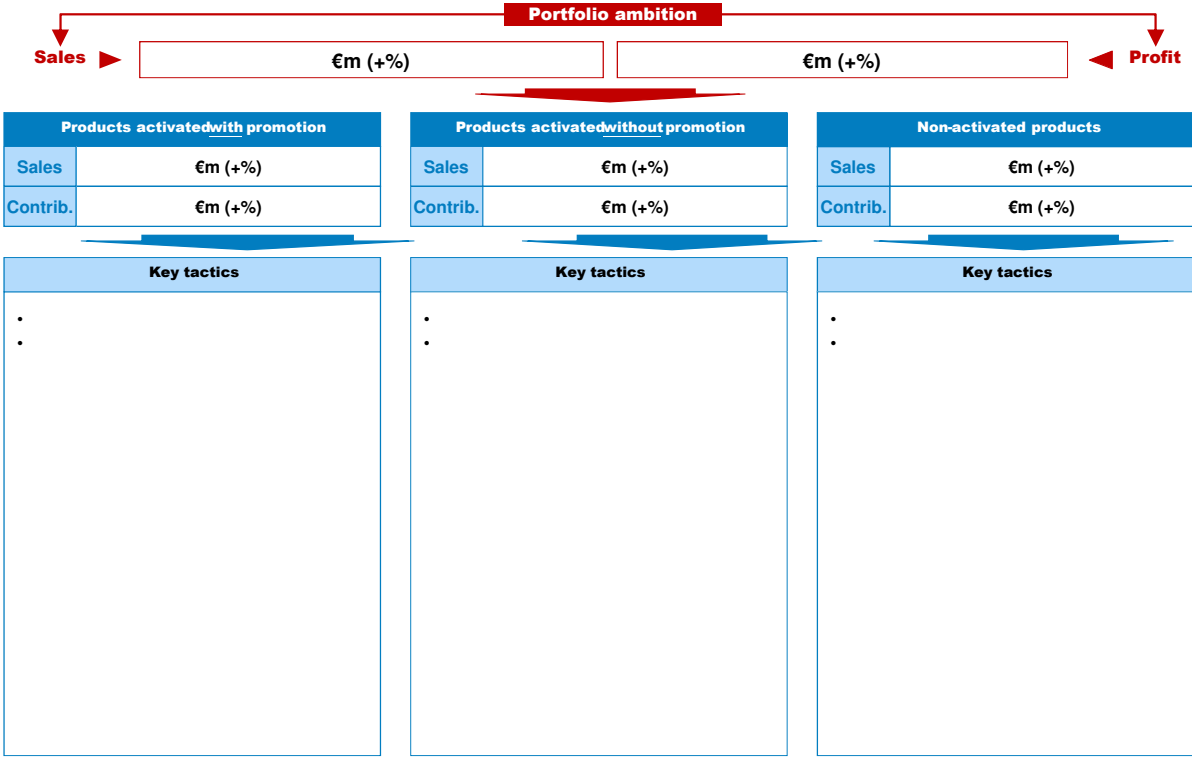
Promotional decisions on selected "activable" mature products should be made in compliance with precise objectives and management guidelines

## Mature products' management – Investment decisions



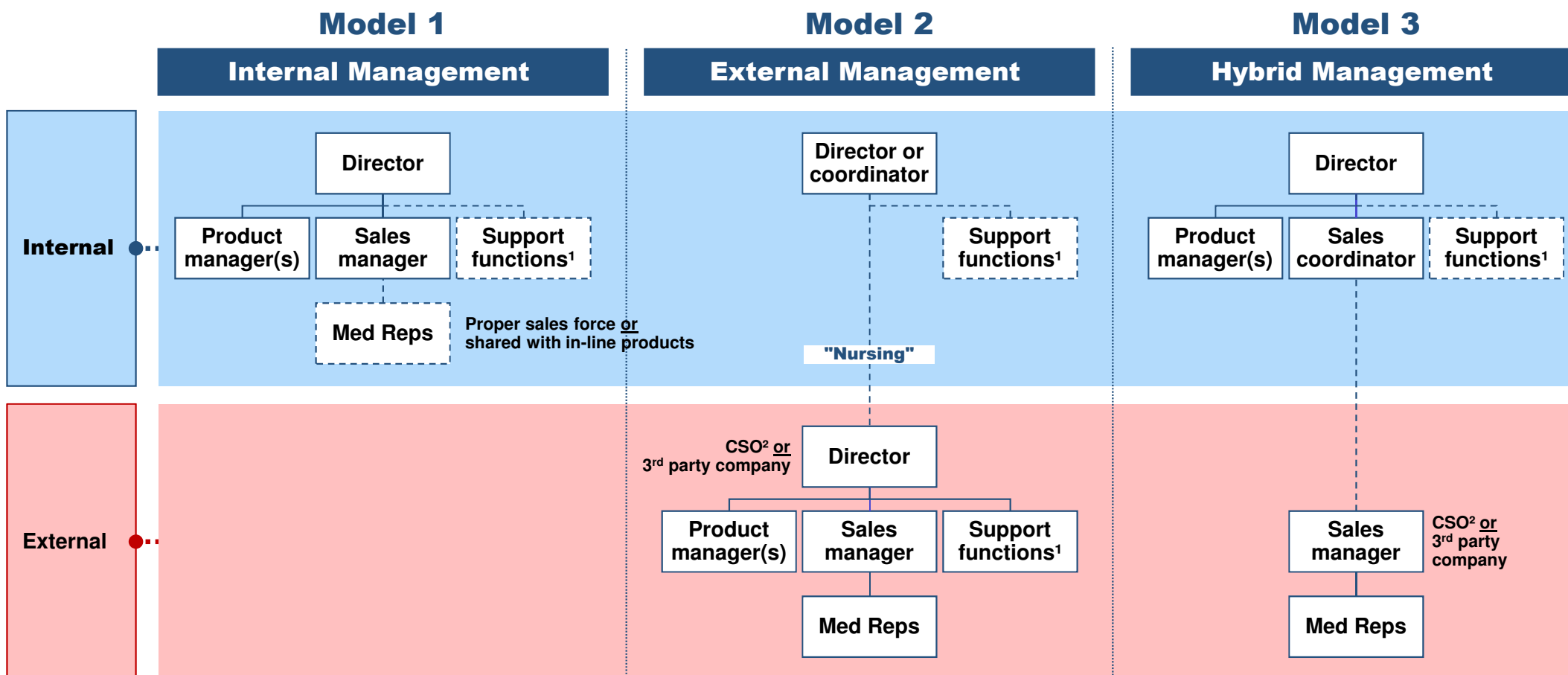
The Portfolio Strategy Card has been designed to summarize investment decisions for the different mature product segments, in one page

### “Portfolio Strategy Card”

Format			Comments
			<ul style="list-style-type: none"> <li>Products can be classified into three categories: <ul style="list-style-type: none"> <li>Products activated <u>with</u> promotion</li> <li>Products activated <u>without</u> promotion</li> <li>Non-activated products</li> </ul> </li> <li>Sales and profit objectives are set for the entire portfolio and for each category</li> <li>Decisions re. activation levers are summarized per product or product group (incl. packs, if any)</li> <li>Targeting and multi-channel approaches are considered transversally (sales force support can also be split between external and internal, if relevant)</li> <li>Non-activated products are split into three subgroups: <ul style="list-style-type: none"> <li>Milked products</li> <li>Products not launched but for which MA is maintained</li> <li>Pruned products (licensing-out, cession)</li> </ul> </li> </ul>

Three different organizations are usually considered to manage mature products at country level

**Organizational models to manage mature products**



Doted line boxes = shared functions within internal organization

**Physicians saturation vis-à-vis face-to-face calls and the emergence of “new players” pushed companies to investigate alternative promotional channels**

**Multi-channel approach – Changes in the environment**

- Strengthening of CRM<sup>1</sup> tools allowing for a more precise profiling of customers

- Strong detailing pressure of companies on the same targets of high potential physicians
- Evolution of product portfolios (increasing weight of specialist-oriented products requiring less reps)
- Increasing role of other market players (patient advocacy groups, regional sickness funds, etc.) influencing physician prescriptions

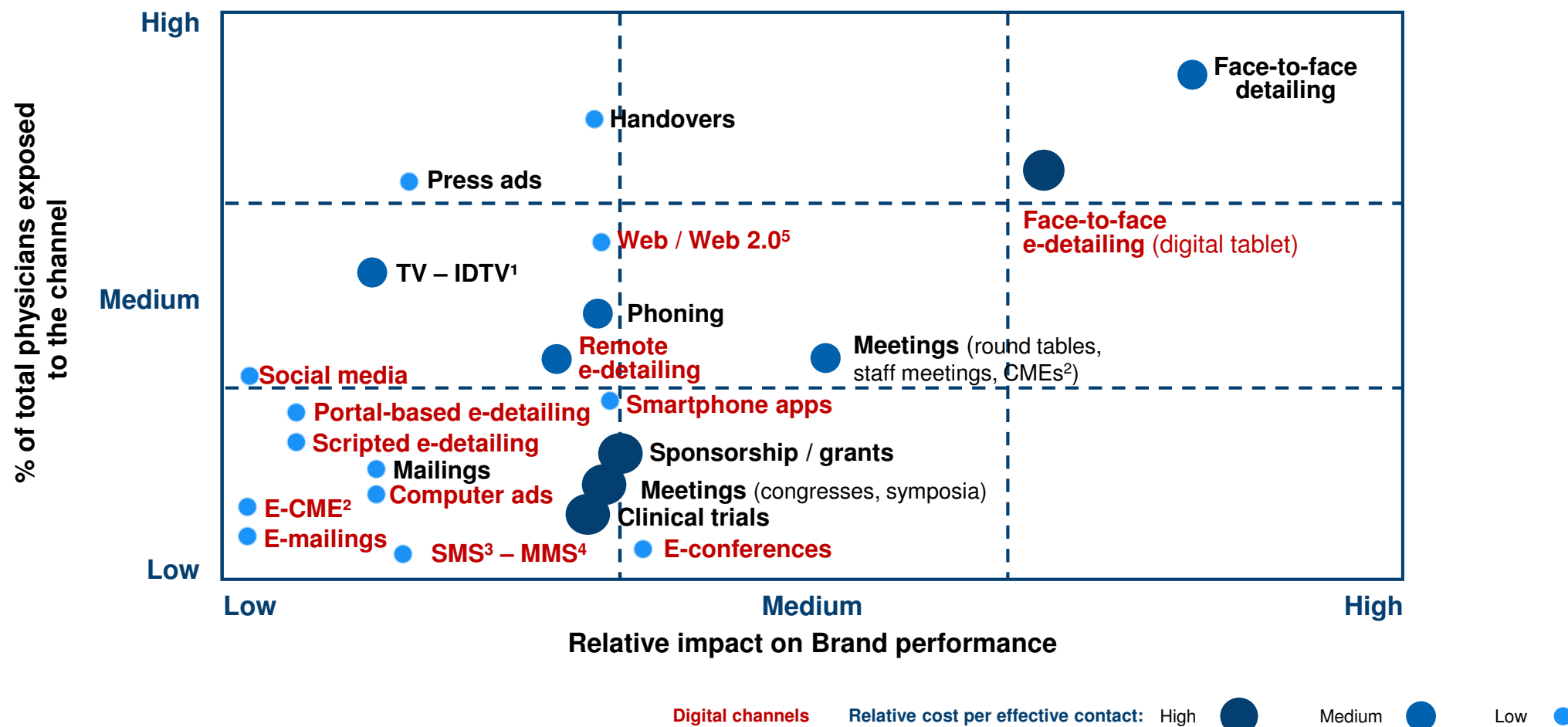


- Higher proportion of physicians refusing face-to-face calls from sales reps
- Tighter control of medical calls by health authorities which aims at:
  - Reinforcing detailing of products' good usage as set in SmPCs<sup>2</sup>
  - Limiting the number of calls to contain the number of physicians' prescriptions
- Need to adapt communication (contents and channels) to multiple targets (prescribers, influencers, payers)
- Reduced marketing and sales force budgets

- Reduction in the number of new active substances with high sales potential, leads companies to try to:
  - Improve the level of return on investment of each promotional activity
  - Maximize the profits of mature products by using more efficient promotional channels
- Less favorable economical context

If the impact of an action may be high on an individual basis, the global result may be limited as the number of clients exposed to the promotional initiative may be too low

**Multi-channel approach – Evaluation mix**



Sources: Smart Pharma Consulting Analyses

<sup>1</sup> Interactive digital television – <sup>2</sup> Continuous medical education – <sup>3</sup> Short message service – <sup>4</sup> Multimedia message service – <sup>5</sup> Including websites and blogs

Two different approaches can be considered to measure out the benefit/risk of an investment variation on “activable” products...

### Assessment of product sensitivity to promotion

#### Approach n°1

Anticipate expected impact in view of:

Past experience

Benchmarking

Ambitions

Propose best guess evaluation  
(e.g. expected sales and/or market  
share variations)  
+/- pilot test / monitoring method

#### Approach n°2

Evaluation of required impact to:

Cover investment

Maintain sales levels

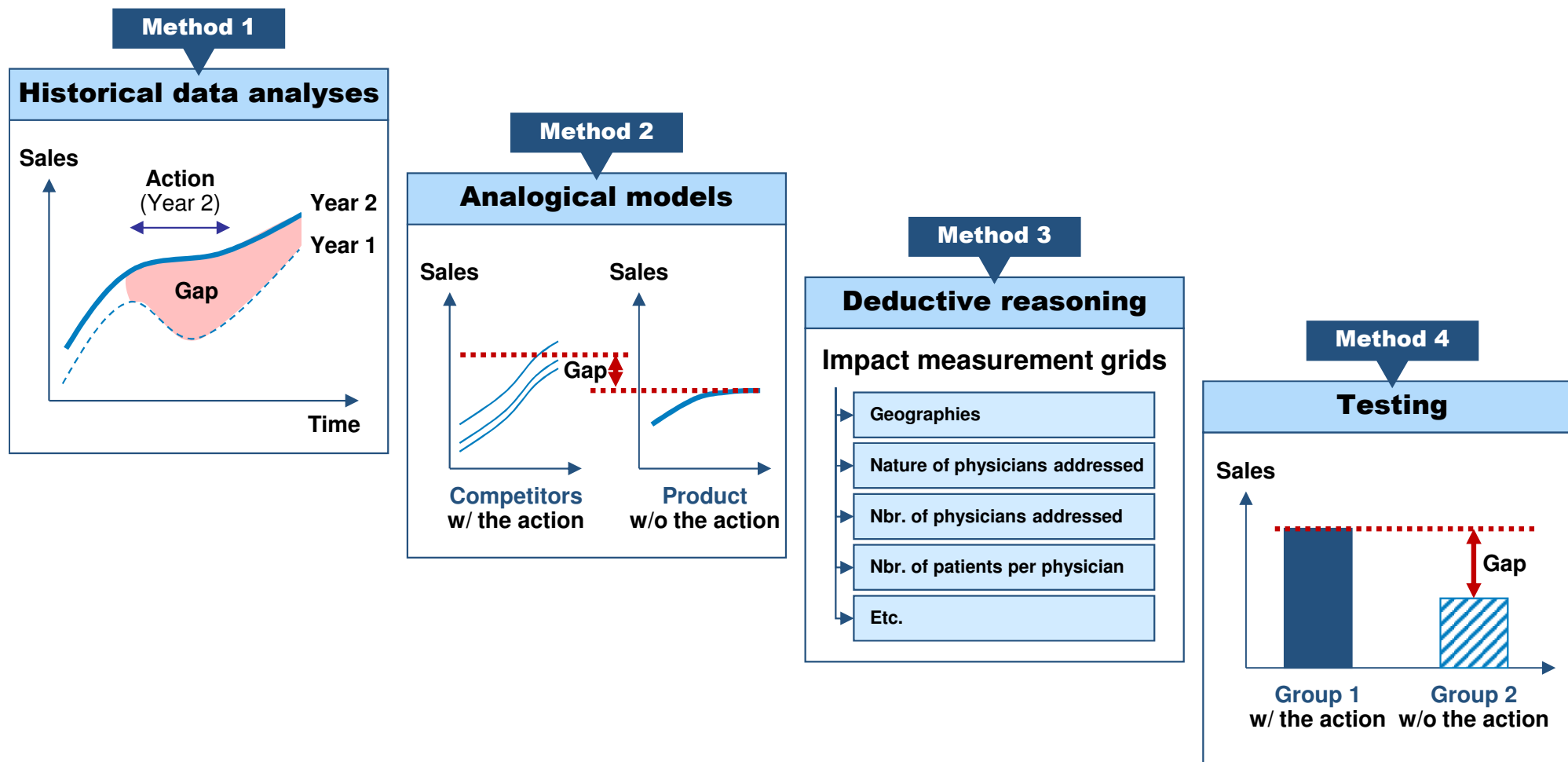
Maintain profit levels / ratio

Determine minimal impact  
(e.g. required sales and/or market  
share variations)  
to break even



... and up to 4 different methods can be used to quantify the impact of promotional investment decisions on products sales and profit trends

## Methods to evaluate the impact of promotional investment decisions



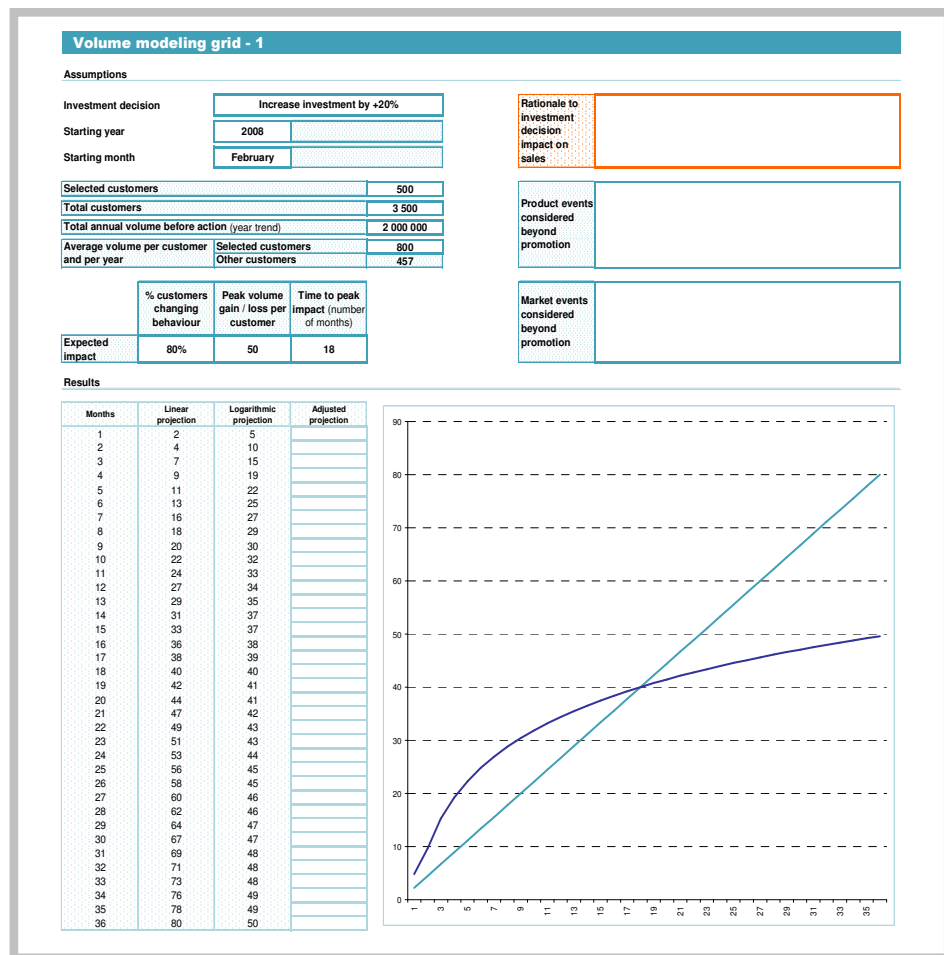
Statistical methods should be considered in view of data availability and the capacity to isolate a specific action from the overall investment

## Statistical methods to measure investment impact

	<b>Vs. control group</b> (geography)	<b>Vs. baseline</b> (time)	<b>Vs. benchmark</b> (experience)
<b>Description</b>	<ul style="list-style-type: none"> <li>Analyses comparing product performance in a group / area with the action and a group / area without the action</li> <li>Product usually compares to itself in both groups / areas, simultaneously</li> </ul>	<ul style="list-style-type: none"> <li>Analyses comparing product overall performance with and without the action (no control group), in a sequential way (Y Vs. Y-1, Q Vs. Q-1)</li> <li>Product usually compares to itself (intrinsic approach) or to competitors (extrinsic approach)</li> </ul>	<ul style="list-style-type: none"> <li>Analyses comparing a product performance with a specific action to another product performance in the absence of this action (investment levels and marketing mixes need to be quite homogeneous, exclusive of this specific action)</li> </ul>
<b>Methods</b>	<ul style="list-style-type: none"> <li>Ad hoc surveys monitoring Rx changes in pre-determined sub-populations</li> <li>Panel-based/P&amp;L analyses comparing areas with and without selected action with standard parameters (e.g. sales, sales growth, market share, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Ad-hoc surveys monitoring Rx before and after the action</li> <li>Panel-based/P&amp;L analyses measuring variations Vs. baseline trends with standard parameters (e.g. sales, sales growth, market share, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Ad hoc surveys monitoring Rx changes of both products</li> <li>Panel-based analyses measuring performance trends of both products with standard parameters (e.g. sales, sales growth, market share, etc.)</li> </ul>
<b>Examples</b>	Measuring the impact of a congress on invitees prescription behaviors	Measuring product sensitivity to sales force variations	Comparing the performance of products with two different promotional mixes
<b>Applications</b>	<ul style="list-style-type: none"> <li>Analyses usually enable to identify an impact (either neutral or positive)...</li> <li>... though without allowing any direct mathematical transposition to product overall sales</li> </ul>	<ul style="list-style-type: none"> <li>Analyses enable to identify an impact (either neutral or positive), on a marginal or general basis (entire investment considered)</li> <li>Direct mathematical transposition to product overall sales usually possible</li> </ul>	<ul style="list-style-type: none"> <li>Analyses enable to say that the performance could have been equal or better with the action</li> <li>The direct mathematical transposition to product overall sales may be possible, though with much caution</li> </ul>

Logical grids objective is to anticipate the likelihood of a breakeven / significant positive impact of an action, through a step by step approach

## Impact evaluation grids

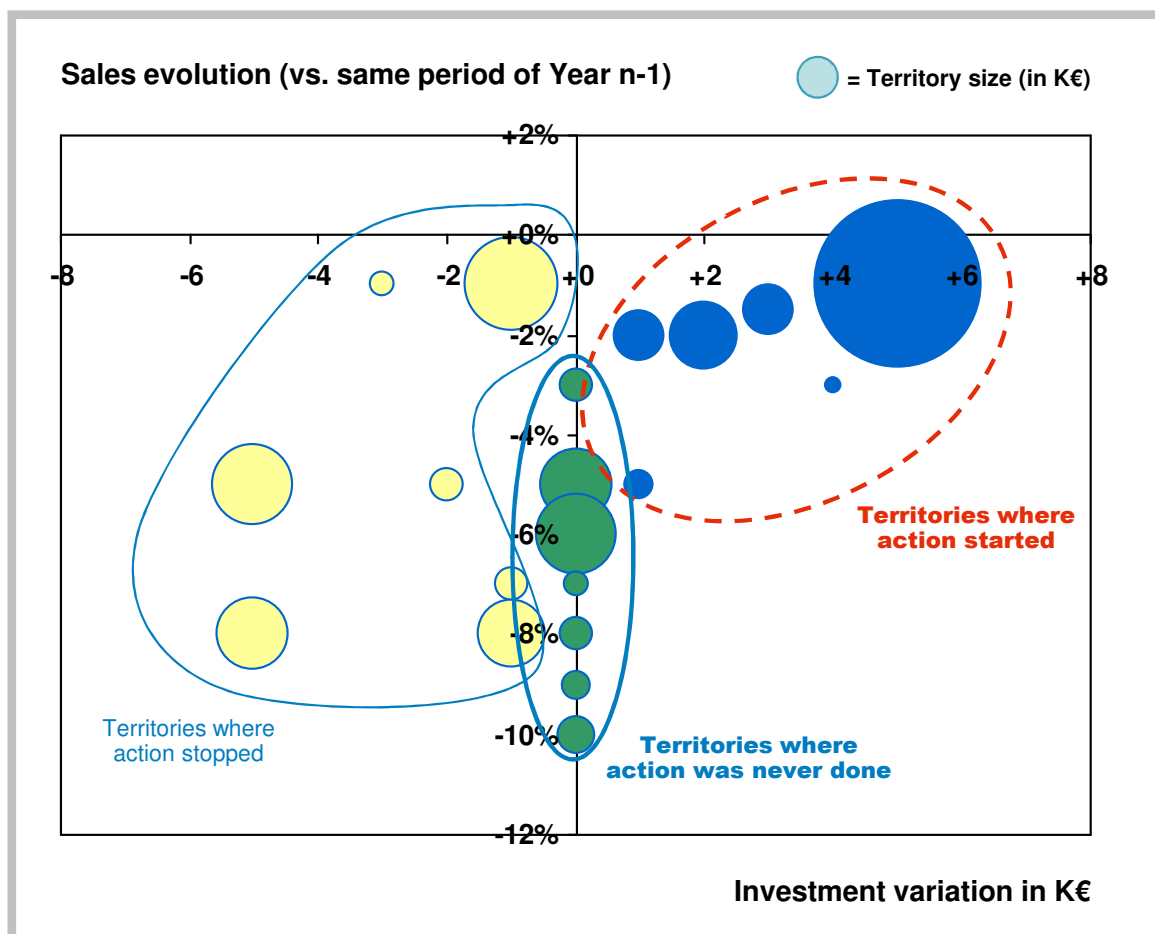


### Comments

- Impact evaluation grids aim at measuring the impact of an action, while going through **logical steps**, e.g.:
  - % of physicians to be accessed with the action
  - % of physicians accepting to participate into the action
  - % of physicians convinced by the action
  - Physicians weight in total product sales before action
  - Performance trends change among physicians changing their behavior (gain either in terms of market share or sales growth)
  - Related sales gain after action at local / national level
  - Action cost
  - Net result
- Most parameters would need to be populated via ad hoc surveys, however, the **beforehand evaluation** of expected impact without those ad hoc surveys can also be an excellent means to properly calibrate an action
- Impact evaluation grids should be used **for major actions only**

Logical reasoning should ideally be complemented with testing, when *a priori* evaluation seems to be favorable, to verify action efficiency

## Testing of the impact of invitations to congresses in selected territories

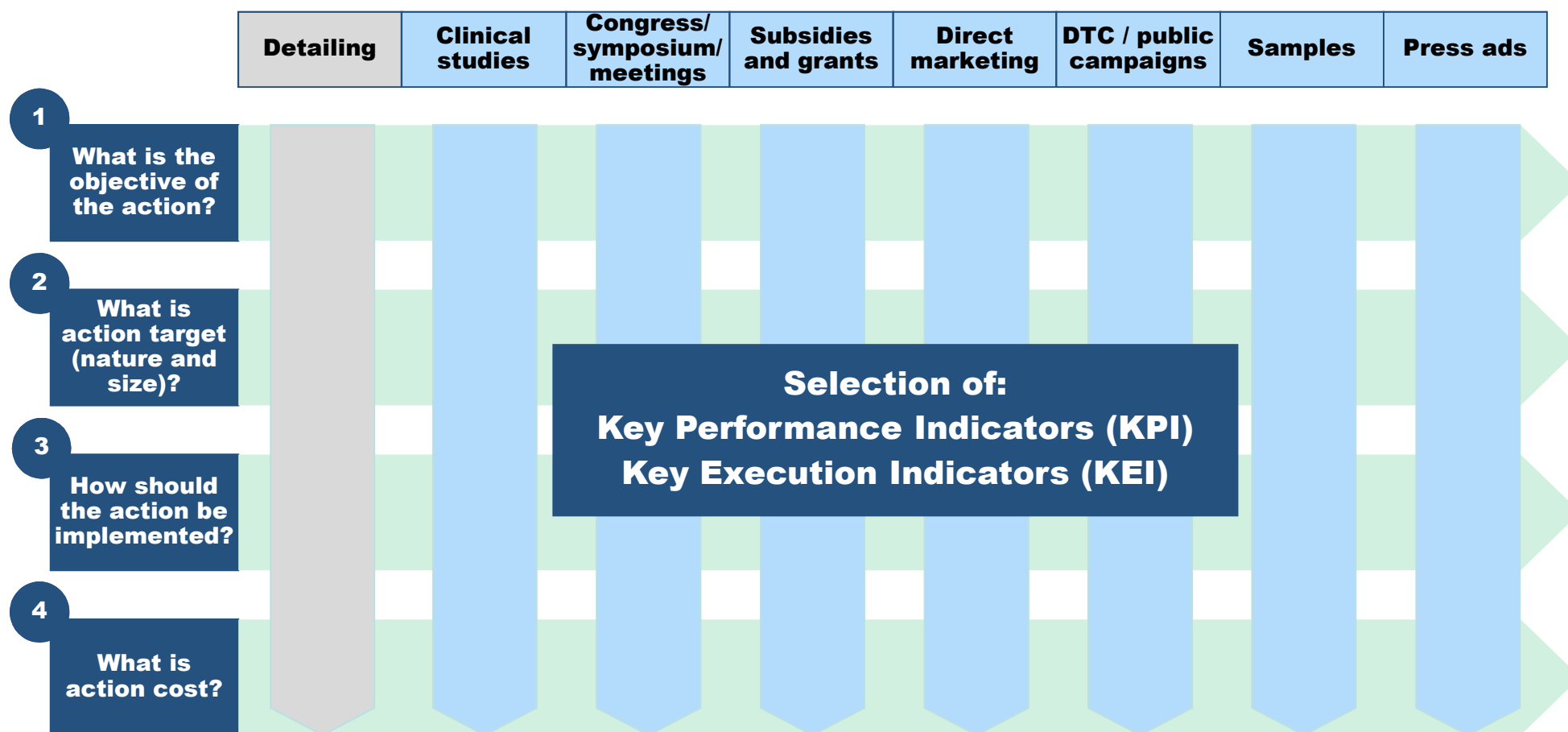


### Comments

- Sales evolution should be measured for a specific period of time
- Period calibration is the most difficult part of the exercise, and should take into account:
  - Action pre-launch (e.g. formal invitation by Reps for a congress)
  - Action own time (e.g. congress date)
  - Action monitoring (e.g. Reps visit to get physicians feedback)
- Action impact is usually measured either instantly or up to 3 months after action initiation, for mature products
- There is no need to measure out systematically the impact of stopping the action; however, if territories are vacant or action did stop for any reason, it might also be interesting to consider them into the analysis

Four questions would need to be answered before implementing any action and monitoring it with KPI<sup>1</sup> and KEI<sup>2</sup>

**Investment implementation – Key questions to be answered before acting**



DTC = Direct to consumer

### General recommendations

- **Mature brands** representing as much as 30% to 50% of certain big pharma total sales and 60% to 70% of their profits, performance optimization should be one of their **strategic priorities**
- The opportunity of **optimization** should **be assessed** brand **by brand** and country **by country** (e.g. *Branded generics competition like in Eastern European countries have a totally different impact on original brands compared with the one observed with unbranded generics like in Western European countries*)
- **Decision to invest** in promotion should be supported by **cost-efficient** market studies and **analyses**, rather than intuitive considerations, as it is too often the case
- **When** mature brands have shown to be **sensitive** to **promotion**, the level of effort should demonstrate an **impact** on performance, **at national level**
- **Targeted physicians** should include **only moderate** and **high prescribers** of the mature brand (*the primary objective being to remind them about the brand and not to convince them. After 15 to 20 years in the market, it is too late to convince non and low prescribers*)
- If HCPs are increasingly embracing **digital technology**, it is **far to be a panacea**
- Pharma **companies**, such as **Pfizer** or **Novartis**, are **structured to tackle** their **mature portfolio strategy head-on**, via **cross-functional lifecycle management teams** or **dedicated business units**

### **Four Key Success Factors**

1. **Mature products** should be **recognized** by the corporate management committee as a **key strategic lever**
2. Mature products **franchises** or **BUs** should **be set-up at national level** (to better address local specificities), while remaining **lean** and **agile**, **capitalizing** as much as possible **on shared support functions** (i.e. finance, manufacturing, supply, regulatory, legal, BD, medical, commercial, etc.)
3. **Collaborators in charge** of managing mature products should: be **experienced**, have **no preconceived idea**, have an **entrepreneurial mindset** and be able to **mobilize** support functions throughout the company
4. Decision-making **processes** should be **fact-based** with a **permanent double valuation** at **global** and **local levels** so that trade-off analysis can be carried-out



Introduction	p. 2	3. Marketing & Sales	p. 129
1. Strategy	p. 6	Brand Preference	p. 130
Corporate Reputation	p. 7	High Impact Interactions (H2I)	p. 144
Patient Centric Strategy	p. 23	Mature Brand Management	p. 172
Market Access	p. 50	4. Management (Bonus 2017)	p. 193
Creativity & Performance	p. 68	Smart vs. Good Managers	p. 194
KOL Partnership Model	p. 86		
MSL Best Practices	p. 111		

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The ambition of this section is to introduce a position paper to be published in 2017 which will demonstrate why good managers should strive to become smart managers

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**Key issues addressed**

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1. **What** are the key management models?

2. What are the managers profiles?

3. **How** to be a smart manager?

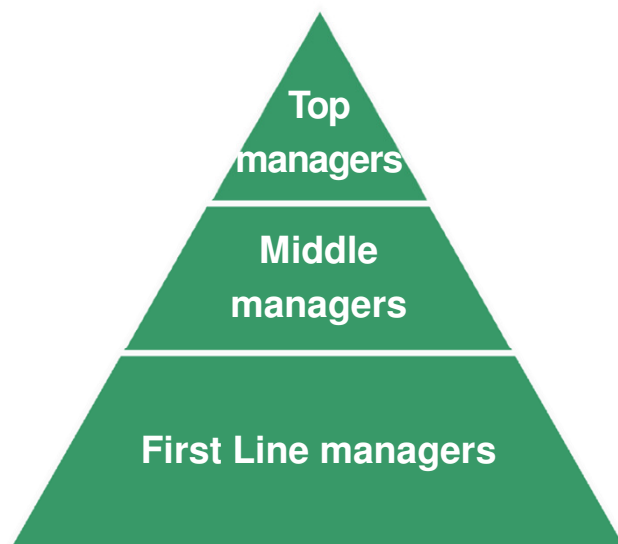
*“Management is the art of getting things done through people”*

– Mary Parker Follet

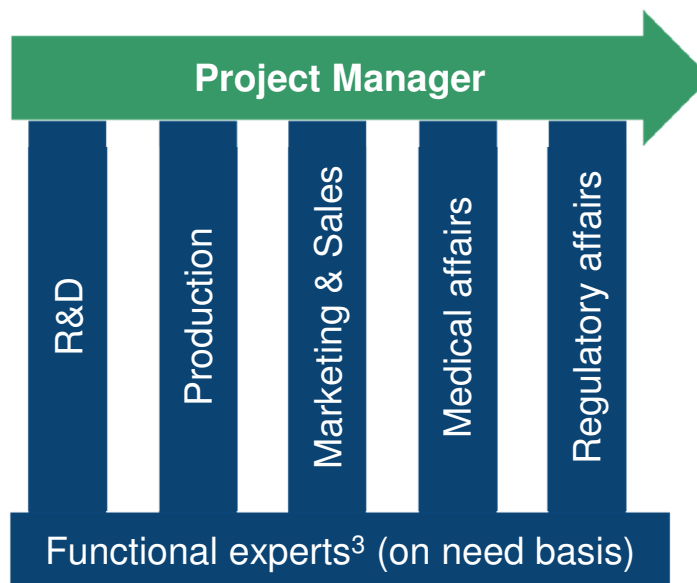
There are, basically three types of management models: the vertical and horizontal models which are conventional and the concentric model which is an innovative one

**Typology**

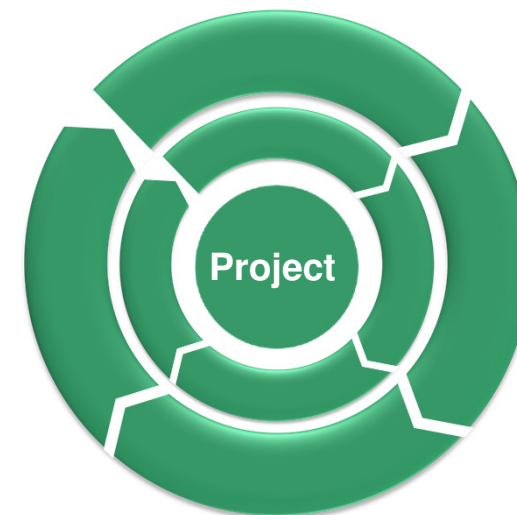
**Vertical Management Model<sup>1</sup>**  
(Hierarchical management)



**Horizontal Management Model<sup>1</sup>**  
(Transversal management)



**Concentric Management Model<sup>2</sup>**  
(Decentralized management)

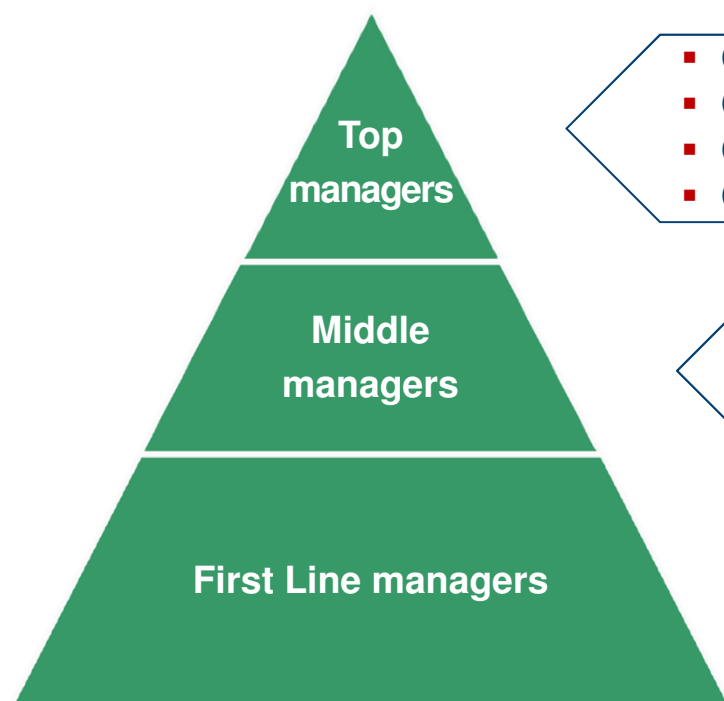


**This “Command & Control” management model is efficient, facilitating decision-making and monitoring, but often too rigid to efficiently adapt to situational changes**

### **Vertical Management Model**

The vertical management model is hierarchical, with managers giving information and orders from the top to the bottom. The chain of command is well-defined and the level of control is in general high

#### **Roles & Responsibilities of Managers**



- Corporate purpose, mission, vision and values determination
- Corporate objectives, strategy (incl. M&A) and budget setting
- Corporate organization design and policy making
- Coordination and control of activities across departments<sup>1</sup>

- Implementation of the corporate strategy and organizational directives
- Crafting of the strategy and corresponding tactics to achieve the objective set for their department, while ensuring an efficient resource allocation
- Management of First Line Managers from their department
- Coordination and control of activities of their department

- Implementation of the strategy and the supportive operational activities, directly or, by managing their subordinates (e.g. medical representatives) within the limits of their budget
- Management, on a daily basis, of their subordinates

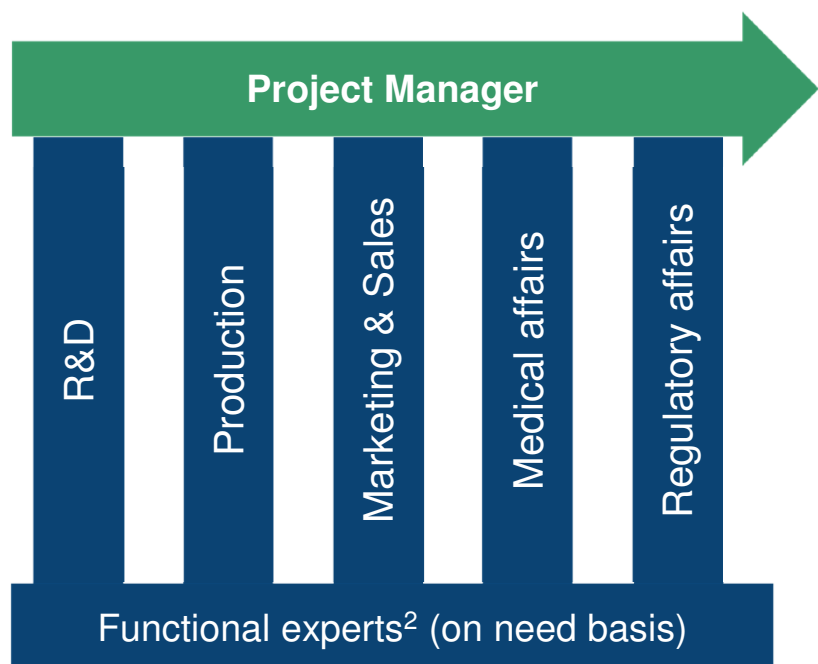
Sources: “Fundamental of Management, Management Myths Debunked”, S. Robbins et al. – Smart Pharma Consulting

<sup>1</sup> R&D, Market Access, Production, Medico-Marketing, Sales, Finance, Human resources, etc.

**Project managers' role is to specify, organize and plan the execution of projects, while creating and sustaining the engagement of team members until their closing**

### Horizontal Management Model

The horizontal management model has a less-defined chain of command and the priority is given to work in teams around projects or specific tasks, lead by project managers or team leaders, respectively



### Roles & Responsibilities of Project Managers

- Project management requires the mobilization of financial and expert resources from different departments<sup>1</sup> on an *ad hoc* basis to achieve a clearly defined objective
- Project Managers, like managers of the Vertical Management Model, must plan, organize, lead and monitor the work of functional experts that have been assigned to the project and take corrective actions, whenever required
- Thus, they animate the project team (definition of roles and responsibilities, consciousness raising, mobilization, communication, delegation, control) to carry the project to its term within the time and budget constraints set
- Functional experts report during the course of the project to the Project Manager whose authority flows horizontally across department boundaries, but they also continue to report to the head of their department whose authority flows downwards (vertically)<sup>2</sup>

Sources: "Fundamental of Management, Management Myths Debunked", S. Robbins et al. – Smart Pharma Consulting

<sup>1</sup> R&D, Market Access, Production, Medico-Marketing, Sales, Finance, Human resources, etc. –

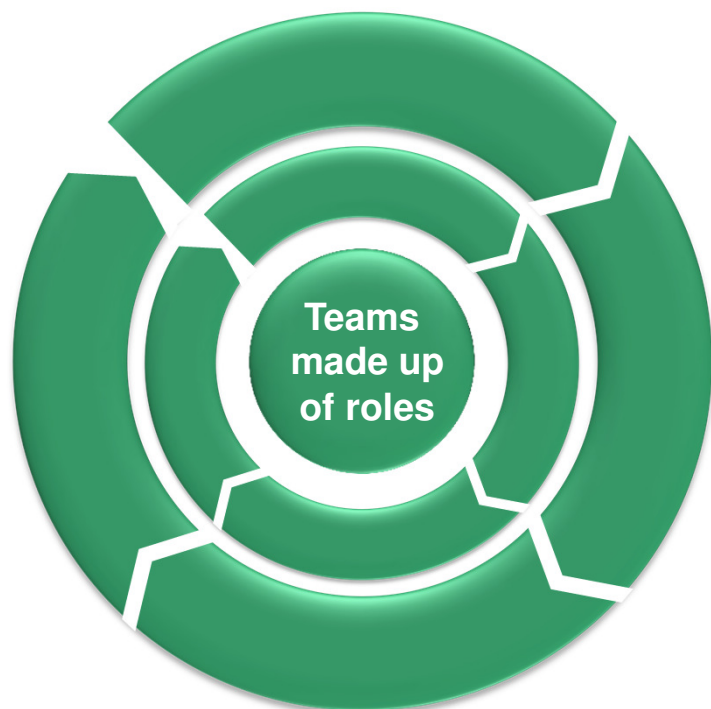
<sup>2</sup> This type of organization is also called matrix organization

**Concentric management model, like holacracy, is an hybrid model ensuring reliability of hierarchical organizations and adaptability of self-managed organizations**

**Concentric Management Model (e.g. Holacracy<sup>1</sup>)**

This is a decentralized model of management which organizes companies around the work that needs to be done instead of people who do it. It makes companies more flexible, more adaptable and more responsive to change

**Roles & Responsibilities**



- A constitution set the rules of the game and redistribute responsibilities
- Holacracy is organized as a series of nested teams (circles) made up of a set of roles, grouped together around specific project team, department, business unit, support function, etc.
- Role definitions are constantly updated and clarified based on the day-to-day needs of the teams
- The people who know the most the work to be done are empowered
- People fill multiple roles, and thus are members of several teams
- Teams have their own governance which is an ongoing process
- Issues are added to the agenda when any team member senses a gap between how things are and how they could be addressed in a consensus manner
- Holacracy creates fast and agile organizations to solve tactical issues

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**The Smart Manager, as we define it, is a Good Manager who knows and understands strategic issues in which its actions and its collaborators actions must be framed**

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**Definitions**

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**Good Managers**

A Good Manager is responsible for planning, organizing, leading and monitoring the work of collaborators, while developing them, and taking corrective actions when necessary, to achieve in the most efficient manner the objective set

**Smart Managers**

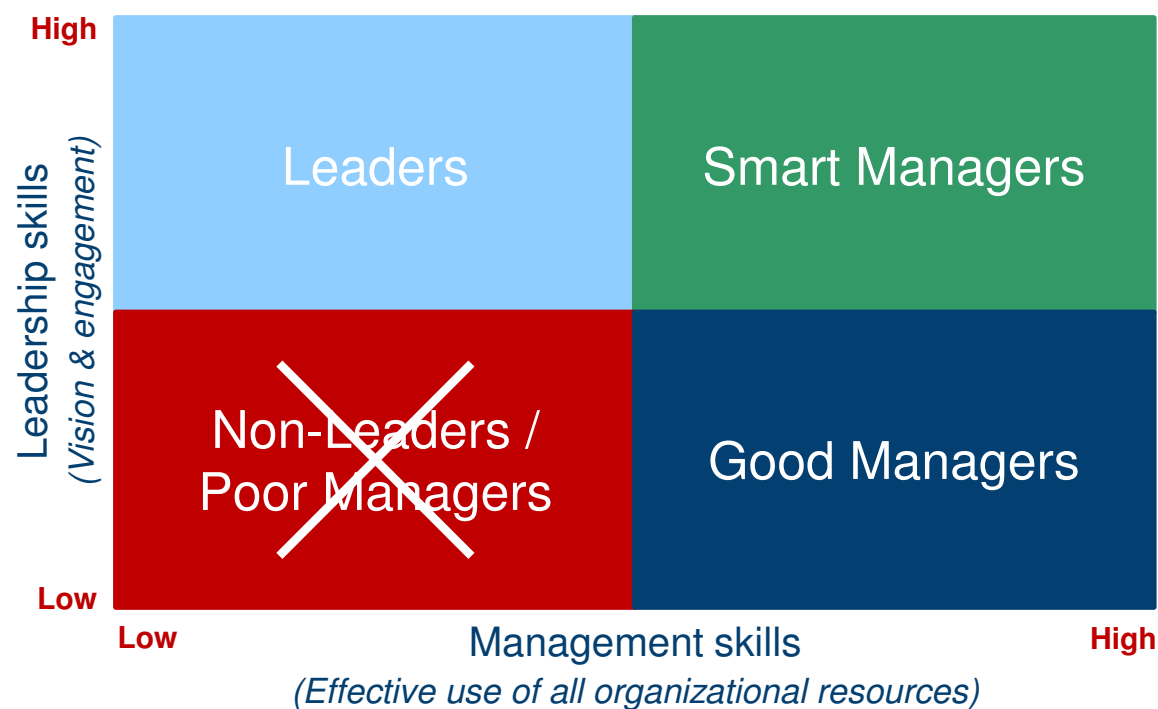
A Smart Manager knows and understands the environment, is able to contribute to and express the purpose, the mission, the vision and the values of the company; to engage his collaborators, give a meaning to their actions and frame them within a clear strategy to achieve the shared objective set



The Smart Manager is a visionary who has the ability to keep his collaborators engaged and motivated while meeting company's objectives in an efficient manner

**Leadership & management skills**

The Manager / Leader matrix



- **Leaders** show the way to their collaborators by creating and communicating a vision through their assertiveness. They excel at inspiring and engaging people so that they will strive willingly to reach organizational goals
- **Good Managers** are able to plan, organize and monitor the work of organization members, using all available organizational resources to reach a given organizational goal
- **Smart Managers** combine the skills and competencies of leaders and of good managers. They are also specifically characterized by the following dimensions:
  - High agility of mind to adjust to external and internal changes
  - Perceptual acuity to anticipate changes
  - Quality of judgment to formulate and select the appropriate solutions
  - Credibility to get decisions accepted by collaborators

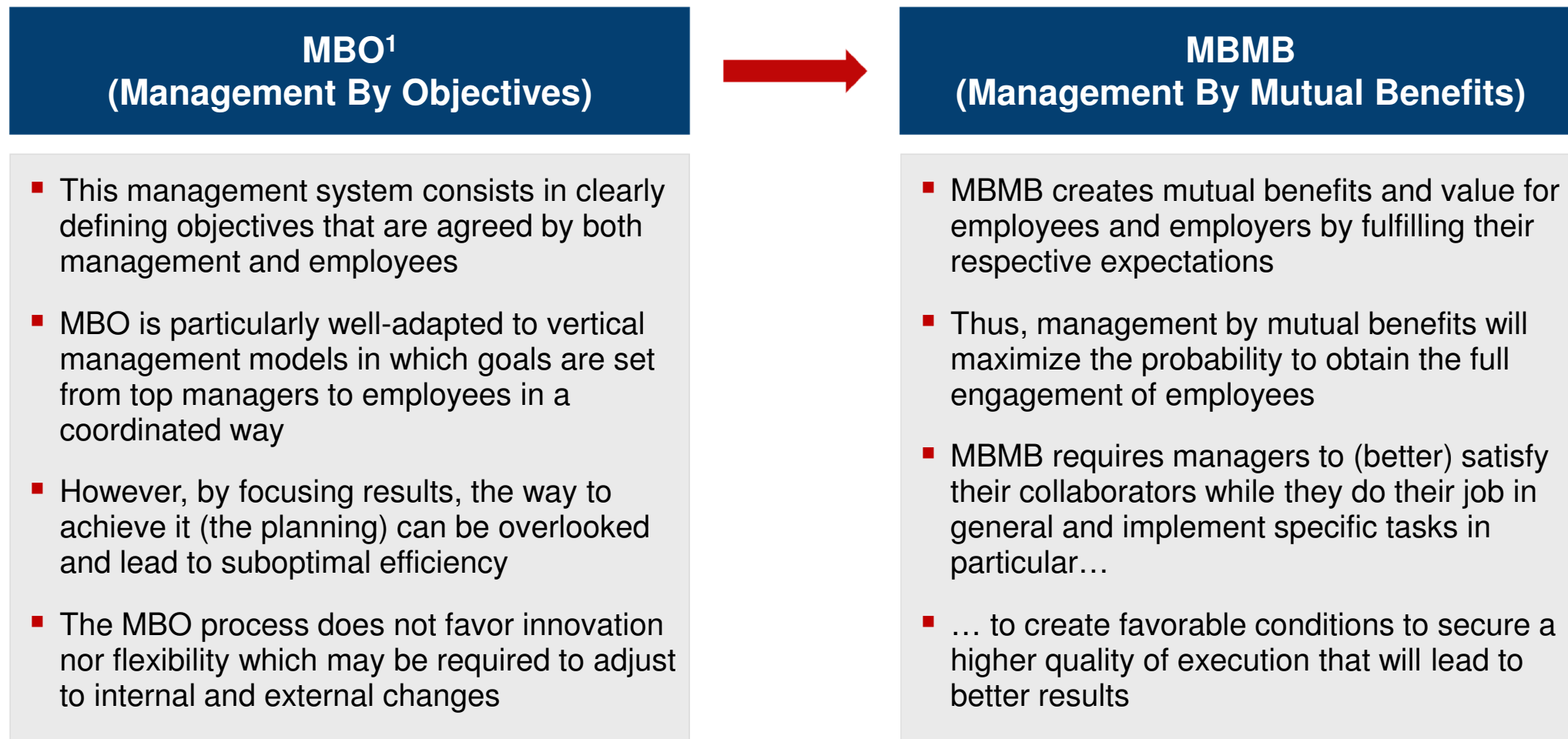
*“Management is about coping with complexity. Leadership is about coping with change” – John P. Kotter*

**Smart Managers will manage by mutual benefits (MBMB) to get – as much as possible – the full and sustainable engagement of their collaborators**

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**Management system**

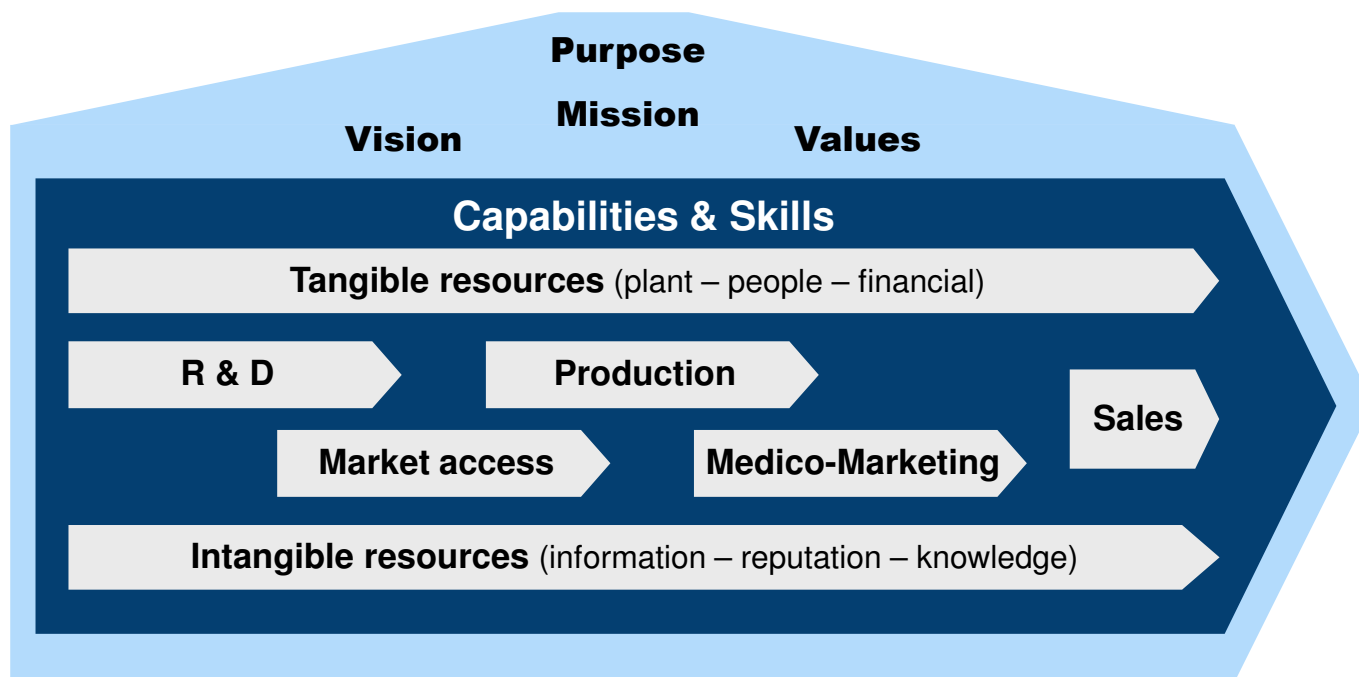
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The Smart Manager participates to the crafting of the market strategy and ensures the resources of the company he works for are efficiently mobilized

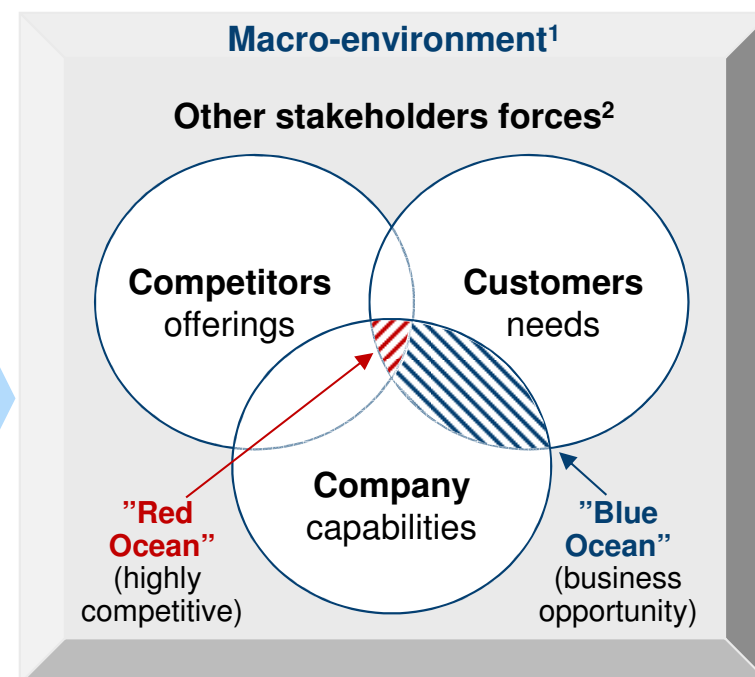
**Contribution to strategy crafting**

**Company's business model**



**Strengths & Weaknesses**  
(Competitive advantage)

**Market strategy**



**Opportunities & Threats**  
(Attractiveness & Key success factors)

**Ambition & Strategic priorities**

Sources: Adapted after C. Kim et R. Mauborgne 2005 - D.J. Collis, HBR April 2008, M. Porter 1985 - Smart Pharma Consulting

<sup>1</sup> Political / legal, economic, socio-demographic and technological factors –  
<sup>2</sup> Including suppliers, new entrants, substitutes, complements

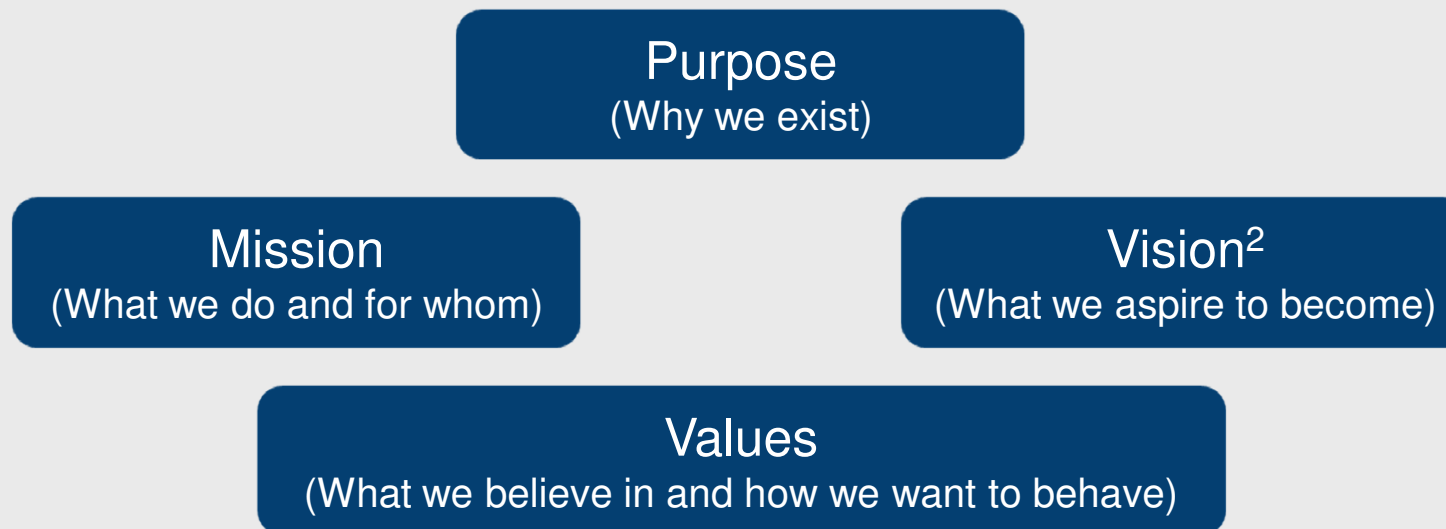
**The Smart Manager should be able to participate to the elaboration of purpose, mission, values, and vision statements and ensure they are understood and applied**

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**Purpose – Mission – Values – Vision**

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- The core company statements (i.e. Purpose – Mission – Vision – Values) are needed to put collaborators in the right mind-set before developing the strategy
- The Smart Manager should be a contributor to their development, translate them at the level of their scope of responsibility<sup>1</sup> and make sure their collaborators understand, share and comply with them in their daily activities



Smart Managers can use the KUDOS<sup>1</sup> formula which has shown to be a useful tool to evaluate, draw priorities and find solutions to boost their Smartness index

### The KUDOS Formula

- Smartness depends on level of knowledge, analytical skills to understand, judgement capabilities to make appropriate decisions and ability to ensure quality of execution
- We have designed the **KUDOS** formula to help Managers and their collaborators become smarter:

**K**nowing x **U**nderstanding x **D**eciding x **O**perationalizing = **S**martness index



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

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

## Core capabilities

### 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 (STAR<sup>1</sup>)**

<sup>1</sup> Sales Techniques Application for Results (training courser)



### 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**