Strategic KOL Engagement Planning...

Concepts Methods & Tools ... For a better Efficacy & Efficiency



Smart Pharma Consulting Position Paper

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1. Introduction

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

Context & Objective -

- KOLs¹ are part of the means used by pharma companies to:
 - Develop their products through pre-clinical and clinical trials
 - Disseminate information (scientific, medical, therapeutic, etc.) to raise health authorities, payers, HCPs (Health Care Professionals), PAGs (Patient Advocacy Groups), individual patients awareness to optimize the positioning and the usage of their products

This position paper:

- Reviews the best practices in terms of KOL engagement
- Proposes a simple but rigorous approach and...
- ... a set of practical tools...
- ... to recruit, engage and manage KOLs

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

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Sources: Smart Pharma Consulting

¹ In this position paper, the definition of KOL is limited to influential physicians

Strategic KOL Engagement Planning for a better Efficacy & Efficiency



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

- Working definitions (1/2) -

KOL (Key Opinion Leader)

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



Sources: Smart Pharma Consulting

¹ Such as members of governments, of health authorities, of learned societies, of patient advocacy groups, journalists, pharmacists, nurses, etc.

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

Working definitions (2/2) -

KOL Engagement

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

Strategic KOL Engagement Planning

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

Sources: Roche internal documents (2015) – Smart Pharma Consulting

¹ People from different departments (e.g. medical, marketing, sales, etc.) can be in regular contact with the same KOL



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

Types of KOL engagement

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





Sources: Arx Research (2017) – Smart Pharma Consulting analyses



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

KOLs engagement & Influencing factors

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





Sources: Arx Research (2017) - Smart Pharma Consulting analyses



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



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KOL Management organization at pharma companies

 Functional and budget responsibility for KOL management are mainly in the hands of Medical Affairs departments Decentralized organizations are used by 40% of companies but recommended by only 3% of them due to lack of coordination and consistency

Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: Abb Vie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses

* One respondent considers there is no ideal system to manage KOLs. It depends on the business needs



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

Main KOLs services & assessment



Mean score: 75

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

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

Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: Abb Vie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses



Evaluation of KOL Management & Engagement

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

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



Note: Behavior & personality has been mentioned by one interviewee, as well as KOLs field of interest *"In case of doubts, Global Medical Affairs may contact local Medical Affairs to get their own opinion regarding a Global KOL"*

Sources: Interviews of 8 Senior Medical executives from Bayer, BMS, Celgene, Gilead, Janssen, MSD, Pfizer, Roche – Smart Pharma Consulting analyses

¹ Therapeutic Area

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



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

Smart Pharma Consulting analyses

Sources: Interviews of 8 Senior Medical executives from Bayer, BMS, Celgene, Gilead, Janssen, MSD, Pfizer, Roche

¹ Several answers possible

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

Global KOL engagement planning & execution follow-up

Global KOL engagement plans



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

Execution quality follow-up

System to monitor the implementation of Global KOL engagements



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

Main difficulties while engaging with Global KOLs

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Poor internal alignment and multiple contact points

Overbooked and overused KOLs

Sources: Interviews of 8 Senior Medical executives from Bayer, BMS, Celgene, Gilead, Janssen, MSD, Pfizer, Roche – Smart Pharma Consulting analyses

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



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Sources: Best Practices, LLC (2014 & 2016) based on 33 companies, amongst which: Abb Vie, Amgen, Bayer, Genentech, Genzyme, Janssen, Merck & Co, Pfizer, Roche – Smart Pharma Consulting analyses

¹ Whenever required by the compliance rules – ² Internal and external sources

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



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

Sources: Smart Pharma Consulting



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



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Sources: Smart Pharma Consulting

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



The global objective of KOL engagements must support

one or several CSFs and thus, contribute to fulfill

the strategic imperatives to reach the Brand Strategic Objective

Sources: Smart Pharma Consulting

¹ Critical Success Factor

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



Global vs. individual objective setting



Define specifically what is expected from each KOL to support the product and what support each KOL expects from the pharma company, on a professional stand point

Sources: Smart Pharma Consulting

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



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

Methodology	
Key questions	What to do?
 What are the relevant selection criteria to be used considering the final objective? 	 Review the relevant criteria (e.g. level of influence, scope of influence, scientific/media awareness, membership of a network, presence in Internet, etc.) Select a limited number of relevant criteria
 What information should be collected? How to collect and analyze this information? 	 Review internal / external databases to qualify KOLs Assess the number of publications, quality of journal, the impact factor, Almetrics¹, quotes, lectures during conferences and congresses, etc.
	-
 What is the scope of influence and the degree of interest of the KOL for the 	 Map a preselection of KOLs on a matrix according to the most relevant criteria
brand and the related disease(s)?	 Identify KOLs networks of collaboration and influence (e.g. cooperative groups)
 Who are the KOLs that should be engaged? For which kind of engagement? 	 Select the KOLs Preliminarily define the types of engagement to carry out with the selected KOLs
	 Key questions What are the relevant selection criteria to be used considering the final objective? What information should be collected? How to collect and analyze this information? What is the scope of influence and the degree of interest of the KOL for the brand and the related disease(s)? Who are the KOLs that should be

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Sources: Smart Pharma Consulting

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



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



Sources: Smart Pharma Consulting

¹ Patient advocacy groups



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

- How to qualify KOLs? (1/2) —

	What data to collect?	How to collect data?	How to analyze data?
	 Education (e.g. university – hospital) Medical activity/position (e.g. specialty, medical department, status in the medical department) Teaching activity/position (e.g. topics taught, professor, lecturer) Field of expertise and interest (e.g. specific disease, pharmacological route, mode of action, medical technique) 	 Internet search, direct search Field research (e.g. peers, hospital pharmacists interviews, etc.) Probing by collaborators from the medical department (e.g. MSLs¹) and collaborators from other departments of the pharma companies (data could be stored and shared on a platform) 	 Being head of hospital and professor is a plus Reputation of the hospital/teaching hospital or of the private institution where the KOL works should be considered Global or International scopes of influence are preferable, in general, to national or local levels (but it depends on the objective)
•	Membership in learned societies (titles / positions / activities) and/or in more or less structured networks	 KOL Management vendors (e.g. Truven; KOL, LLC; OpenQ; Veeva Systems) 	 Being a member of the management board of a learned society is a plus in terms of potential level of influence

Sources: Smart Pharma Consulting

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¹ Medical Science Liaisons



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

- How to qualify KOLs? (2/2) -

What data to collect?	How to collect data?	How to analyze data?
 Communication activities # articles published (impact factor¹, Almetrics², peer-/non peer reviewed journals, principal investigator (PI), etc.) # of training/teaching activities p.a. (CME³) # of lectures (congresses, symposiums, round tables) Presence on the Internet # of quotes by journalists in current year 	 Review of published scientific articles (PubMed/Medline, Google scholar, Expertscape, Cochrane Library) Evaluation of training/teaching activities and lectures by interviewing peers and collaborators of pharma companies Google searching for presence and quotes on the Internet 	 The higher the impact factor is, the better KOLs should be ideally positioned as 1st or last author in articles A high number of training/teaching seminars and lectures is a plus The perceived quality of articles, training, teaching and lectures should be assessed
 Partnership activities Types of activities (e.g. lectures, clinical investigations, advisory boards) With the company and its competitors Potential level of interest (inclination to support the development/the proper use of a brand) 	 Review of past performances with the company or its competitors (e.g. probing by collaborators of the company) Interviews of peers 	 Verbal (e.g. lectures, courses) and written communication (e.g. articles, websites) KOLs should express their field of interest over the long term and their expectations from an engagement with the pharma company

Sources: Smart Pharma Consulting

¹ It measures the average frequency with which the article has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the number of times its articles are quoted-² Collects and collates disparate information on the online activity surrounding scholarly content-³ Continuous medical education



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

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— Scoring of candidate KOLs

Illustrative

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

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

Sources: Niche Science & Technology (2016) – Smart Pharma Consulting analyses

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¹ Average of the marks obtained – 2 [Expertise x Awareness]/2

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



Sources: Smart Pharma Consulting

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

– How to convince KOLs to partner?

What do KOLs want through engagements?

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

What should pharma companies propose to KOLs?

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

Sources: Smart Pharma Consulting

¹ Investigator Initiated Trials-² Especially for Rising Opinion Leaders



Entering KOLs

KOLs entering the reservoir of

Depending on the needs to be

of the KOL, the expected

engagement will be:

fulfilled, the expertise and motives

Either strategic and renewed for

Or tactic and carried out on an

specific activity (e.g. lecture,

ad-hoc basis (transaction) for a

several years (partnership)

objectives

partners should fulfill specific

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

Dynamic management of selected KOLs

Current pool of selected KOLs

- Guidance for new product development
- Data generation (pre-clinical or clinical)
- Creation of credible and persuasive medical content
- Advice regarding product strategy (e.g. positioning)
- Facilitation of patient access to new therapies
 - To manage dynamically and efficiently a pool of KOLs, it is important to stick to certain rules:
 - The objective of the collaboration should be clearly set to avoid any misunderstanding
 - The expected engagement from the KOL and services from the pharma company should be specifically defined
 - The fulfilment of the contractual obligations should be closely monitored and the gaps, if any, filled up by mutual agreement

Leaving KOLs

- KOLs may leave the reservoir of partners on the basis of a:
 - Joint decision (e.g. completion of an ad-hoc agreement)
 - Decision made by the pharma company (e.g. engagement not satisfactorily fulfilled, difficulty to collaborate with the KOL)
 - Decision made by the KOL (e.g. mismanagement of the relationship by the company, lack of interest in the product or the requested activities)

Sources: Smart Pharma Consulting

clinical study)

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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





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Sources: Smart Pharma Consulting

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¹ Access limited to KOLs – ² Each KOL should have a dedicated KOL Manager (e.g. a MSL) – ³ Continuous Medical Education – ⁴ Such as lectures to sales forces, face-to-face meetings with the marketing team, etc. – ⁵ Such as visual aids, leaflets for patients

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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



H: Higher – M: Medium: – L: Lower

Sources: Smart Pharma Consulting

¹ Continuous Medical Education – ² Physicians, pharmacists, nurses, etc.

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

– Potential value of KOL activities (2/2) – 3 KOLs, especially if they are supposed to KOLs may play an effective role during sign or co-sign the corresponding internal meetings by: publication, may be very helpful to: - Informing / training medico-marketing teams Participate to the design of the study about scientific trends and position of Participation **Participation** competitors - Carry out the study (either about a given to internal to scientific pathology only or a pathology & its treatments Being invited as a "guest star" to show meetings studies involving the pharmaceutical company collaborators the ability of the pharma product) company to partner with top medical leaders Playing a role with sales reps (e.g. selling Involvement of KOLs in medical/clinical _ forums) studies will depend on their field of interest Advisory board meetings with KOLs should KOLs may collaborate with the marketing be preferred to individual meetings with team by contributing to the creation of KOLs when the objective is to get advice on: promotional materials - Estimating the impact of key market trends: Advisorv Promo Thus, they can create value by: Scientific innovation board material Suggesting messages New product development review member Developing a scientific rationale to support Evidence generation messages/claims of the products Market access strategy Assessing and editing the content of Marketing strategy (positioning) promotional materials (visual aid, booklet...) - New ideas or concepts

Sources: Smart Pharma Consulting



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

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KOLs challenges – motivators – expectations

Challenges

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

Motivators

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

Expectations from pharma companies

- Fair market value remuneration
- Presence in KOLs field of expertise
- Consistency, communication, support and interaction
- Value-adding interactions with pharma companies collaborators

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- Research assistance
- Credibility and commitment to patient care
- Continuous engagement
- Genuine involvement & meaningful partnerships
- Transparency

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

Sources: Pharma's Guide to Effective KOL Engagement, Phanish Chandra (August 2017) – Smart Pharma Consulting

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

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Top 10 poor pharma companies practices & key learnings

Top 10 poor practices

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



 Ensure a consistent and coordinated communication between the pharma company and the KOLs

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Sources: Study carried out in the UK, Uptake Strategies (January 2014) – Smart Pharma Consulting analyses

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

- KOL engagement plan (1/2) ·



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

Sources: Smart Pharma Consulting

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



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

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Sources: Smart Pharma Consulting

¹ If allowed by national and corporate regulations -² It is recommended to assign one KOL manager who is the preferred point-of-contact for the KOL - ³ Ideally, twice a year - ⁴ Ideally, once a year

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



Sources: Smart Pharma Consulting



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

Structure of a Consolidated KOL engagement plan -

Illustrative





Sources: Smart Pharma Consulting

¹ Key performance indicators – ² Key execution indicators



Illustrative

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

Individual KOL engagement plan - ID Card -

Private hospital -KOL Medical Medical MD - head of medical department -First name – surname Public hospital status professor of medicine, etc. setting name Teaching hospital E.g. therapeutic area, organ, pharmacology, Publications – Lectures – Impact Numerical scale to be Expertise academic and/or clinical research. Awareness Communication skills - Network Index¹ determined scientific advisory boards, etc. **Degree of** Points of E.g. mobility, adherence to deadlines, Low – Moderate – High Ranking Interest vigilance quality of presentation documents, etc. **Primary objectives** of the collaboration **Specific activities** planned within the engagement¹ **Duration of the agreement** Type of agreement Transactional agreement: from: ---/---Annual: to: ---/---/--from: ---/---Partnership agreement: Multi-year: to: ---/---/--

Sources: Smart Pharma Consulting

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¹ 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.

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

— Individual KOL Engagement Plan – KOL Activity Card — Illustrative

Key implementation steps	Timing	Points of caution	Exp	pected output / va of the activity for.	llue
•		•	the KOL herself/himself	the pharma company	3 rd parties
•		•			
•		•	•	•	
•		•			•
•		•			

Feasibility (High – Moderate – Low)	Key Execution Indicators	Key Performance Indicators
Technical	•	These indicators measure the quality of	These indicators measure the impact (autout/value/leareft), of the activity for
Regulatory	•	execution of the activity	(output/value/benefit) of the activity for the different targets (the KOL, the
Financial	•		pharma company and possibly for 3 rd parties, like peers, patients, PAGs)

Sources: Smart Pharma Consulting



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

Individual KOL Engagement Plan – Partnership-based Service Card —— Illustrative

Pharma company services	 Access to scientific information, technical support to publish articles, provision of training/teaching materials, organization of peer meetings, etc. 	Objectives	•	Pharma company contact point	
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Key implementation steps	Timing	Points of caution	Expected o of the sei	utput / value vice for…
•		•	the KOL herself/himself	the pharma company
•		•		
•		•		
•		•	•	•
•		•		

Feasibility (I	High – Moderate – Low)	Key Execution Indicators	Key Performance Indicators		
Technical	•	• These indicators measure the quality of		These indicators measure the impact of the service provided to the KOL	
Regulatory	•	execution of the service provided to the KOL		the service provided to the KOL	
Financial	•				

Sources: Smart Pharma Consulting



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

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

KOLs activities	Key execution indicators (KEIs)	Key performance indicators (KPIs)
 Lecture during symposia or congresses 	Interest (10-point scale)Utility (10-point scale)	 Global level of satisfaction of attendees (10-point scale) Inclination of attendees to support & prescribe
 Training of peers 	 Practicality (10-point scale) Implementation¹ (10-point scale) 	 the product: Number of lectures/trainings/publications Quality/objectivity of messages conveyed to peers, pharmacists, PAGs, etc.
 Article writing 	 Acceptance by recognized journals (scientific, medical, or in lay press, etc.) Post on highly regarded websites 	 Impact factor and Altmetrics² (for scientific / medical journals) Number of broadcasted issues for lay press
 Press conference 	 Number and quality of press conferences conducted 	Number of views / likes on InternetContribution of content to support the product
 Participation in scientific studies 	 Implementation (number of patients recruited, timing, actual costs vs. budget) 	 Publication of an article in a renowned scientific journal Impact of the publication on product reputation

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Sources: Smart Pharma Consulting

¹ Logistics, timing, actual costs vs. budget – ² Collects and collates disparate information on the online activity surrounding scholarly content



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

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

Pharma company services	Key execution indicators (KEIs)	Key performance indicators (KPIs)
 Access to scientific information 	Interact (10 point coole)	 Global level of satisfaction of KOLs (10-point scale)
 Organization of peer meetings with top global / international KOLs 	 Interest (10-point scale) 	 Inclination of KOLs to support the pharma company products:
 Publications support 	 Utility (10-point scale) 	 Number of lectures / trainings / publications
 IIT¹ support 	 Practicality (10-point scale) 	 Quality/objectivity of messages conveyed to peers, pharmacists, patients, etc.
 Slide kits for training / teaching programs 		 Increased level of KOLs awareness and reputation
 Ad hoc support on demand basis 	 Implementation² (10-point scale) 	 Increased level of products awareness and reputation

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Sources: Smart Pharma Consulting

Strategic KOL Engagement Planning for a better Efficacy & Efficiency

May 2019

¹ Investigator Initiated Trails-² Logistics, timing, cost vs. plan

Smart Pharma Consulting

Future trends in KOL Engagement Planning

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

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Sources: Study carried out in the UK, Uptake Strategies (January 2014) – Smart Pharma Consulting analyses

Strategic KOL Engagement Planning for a better Efficacy & Efficiency



Recommendations for a Successful KOL Engagement Planning

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

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

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Sources: Smart Pharma Consulting





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

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- 9. Hospital & Institution Relationships in Regions
- 5. Pharma BD&L

Strategic KOL Engagement Planning

- This position paper proposes an approach and a selection of enabling tools to help pharma companies effectively and efficiently engage with KOLs (Key Opinion Leaders)
- We recommend an approach in four steps:
 - 1. Objective setting 3. KOL engagement
 - 2. KOL selection 4. KOL monitoring

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 - Our teaching and training activities
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- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
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 Best regards

Best regards

Jean-Michel Peny