

# Unleashing the Power of Key Opinion Leaders

a Roadmap to Excellence  
in Precision Diagnostics

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**H**ave you ever wondered why certain biotech companies consistently thrive while others face challenges year after year? Although numerous factors contribute to this phenomenon, a crucial aspect that stands out is their failure to prioritize the early cultivation of key opinion leaders (KOLs) who can advocate for their products or services. Whether you're a venture-backed startup, a mid-stage commercial organization, or even a publicly traded company, it is imperative to undertake fundamental business planning steps that are essential for effectively developing and executing a thoroughly developed KOL strategy, thereby ensuring long-term success.

To establish a solid understanding, let's start by defining the essence of what a KOL is. KOLs are trusted, well-respected influencers with proven experience in a particular field.<sup>1</sup> They are recognized authorities whose expertise and insights hold significant weight among their peers and wider audiences. These individuals are esteemed for their deep knowledge, experience, and ability to shape opinions, making them vital players in driving innovation,

advancements, and decision-making within their respective areas of expertise.

The landscape of identifying and engaging with KOLs has significantly transformed over time. Previously, marketing teams could easily pinpoint influential thought leaders in specific disease states and focus on winning over their support. However, those days are long gone. The traditional methods of simply approaching physicians for lunch meetings or approaching speakers at conferences no longer suffice. The dynamics have evolved.

In today's reality, finding and recruiting KOLs has become considerably more intricate. Numerous emerging barriers and roadblocks, including government regulations that restrict interactions with physicians, have complicated the process. It is no longer as simple as it once was.

Therefore, it is crucial to grasp the changing dynamics and understand that if you haven't already developed a well-crafted KOL strategy, you are already lagging. Your competitors have likely taken proactive steps in this regard. To

remain competitive, it is essential to recognize the urgency and promptly invest efforts in establishing an effective KOL strategy. Delaying this strategic development puts your company at a disadvantage in the fast-paced precision diagnostic marketplace.

The process of identifying KOLs in a specific disease state involves navigating a multitude of complexities. There are several crucial factors to consider. For instance, you need to assess their association with internationally recognized medical centers. Additionally, their research contributions and publications play a significant role in establishing their expertise.

Furthermore, being an invited guest speaker at major conferences to present groundbreaking clinical data adds to their credibility. It's important to note that the influence of a KOL is a culmination of these factors and more.

To ensure a comprehensive selection, it is essential to identify and prioritize your top-50 KOLs in your desired disease state. However, it is worth acknowledging that the process is not without challenges, and not all candidates will make the final cut. Therefore, a diligent and strategic approach is necessary to ensure success. Now, the question arises: how do you embark on this journey of identifying the top-50 KOLs in your desired disease state? Where should you begin this endeavor?

Time becomes critical if you are a startup or mid-stage commercial organization with limited experience and resources, or if you are venturing into this type of activity for the first time. In such cases, it is recommended to explore outsourcing options for all or parts of this process. Management consulting firms specializing in the identification, recruiting, training, and developing KOLs can provide valuable assistance. With their industry expertise and global reach, these firms can help you develop a well-thought-out and

carefully planned KOL strategy that aligns with best practices. Furthermore, they can provide added support in implementing, executing, and managing the strategy to ensure its optimal effectiveness.

To kickstart the process, it is highly recommended that you conduct an internal cross-functional brainstorming session involving your R&D, medical, scientific, and sales teams. This collaborative effort serves as a starting point for identifying the top KOLs in your targeted disease state. During this session, various methods come into play to identify these influential figures. You begin by examining their publications, podium speaker events, and even their presence on social media platforms. It is essential to consider their affiliations and educational backgrounds. However, it's important to emphasize that one of the most significant factors is word-of-mouth recommendations from their peers. In this exercise, involving your scientific and sales teams is crucial, as they can contribute a wealth of valuable insights and ideas. By employing a process like this, you can swiftly identify and prioritize the KOLs you wish to engage with. This allows you to establish a stack rank, streamlining your efforts in reaching out to the most relevant and influential KOLs in your focused disease state.

Moving forward, it is essential to examine the composition of the committees responsible for overseeing a particular disease state. For instance, let's look at cancer. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) encompasses a set of recommendations that cover the spectrum of care, including prevention, diagnosis, and treatment of various malignancies.<sup>2</sup>

If we consider breast cancer, it is highly likely that the guidelines committee responsible for

overseeing this disease state is chaired by one of the country's most influential KOLs, who holds significant sway within the industry. These guidelines committees typically include around twenty-four KOLs with diverse backgrounds, representing different stages of their careers. At this point, your scientific team can aid in performing a PubMed search, which will yield a vast collection of approximately 35-million biomedical literature citations sourced from MEDLINE, life science journals, and online books.<sup>3</sup>

If you begin by examining the individuals on the guidelines committee, you will come across articles where some are lead authors, some as senior authors, and various other authors in between. The relationship these individuals have with their co-authors is a crucial aspect of this process. Once you have compiled your list, it is time to engage in an influencer mapping exercise. This involves identifying connections that go beyond shared publications, considering factors such as institutional affiliations, educational backgrounds, committee membership, and more. The purpose of this exercise is to identify and map these KOLs at a deeper level. This initial phase will prove invaluable when developing KOL target packages for your scientific and commercial teams in the future.

The next step is to initiate contact and establish engagement with these KOLs. It is crucial however to understand that each of these KOLs maintains a very hectic schedule and gaining access to them can be extremely challenging. They are occupied daily with clinical responsibilities, patient consultations, research endeavors, that includes attending both domestic and international conferences. In such instances, outsourcing this aspect of your KOL program to a consultancy with established KOL relationships and expertise can be extremely beneficial. The consultancies

can provide the necessary support and facilitate connections with the desired KOLs, thus simplifying the process for you.

Consultancies can assist you in taking the initial step of identifying and reaching out to these KOLs on your behalf. Another approach is to plan an advisory board meeting during a prominent industry conference. With your guidance, these consultancies can identify the relevant KOLs and commence the recruitment process (it's important to note that this undertaking is neither quick nor inexpensive, so caution is advised). Once the KOLs are identified, non-disclosure agreements and consulting contracts will be negotiated and finalized, while arrangements for the venue, transportation, and accommodations will need to be made. It is important to recognize that this phase alone requires several months of advance planning before any conference, so prudent scheduling is crucial.

An exceptional and innovative alternative is the **Insights on Demand** virtual advisory board, a unique service exclusively provided by The Deerborne Group. This service offers clients immediate access to a scientific advisory board (SAB) comprising internationally recognized scientific experts. Clients have the flexibility to request virtual access to individual SAB members based on their specific needs or book the entire SAB. Whether seeking guidance on new strategies or overcoming difficult challenges, the Insights on Demand virtual advisory service enables clients to quickly connect with hard-to-reach KOLs in a matter of days, not weeks or months. Clients are relieved from the burdens of identifying and recruiting advisory board participants, scheduling venues, and making advanced travel arrangements. The Insights on Demand virtual advisory service ensures unparalleled flexibility, granting clients a more

straightforward and cost-effective means to access the expertise and strategic counsel of these KOLs.

Advisory boards at conferences serve as an excellent starting point to gather valuable qualitative feedback from KOLs in a relatively quick manner. The majority of KOLs tend to attend most major conferences within their field of specialization, providing an opportunity to establish connections. However, it's important to note that this process requires time and a great deal of patience. Engaging with KOLs can involve various interactions such as breakfast meetings, lunches, dinners with your team or their colleagues, or even a casual cup of coffee early before clinic (often spanning months or even years).

As you build ongoing relationships and interactions, it becomes natural to explore their interest in closer collaboration with your company. KOLs are aware of this progression and must consider their time availability and existing commitments, including potential conflicts of interest within their institutions. Some emerging KOLs may be inclined to promote their own personal brand and would find participation on an SAB as an esteemed opportunity. Alternatively, if your company has secured a "pay-to-play" speaking opportunity at an upcoming conference or symposium, you might want to engage one of these KOLs as a speaker. Each KOL will have different motivations for associating with your company, including considerations for remuneration for their time and efforts.

Before delving into the crucial matter of adequately compensating these KOLs for their time and effort, it is essential to provide some background for context. Annually, vast sums of money are allocated towards physicians and their institutions, amounting to billions of dollars in expenditure. According to estimates,

approximately half of all physicians based in the United States receive some form of gifts or payments from pharmaceutical and medical device companies on a year basis.<sup>4</sup>

These gifts vary in scale, ranging from small office items like coffee mugs and pens to even providing complimentary meals for their staff, often known as "lunch & learns." In 2018, the Centers for Medicare and Medicaid Services (CMS) reported payments exceeding \$9.3 billion to physicians and their institutions. It's worth noting that this figure does not include funding for research on new drugs, as industry research funding is typically reported separately.<sup>5</sup>

The substantial amount of money, some of which was being excessively spent on physicians in an inappropriate manner, did not go unnoticed. Eventually, several organizations took notice, including the American Medical Association (AMA) on Ethical and Judicial Affairs, which issued an opinion regarding the gifts received by physicians from the industry. Subsequently, the Pharmaceutical Research Manufacturers of America (PhRMA) proactively adopted a voluntary ethical code to regulate the nature of gifts given to physicians. This meant that items such as pens and novelty gadgets could no longer be distributed to physicians and their staff, not even on the exhibit floor at conferences. However, it's important to clarify that while voluntary programs exist, there are no actual laws governing the gifts that pharmaceutical companies and medical devices can offer to physicians.<sup>6</sup>

As an outcome of the Affordable Care Act in 2010, the Physician Payment Sunshine Act (PPSA) was implemented. Commonly known as Open Payments, the Sunshine Act establishes a nationwide disclosure program aimed at fostering a healthcare system that is transparent and accountable. Under this act, drug and medical device manufacturers

are obligated to annually report all payments made to physicians, as well as the monetary value of any gifts provided. The reported payments are stored in a publicly accessible database hosted on the Open Payments website. CMS is responsible for making this information available to the public through the Open Payments Program.<sup>7</sup>

Within this program, drug and device manufacturers are required to monitor and record expenses associated with transfer of value exceeding \$100, which may include extravagant dinners, retreats, and similar events. It's crucial to note that this program is not an option; it is a federally mandated initiative. As these interactions can occur across different departments within a company, such as research and development (R&D), medical, scientific, or sales, various Customer Relationship Management (CRM) and expense management systems are available to assist in consolidating and managing these records. Utilizing such systems ensures that your company remains compliant and operates with transparency and integrity.

When it comes to compensating KOLs for their time and effort, it can become a challenging task given the oversight. Despite the absence of a consensus, there are fair market value (FMV) studies available that offer some guidance on determining appropriate compensation for KOLs. These studies consider factors such as your company's internal tier designation, the KOLs specialty, geographical location, and more. Numerous consultancies specialize in keeping you updated and compliant in this area. Research published by Cutting Edge Information indicates that rates in the United States have historically ranged from \$210 to \$237 per hour (with potential for significantly higher rates based on tier classification). It is important to note that different regions have

their own policies and practices, necessitating awareness and compliance in those respective areas as well.

In France, there is a public database called "Transparency in Healthcare" that imposes requirements on pharmaceutical and medical device manufacturers. They are obligated to disclose the value of gifts, contractual agreements, and remunerations offered to healthcare professionals.<sup>8</sup>

It is imperative however to emphasize the importance of seeking external guidance to navigate these regulations effectively and prevent any unintended compliance issues.

Having covered the aspects of identifying and recruiting KOLs and understanding the rules and regulations concerning their compensation, let's now shift our focus to the subsequent steps once you have successfully onboarded your KOLs. What comes next in the process?

Most KOLs are driven by their own agendas rather than purely altruistic motives, as mentioned earlier. It is likely that they have specific goals, such as publishing their research or securing funding. However, there are usually areas of shared interest that can be capitalized upon. For instance, if you are planning a trial, it is worth exploring whether the KOL, along with other KOLs from their institution, would be interested in participating. Collaborating with these KOLs can facilitate the development of the trial protocol, although managing the politics of multiple potential principal investigators may be necessary. Nonetheless, even the involvement of their institution as a contributing site can be beneficial.

Successfully navigating an institution's internal review board (IRB) can be a challenging task. While your KOLs can assist in facilitating the process, it's important to note that they most

likely will not take responsibility for driving it forward. Ultimately, it falls upon you and your team to take the lead. One approach to expediting the trial process is to utilize an external institutional review board (IRB) that is accepted by the KOLs institution. These external organizations claim to reduce review times by up to 50%.<sup>9</sup> Assuming the trial receives approval, it is crucial to ensure ongoing compliance and proper registration. At this point, it becomes the responsibility of your KOLs to enroll patients, complete case report forms (CRFs), and carry out related tasks. It is worth emphasizing that if you lack experience in conducting trials, it is highly advisable to outsource this to a consultancy that specializes in clinical trial management. Alternatively, you should consider hiring an experienced clinical trial coordinator to oversee these activities within your organization.

If the opportunity arises, it is highly recommended to present a “trials in progress” poster at a major conference. Your KOLs will be enthusiastic about assisting in making this happen and may even present the data during the poster sessions. Furthermore, it warranted, your KOLs can collaborate with your organization to write and publish a paper in a peer-reviewed publication. The next exciting milestone is the opportunity to present your final data on the podium at a prominent conference, and you KOLs will gladly take on this responsibility. It is truly fulfilling to be in the audience when your KOL is introduced and invited on stage. They will introduce the topic, disclose their involvement as paid participants in the trial and present their presentation of the data by your company. This transparent process is well understood by everyone involved. By this point, you have likely invested over three years into the relationship, and if you have nurtured it appropriately, you can anticipate many more fruitful years to come.

Developing and executing a comprehensive and forward-thinking KOL strategy demands a profound comprehension of the subject matter, robust processes, specialize expertise, and the ability to connect with these esteemed technical and scientific professionals. The entire process can present a significant challenge for any organization lacking the necessary background, expertise, and established networks to successfully develop and implement such a strategic approach. Through dedicated adherence to this roadmap, you will be able to create and execute an insightful and thoroughly vetted KOL development strategy. This will enable you to gain a competitive advantage, thus ensuring a promising and enduring future for you and your company in the years to come.

## About The Deerborne Group

The Deerborne Group is a strategy consulting firm that focuses exclusively on the global genomics and precision diagnostics marketplace. The group's primary focus is advising corporations, venture capital, and private equity firms on commercial, operations, and corporate strategies, helping them to identify opportunities, minimize risks, and overcome management challenges. Readers are encouraged to share this paper among their friends and colleagues. For further information, visit **The Deerborne Group**, or follow us on **LinkedIn**, **Facebook**, **Twitter**, or Instagram.

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