KOL Tiering in the US Pharmaceutical Industry: Definition, Criteria, and Best Practices

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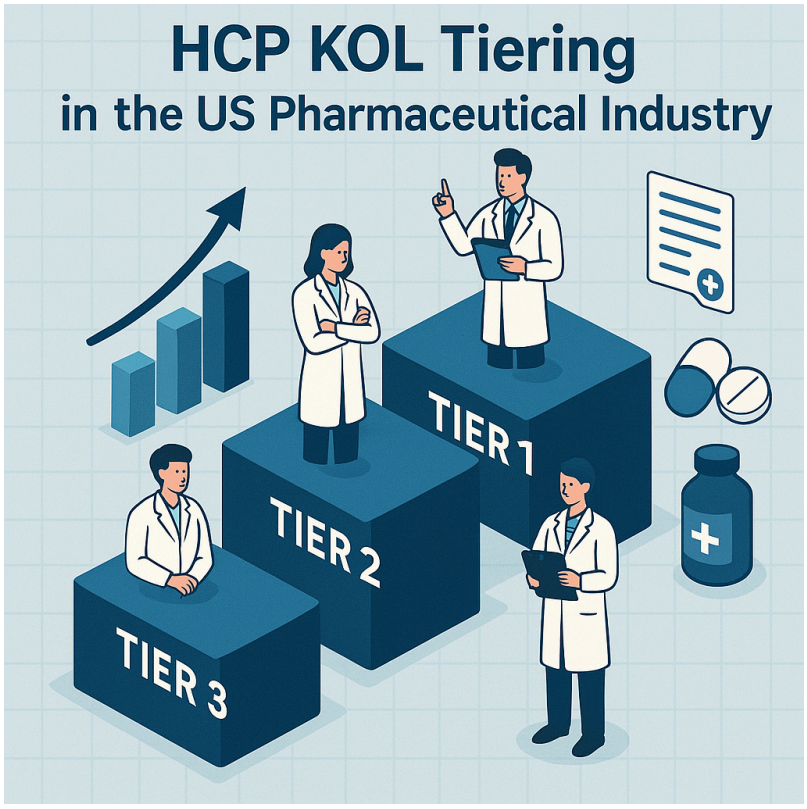

KOL Tiering in the US Pharmaceutical Industry: Definition, Criteria, and Best Practices

Pharmaceutical companies in the United States heavily rely on **Key Opinion Leaders (KOLs)** – influential physicians and scientists – to inform and support their medical and commercial strategies. Given the vast number of experts in any therapeutic area, organizations use **KOL tiering** to prioritize who to engage and how to allocate resources. In simple terms, KOL tiering means categorizing these thought leaders into different levels (Tier 1, Tier 2, Tier 3, etc.) based on their influence and relevance. This in-depth article explains what KOL tiering is, why it's strategically important, how tiers are determined, and how engagement strategies differ by tier. It also provides real-world examples (in oncology and rare diseases), a sample tiering framework table, insights into technology platforms for KOL management, and best practices including U.S.-specific compliance considerations.

What Is KOL Tiering and Why It Matters

KOL Tiering is the practice of ranking or segmenting key opinion leaders into discrete levels of importance or influence. Typically, companies group KOLs into three tiers (Tier 1, Tier 2, Tier 3) – though some may use more nuanced categorization – with Tier 1 being the highest priority or most influential group (about:blank). The majority of pharmaceutical manufacturers favor a three-tier system for segmenting thought leaders (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...), reflecting a common industry approach to manage KOL relationships in a structured way. In essence, KOL tiering helps answer *"Who are our most important experts?"* and *"How should we engage each group differently?"*.

Strategic importance: Implementing a clear tiering strategy allows pharma teams to focus their efforts and resources where it counts most. Top-tier KOLs have broad influence on medical practice and policy, so engaging them can shape treatment guidelines, product perception, and adoption on a large scale. Lower-tier (but still important) KOLs often drive "grassroots" influence at the local level, impacting day-to-day prescribing and peer discussions. By segmenting KOLs, companies ensure that **global thought leaders** receive high-touch engagement for big-picture strategy, while **regional and local influencers** get appropriately tailored support for community-level impact (about:blank). This alignment of engagement with KOLs' level of influence leads to more efficient and effective medical affairs and marketing activities (about:blank) (about:blank). In fact, a data-driven tiering approach is seen as essential for successful product launches and

ongoing education efforts, enabling teams to identify "the right experts to help achieve the team's goals" (about:blank).

Another reason KOL tiering is critical is **resource optimization**. Pharma companies have limited time and budget for KOL engagements (advisory boards, speaker events, one-on-one visits, etc.), so they must prioritize. For example, one survey noted that companies place especially high expectations on their Tier 1 KOLs and correspondingly devote significant engagement to them (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...). Without tiering, there's a risk of spreading efforts too thin or focusing on the wrong individuals. An organized tiering system brings clarity – **Tier 1 KOLs** are typically involved in key strategic decisions and major events, **Tier 2 KOLs** might be engaged for regional initiatives and periodic consultation, and **Tier 3 KOLs** are usually kept on the radar for local influence or future potential. This doesn't mean Tier 3 are unimportant – rather, their impact is more localized, and they can be cultivated over time. Ultimately, KOL tiering aligns the level of engagement (and investment) to each KOL's ability to impact the success of a drug or therapeutic area.

Typical Criteria for KOL Tiering

Pharmaceutical teams use a mix of **quantitative and qualitative criteria** to evaluate a KOL's influence. Tiering criteria are designed to measure a KOL's scientific contribution, reach among peers, clinical practice impact, and other relevant factors. Each company may have its own scoring system, but common **KOL tiering criteria** include (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL Tiering: Enhancing Targeted Outreach in Healthcare):

- **Scientific Contribution & Leadership:** Perhaps the most important factor is a KOL's academic and research impact (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). This includes the number and quality of **peer-reviewed publications** (especially in top journals), involvement in **clinical trials** (e.g. serving as a principal investigator in pivotal studies), contributions to **clinical practice guidelines or consensus statements**, and recognition by peers (such as awards or leadership positions in medical societies). A KOL who has authored landmark trial results or helped write national treatment guidelines wields significant influence and would likely be tiered higher (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). For example, a rare disease KOL who has published extensively and led patient registries would score high on scientific contribution (KOL mapping: Rare disease stakeholder engagement - Putnam).

- **Level of Influence (Sphere of Influence):** KOLs can be **international, national, regional, or local** in their reach. Companies assess whether a physician's influence extends globally or is more confined to a specific geography or institution (about:blank). **Global/National KOLs** (often Tier 1) are those who shape opinions across countries or an entire nation – they speak at international congresses, have widely cited research, and are known by specialists worldwide (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Regional KOLs** (Tier 2) might be highly respected within a country or region, leading local conferences or guidelines (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Local Thought Leaders** (Tier 3) may not publish much research, but they are the "go-to" experts in their community or institution whom other physicians turn to for advice (about:blank) (about:blank). The sphere of influence is a key qualitative measure – for instance, an institutionally influential physician who mentors others and shapes local practice might be considered a KOL even without global fame (about:blank).

- **Clinical Practice Impact (Prescribing Behavior & Patient Reach):** Especially in commercially driven analyses, companies look at how a KOL's own practice reflects influence. This can involve **prescribing behavior or patient volume** – e.g. is the physician a high prescriber of relevant therapies, indicating they treat a large number of patients in the disease area? A doctor who sees a high volume of patients or runs a renowned clinic can be an opinion leader through sheer clinical experience. However, volume alone doesn't make a KOL – it must be coupled with peer influence. As one guide notes, a practitioner with high prescription volume but low scientific contribution might be a "high-volume practitioner but not a thought leader" (about:blank). Thus, companies balance this factor: in a *crowded primary care field (e.g. diabetes)*, patient volume and community peer referrals might carry more weight, whereas in a *specialized rare disease*, volume is less important than research expertise (about:blank).

- **Geographic Relevance:** In the U.S., **geography matters** for practical reasons. A KOL's location can be crucial if a company is launching a product in specific regions or needs local advocates. Pharmaceutical field teams often map KOLs to **key markets or healthcare regions**, ensuring each important area has influential voices. For example, if a company needs to educate clinicians in the Northeast U.S., a highly influential doctor in Boston might be tiered higher for that region than an equally qualified doctor based elsewhere. Geographic relevance is often tied into the **tiering strategy** by labeling KOLs as global, national, or regional/local leaders (about:blank). Ensuring coverage across geographies is especially important for diseases that have regional centers of excellence.

- **Professional Authority & Peer Network:** This criterion looks at a KOL's roles and recognition among professional peers. It includes positions like **academic appointments** (e.g. professor at a top university), leadership roles in **professional societies or associations**, membership on **editorial boards of journals**, and invitations to serve on **regulatory or guideline committees**. These indicators show that the expert is respected and listened to by others. For instance, being the chair of an oncology department or the president of a specialty society confers influence beyond one's own practice. KOL mapping often combines such qualitative reputation indicators with quantitative metrics (about:blank). A local physician without titles might rank lower than one who heads a society committee – unless that local doctor has an exceptional informal following.

- **Digital Presence and Outreach:** In today's world, a KOL's **digital footprint** can greatly extend their influence (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). Many leading experts share insights on Twitter, LinkedIn, medical forums, or via blogs and podcasts. Companies assess the KOL's **social media reach** (number of followers, engagement levels) and contributions to **online medical education** (webinars, virtual panels) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). A KOL with tens of thousands of followers who actively discusses new research online can shape opinions far beyond their physical location – these individuals are sometimes called *Digital Opinion Leaders (DOLs)*. For example, a cardiologist who hosts a popular podcast on heart disease or is frequently cited on Twitter for commentary at conferences could be tiered higher due to digital influence. **Mentions in digital media**, participation in online Q&As, and general e-reputation are increasingly factored into tiering decisions (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare).

- **Collaborative History and Industry Engagement:** While not a pure indicator of influence, pharma companies may also consider a KOL's past interactions with industry. KOLs who have served on advisory boards, given paid talks, or consulted on research for pharmaceutical companies have a **collaboration history** that might make future engagement easier (or, if overdone, could raise conflict considerations). A track record of **positive collaboration** might bump a KOL into a higher tier as a known quantity. On the other hand, companies must ensure they include **emerging experts** ("rising stars") who haven't worked with industry before but have growing influence. Some firms formally score KOLs on openness or interest in collaboration (often gauged qualitatively via Medical Science Liaisons' feedback). In any case, having objective criteria – like those above – is crucial to keep tiering fair. An example framework from a consulting project in rare disease used a **matrix of metrics** (publications, trials, registry leadership, society roles, key conference presentations, social media influence, and even data on research/speaking payments) to score and tier KOLs (KOL mapping: Rare disease stakeholder engagement - Putnam).

> **Note:** KOL tiering criteria can vary by company and therapeutic area. Some organizations use strict point-based algorithms (e.g. assigning weights to publications vs. presentations vs. prescriptions), while others allow qualitative judgment by medical affairs leaders (KOL Mapping Done Right - Climedo) (KOL Mapping Done Right - Climedo). Best practice is to define clear criteria upfront – for example, requiring a minimum number of publications or trials for someone to be considered a "KOL" in the first place (KOL Mapping Done Right - Climedo). This reduces subjectivity and ensures that tier assignments are grounded in evidence of influence. It's also important to update these criteria over time and re-assess KOLs annually or as new data emerges, because influence is dynamic (new experts rise, others retire or become less active) (about:blank).

Segmenting KOLs into Tiers (Tier 1, 2, 3) and Engagement Strategies

After evaluating KOLs on criteria like those above, pharma teams **segment the KOL list into tiers**. While the exact definitions can differ, a typical breakdown is:

- **Tier 1 KOLs:** The top-tier thought leaders – usually a select few (often a few dozen or less per therapeutic area in a country). These are the *elite influencers* who are nationally or internationally renowned in the field (about:blank). They often have prolific scientific output and hold positions that shape the direction of the specialty (e.g. guideline authors, heads of research committees, famous clinicians at leading institutions) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Tier 1 KOLs are the key strategic partners** for a pharma company. They are engaged in deep scientific dialogue, advisory boards, early product strategy, and are kept closely involved throughout a product's life cycle (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs). Because of their influence, Tier 1 KOLs lend credibility and can essentially champion a new therapy among the wider medical community.

- **Tier 2 KOLs:** The mid-tier influencers – a broader group (perhaps dozens to a hundred individuals) who have significant influence, typically at a national or regional level, but not quite the top handful. These could include respected **regional experts** (e.g. a well-known specialist in a particular state or cluster of states, or a prolific clinical trialist who isn't a household name beyond their network). They might be prominent at **major hospitals or regional health systems**, lead local chapters of medical associations, or be rising stars in academia. Tier 2 KOLs often have moderate publication records and some involvement in multicenter trials or speaking forums (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). Pharma companies view Tier 2 KOLs as important **amplifiers and validators** – they can spread new information within their networks and often engage in two-way dialogue with Tier 1 KOLs. Engagement with Tier 2 tends to be focused on regional advisory meetings, speaker programs, and continued medical education events. They may be invited to national meetings as attendees or panelists, but not necessarily as keynote speakers (that's typically Tier 1 territory).

- **Tier 3 KOLs:** The third tier – usually the largest group (could be hundreds) – encompasses **local thought leaders and emerging influencers**. These are physicians who are influential in their **community or institution** but have limited wider recognition (about:blank) (about:blank). For example, a community oncologist who is the go-to person for difficult cases in a mid-sized city, or a young specialist who is very active on social media and starting to publish research. Tier 3 KOLs might not meet all the strict criteria of higher tiers (they may have few publications or not be on guideline panels), but they have frontline knowledge and the **ear of local peers**. They are often the "bridge" to the broader physician population – what they say in local forums or staff meetings can influence colleagues. Pharma companies consider Tier 3 KOLs as either **niche experts** (perhaps in a very specific subtopic) or **future KOLs** to cultivate. Engagement here is usually via Medical Science Liaisons (MSLs) making individual visits, inviting them to local roundtables, or including them in speaker training so they can present data to community physicians. Tier 3 KOLs might have limited industry exposure so far, but they hold *potential for future collaboration* as their careers progress (KOL Tiering: Enhancing Targeted Outreach in Healthcare).

It's worth noting that **tier definitions are not set in stone** – some companies might label only two tiers (e.g. "national KOLs" vs "regional KOLs"), or even four tiers if needed. The underlying concept is to stratify according to influence and **prioritize engagement intensity accordingly** (about:blank). Many organizations use a scoring system that results in a rank-ordered list of KOLs which they then break into approximately three groups (high, medium, low) – aligning with Tier 1/2/3 terminology. One industry survey found that a three-tier segmentation was the

predominant approach among drug manufacturers for thought leader management (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...).

How tiers guide engagement strategy: Once KOLs are tiered, pharma teams design different engagement plans for each tier. For example, **Medical Affairs leadership will devote more time to Tier 1 KOLs** – these top experts might be met by the **Head of Medical or Chief Medical Officer** periodically, involved in early advisory boards (even during pre-clinical or Phase 1 stages), and enlisted as principal investigators for clinical trials or as lead authors on important publications. A ZS Associates white paper emphasizes that Tier 1 KOLs should be **prioritized across the product life cycle, regardless of the type of asset** – meaning from pre-launch through launch and post-launch, these KOLs stay closely engaged (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs). For instance, when preparing a new drug launch, engaging Tier 1 KOLs who are academic researchers or trial investigators *early* (during Phase 2/3) is crucial so that they are knowledgeable and supportive by the time of launch (933508_Driving-agility-to-improve-productivity-in-medical-affairs).

By contrast, **Tier 2 KOLs** might be primarily engaged around launch and growth phases. Companies may host **regional advisory boards** for them (to gather feedback specific to certain areas or sub-populations) and involve them in speaker bureaus to educate physicians in their region. Tier 2 KOLs often serve as faculty for **regional Continuing Medical Education (CME)** events or as co-authors on secondary publications and posters. Commercial teams (like marketing and sales) also coordinate with medical affairs to identify Tier 2 KOLs for regional promotional talks (where allowed) or testimonials – always ensuring compliance. Tier 2s are typically met by MSLs or regional medical directors **quarterly or bi-monthly** to keep them updated (about:blank), whereas Tier 1s might have monthly or more frequent touchpoints.

Tier 3 KOLs receive a lighter but still important touch. The engagement might be as simple as periodic visits by an MSL to share new data or invite them to local educational dinners. The goal with Tier 3 is often to **educate and observe**: make sure they are aware of the latest science (so they can disseminate it locally), and gauge if any are "rising stars" who could be elevated to Tier 2 with more experience. Some Tier 3 KOLs are invited to training programs or mentorship with Tier 1 KOLs. Field medical plans might set lower interaction frequency targets for this tier (e.g. perhaps just a few interactions per year) (about:blank). An example approach is a **call plan** where Tier 1 KOLs get personal visits every 1-2 months, Tier 2 KOLs once a quarter, and Tier 3 a few times a year (about:blank). This ensures effort is balanced according to tier.

To visualize how KOLs might be segmented into tiers, below is an **example of a tiering framework** with illustrative metrics:

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
Tier 1 (Top KOLs)	*Global/National Thought Leaders*. These are the foremost experts who drive the field's direction. Often professors or department heads at major academic centers, guideline authors, lead investigators in pivotal trials.	– 30+ peer-reviewed publications in the specialty – Leadership on national guidelines or professional society boards – Principal Investigator on Phase III trials – Frequent speaker at international congresses and high citation count (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) – Recognized by peers as a key authority (e.g. awards)	High-level strategic engagement: Advisory board membership, early access to data, one-on-one meetings with senior leadership. Speaking at major (inter)national events. Ongoing scientific collaboration (e.g. co-authoring papers). Engage at all stages of product lifecycle (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs).
Tier 2 (Mid KOLs)	*Regional or Emerging National Experts*. Influential within a country or region; may head a department at a big	– ~5-20 publications or significant research contributions – Participation in	Targeted engagement: Regional advisory meetings to gather insights. Involvement in speaker bureaus for their area. Occasional consultation on

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
	hospital or lead notable research in a sub-field. Known among specialists, though not the top global names.	multicenter trials or regional treatment protocols – Leadership in local chapters or regional medical conferences – Serves as a referral expert for difficult cases in region – Moderate digital presence or known within specialist online communities	company initiatives. Regular MSL visits (e.g. quarterly) to update on data. Invites to contribute to publications or case studies.
Tier 3 (Low KOLs)	*Local Influencers and Niche Experts*. Respected at a community or institutional level. May be early in career (rising stars) or focused on patient care with little research, but colleagues value their opinion.	– Few (<5) publications, or primarily clinical practice-focused – Known as a skilled clinician in the community or runs largest local patient support group (about:blank) – High patient volume or high prescription rates locally (indicator of trust in community)	Basic engagement and monitoring: MSL interactions to provide medical updates. Invitations to local educational events, speaker training sessions, or mentorship programs. Goal is to educate and build relationships. Identify those who could take on larger roles. Lower intensity contact (e.g. a few times per year).

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
		(about:blank) – Active in local hospital committees or support groups – Small but engaged network of peers (including on social media)	

Table: Illustration of KOL tiers with example characteristics, metrics, and engagement strategies. (Note that exact criteria and numbers will vary by company and therapy area.)

In practice, the **number of KOLs in each tier** will differ by the size of the field. For a broad disease like diabetes, there may be many Tier 2 and Tier 3 KOLs across the country; for a very rare disease, almost all the key experts might be Tier 1 by necessity (since only a handful of doctors specialize in it worldwide). A hypothetical example from one mapping guide output was a list of about **50 Top-Tier KOLs nationwide, 200 secondary influencers (Tier 2), and 5,000 target HCPs for sales** – each segment then gets a defined engagement strategy appropriate to their level (about:blank) (about:blank).

Engagement strategy differences by tier

A well-designed tiering system directly informs *how* a company engages each KOL segment. **Tier 1 KOLs** are treated as strategic partners: companies will **involve them early in development**, perhaps via investigator meetings or pre-launch advisory boards, to gain mindshare and insights (933508_Driving-agility-to-improve-productivity-in-medical-affairs). By the time of product launch, Tier 1 KOLs are often delivering scientific presentations on behalf of the therapy at conferences or acting as authors on key publications (e.g. presenting Phase III results at ASCO for an oncology drug). It's common in the U.S. for Tier 1 KOLs to be the primary speakers at **national launch events or disease awareness campaigns**, because their endorsement can carry significant weight. For example, an oncology company's disease awareness initiative on a rare cancer *"enlisted top oncologists from major cancer centers to present epidemiology data and patient stories,"* ensuring the campaign featured the **most respected voices** – the result was increased screening and diagnosis rates in that cancer (about:blank). This illustrates how engaging top-tier KOLs can amplify a message and drive real-world impact.

Tier 2 KOL engagement is often about breadth and localized depth. These KOLs might be tapped closer to launch to help **educate regional peers**. A company might arrange a series of regional symposiums where Tier 2 KOLs present new clinical data to community physicians. They can also be invited to contribute to **publication programs** (for instance, writing review articles or case series about the new treatment in local journals). While Tier 1 KOLs are few and thus heavily utilized, Tier 2 KOLs can be more numerous and help extend outreach. These KOLs provide valuable feedback too – e.g. a regional KOL can tell the company about specific local practice patterns or barriers to adoption in their area. They often interact mainly with MSLs or regional medical leads, who relay insights back to the central team.

Tier 3 KOL engagement focuses on **grassroots influence and future development**. A notable trend in recent years is an increased appreciation of local influencers. Pharma companies realized that relying only on big-name KOLs might miss the *"micro-influencers"* who quietly shape day-to-day practice in community settings. For instance, during an insulin launch, one company identified a network of local diabetes educators and physicians who were highly trusted in their cities – these weren't national figures, but by designating them as a **special tier of regional KOLs**, the company invited them to speaker training and equipped them to hold peer-to-peer education dinners (about:blank). This *"community KOL"* strategy led to better grassroots adoption, as local physicians often trust a respected peer from their area more than a distant famous professor (about:blank). Thus, Tier 3 KOL engagement can significantly improve **local uptake** of a therapy. It's a more decentralized approach: rather than a top-down message only from elite experts, it creates many touchpoints of influence throughout the healthcare community.

In summary, Tier 1 drives **broad policy and high-level endorsement**, Tier 2 drives **regional momentum and wider peer influence**, and Tier 3 drives **local adoption and practical feedback**. Companies align their **tactics** accordingly – for example, **advisory input** from Tier 1 is sought on clinical development plans, from Tier 2 on real-world challenges post-launch, and from Tier 3 on patient support needs or referral patterns. Even the **content** provided differs: Tier 1 KOLs might get very detailed unpublished data or be involved in scientific exchange meetings, whereas Tier 3 KOLs might receive more approved educational materials to share locally (about:blank). All tiers are important to a comprehensive engagement plan, but resources are weighted toward the higher tiers for maximum impact.

Real-World Examples: Oncology and Rare Disease KOL Tiering

To make these concepts more concrete, let's look at how KOL tiering plays out in two contexts: **Oncology** (a broad, highly scientific field with many KOLs) and **Rare Diseases** (niche fields with a small number of experts).

Oncology Example: Oncology is a therapy area where KOL influence is paramount – cancer treatments evolve rapidly, and oncologists look to thought leaders for guidance on new therapies. In oncology, **Tier 1 KOLs** typically include the few physicians who **steer national guidelines and major trials** in each cancer type. For instance, the doctors on the NCCN (National Comprehensive Cancer Network) guideline panels for lung cancer or breast cancer, or those who lead Phase III trials that change the standard of care, would be Tier 1. These individuals often have dozens of publications and are frequent keynote speakers at ASCO, ESMO and other top conferences (KOL Tiering: Enhancing Targeted Outreach in Healthcare). They may also serve as advisors to the FDA or NIH on cancer research (KOL Tiering: Enhancing Targeted Outreach in Healthcare). A Tier 1 oncology KOL's endorsement can significantly shape oncologists' perceptions; as such, companies will involve them in trial design, get their feedback on study results early, and feature them in *Scientific Advisory Boards* around a new drug.

Example: For a new immunotherapy launch in melanoma, the company's Tier 1 KOLs might include professors from MD Anderson, Memorial Sloan Kettering, and Dana-Farber – all globally recognized oncologists. These KOLs would likely have been investigators in the trials and would present the data at ASCO. The company would ensure they are well-versed in the product profile and perhaps have them co-author a publication of subanalysis. Meanwhile, **Tier 2 oncology KOLs** could include prominent oncologists in major cancer centers or leaders of oncology networks in various states. They might not be the ones defining global guidelines, but they run influential tumor boards regionally. The company might invite these Tier 2 KOLs to participate in a regional **ad board** discussing how the new immunotherapy fits into local practice or to lead **webinars** for community oncologists. **Tier 3 oncology KOLs** could be experienced oncologists in community hospitals who aren't involved in research but treat many patients and whose opinions are respected by local peers. They might be engaged through the MSL team to gather feedback on how patients are responding to the new drug in real-world settings, and to help identify any barriers (e.g., need for educational materials about managing side effects).

A real-world oncology case highlighting tiered engagement was an **awareness campaign for a rare cancer**. The pharma company identified the key opinion leaders (authors of clinical guidelines for that cancer) and had them front and center in an educational initiative (about:blank). These top-tier KOLs gave talks and webinars on recognizing the cancer's symptoms and the importance of early diagnosis. Because these voices were highly credible, oncologists and other physicians paid attention, leading to measurable increases in screening and diagnoses (about:blank). This shows how leveraging Tier 1 KOLs (global experts) in oncology can drive change. At the same time, oncology companies often maintain a network of Tier 3 **community KOLs** (local oncology leaders) to ensure that information flows to every practice. For instance, if access to a star KOL is limited, companies will have influential community oncologists who can speak at local meetings – spreading the knowledge more broadly.

Rare Disease Example: Rare diseases present a very different scenario. By nature, rare diseases have far fewer patients and typically only a small cadre of physicians who specialize in

them. Often, these experts all know each other and form a tight-knit global community. In such cases, the distinction between tiers can be less about *influence* (since all key specialists might be influential) and more about *roles*. Usually, in a rare disease there are a handful of **super KOLs** worldwide – often researchers who have dedicated their careers to the condition. These would be Tier 1 and likely the ones advising on the drug development. For example, in a rare neuromuscular disorder, Tier 1 might include the 3-5 physicians who run the largest clinical centers in the US or globally and who probably conducted the pivotal trials for the new drug. **Tier 2** might then include other specialists who contribute to research (perhaps investigators in smaller Phase II studies, or authors of case reports) or who lead major clinics in other countries/regions. **Tier 3** could extend to doctors who see patients with the condition occasionally or are involved in patient advocacy groups, etc., but not deeply involved in research.

Because rare disease KOLs are so few, companies often treat most of them as high priority. In fact, a "tiering" might still be done (to fulfill internal process) but engagement plans could be individually tailored per KOL since each one is important. A consulting case study in a rare disease launch illustrates this: a large biopharma preparing to launch a rare disease drug asked for a comprehensive stakeholder map. The solution involved developing a **tiering criteria** to classify KOLs by overall expertise/influence and mapping potential roles for them (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL mapping: Rare disease stakeholder engagement - Putnam). The criteria spanned everything from publications and clinical trial involvement to leadership in patient registries and social media presence (KOL mapping: Rare disease stakeholder engagement - Putnam) – acknowledging that in rare diseases, even factors like patient community engagement can matter (since KOLs often work closely with patient advocacy groups). They **validated the tiering** with internal and external experts and ended up with a prioritized list of KOLs with assigned tiers and defined engagement roles (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL mapping: Rare disease stakeholder engagement - Putnam). The engagement plan for these rare disease KOLs was then built around each person's capabilities and interests (e.g., some would be clinical trial leads, others patient community educators, etc.) (KOL mapping: Rare disease stakeholder engagement - Putnam).

In rare diseases, a company might decide *all* the top 10 experts globally are Tier 1 (because each has unique value – one might be the diagnostic expert, another the genetic research guru, another the clinical trialist, etc.). They will form a global advisory board that meets frequently. **Tier 2** in this context could include the next set of specialists or perhaps regional doctors in key countries that will be launch markets. For example, if launching in the US and EU, you might have Tier 1 as the global KOLs (some in US, some Europe), Tier 2 as additional important experts in each of those regions or other key markets (like a few more physicians in the US who see many patients but aren't researchers, or leading specialists in countries like Canada, Japan, etc., to support regulatory and launch activities there). **Tier 3** might include physicians who are not specialists but see a few patients (for instance, a neurologist who manages one or two patients with the rare disease and is active in a community forum about it). Engaging those Tier 3 in rare

diseases might involve providing them with education so they can identify patients and refer to centers, rather than relying on them for research input.

One notable aspect of rare diseases is the importance of **evidence generation and education**, since these conditions are not well known. KOL tiering in rare diseases often overlaps with building a KOL-driven *"Center of Excellence"* network. Companies might help facilitate collaboration among their Tier 1 and Tier 2 KOLs to set up diagnostic guidelines, patient registries, or treatment protocols. For example, a company might fund an **expert consortium** led by Tier 1 KOLs to publish recommendations on managing the rare disease – all Tier 1 and 2 KOLs would be co-authors, immediately giving it weight in the community. Tier 3 doctors then follow these recommendations in practice. So, while the structure of tiers exists, in rare diseases it's common that **Tier 1 and Tier 2 KOLs work very closely together** as a unified group, given the small numbers, and the company treats them almost all as top-tier partners.

To highlight criteria differences: the Intuition released by IntuitionLabs notes that for a *first-in-class rare disease drug*, **clinical trial experience and publication might be weighted heavily** to find KOLs who truly understand the science of the novel treatment (about:blank). In contrast, for a common condition (like launching a new diabetes drug in a crowded market), a company might weigh **patient volume and peer influence** more, since many doctors treat diabetes and one needs to find those who can influence prescribing trends (about:blank). This underscores how tiering criteria can flex based on context – in rare diseases, being a scientific leader is critical (otherwise you wouldn't even encounter the disease), whereas in prevalent diseases, sheer clinical experience and local trust also play big roles.

In summary for these examples: In oncology, tiering helps manage a large, stratified pool of experts from world-famous oncologists (Tier 1) to community cancer doctors (Tier 3), aligning engagement from global congresses to local tumor boards. In rare diseases, tiering still occurs but given the small expert pool, nearly all key players might be high-tier; engagement is intensive with each of them to build the knowledge base and medical community for the disease. Both cases benefit from a structured approach: clarity on who the Tier 1 KOLs are (so they can be involved in every critical step) and who the extended network is (to disseminate information widely and ensure no region or patient population is left out).

Role of Technology in KOL Tiering and Management

Identifying, profiling, and continuously updating information on KOLs can be an enormous task – especially in the U.S. with its large healthcare system. Fortunately, in recent years, specialized **KOL management and analytics software platforms** have emerged to assist pharma teams. These tools aggregate vast amounts of data (publications, conference presentations, clinical trial databases, prescription data, social media, and more) to help discover KOLs and assess their influence objectively. They also provide interfaces to **segment KOLs into tiers** and track

engagement. Here we discuss some of the commonly used platforms: **Monocl, Veeva Link, H1, and Medmeme**.

- **Monocl (Definitive Healthcare's Monocl Expert Suite):** Monocl is a comprehensive KOL intelligence platform now part of Definitive Healthcare. It maintains a database of over **15 million global experts** across therapeutic areas (about:blank). Users can search for experts and view **detailed profiles** that include each expert's publications, clinical trial involvement, conference talks, affiliations, and even their social media impact (about:blank). One of Monocl's strengths is its data visualization – it can generate **dynamic maps** of KOL networks, showing how experts connect to each other (e.g. co-authorship, institutional collaborations) and where they are located geographically (about:blank). Monocl also offers modules like *ExpertInsight* (deep profiling), *ExpertConnect* (CRM integration for engagement tracking), and *ExpertClaims* (linking KOL profiles to healthcare claims/prescription data) (about:blank). For example, using Monocl, a company's medical affairs team could quickly find the top 20 oncology KOLs in California, see each person's latest research and collaboration network, and identify which conferences they've spoken at recently (about:blank). Platforms like Monocl have essentially transformed KOL mapping from a labor-intensive one-time exercise into an ongoing, data-driven practice – they are continuously updated as new information comes out (new publications, new trials, etc.) and even send alerts about KOL activities. This allows companies to keep their tiering current (if a Tier 3 suddenly publishes a groundbreaking study, the data will reflect that) (about:blank).

- **H1 (HCP Universe by H1):** H1 is another leading data platform that provides a **360° view of healthcare providers and KOLs**. It aggregates both public and proprietary data: clinical history, scholarly work, trial participation, and even info on patient populations served (about:blank). H1 markets its system as an "AI-powered KOL mapping & engagement" tool (about:blank). It uses algorithms to highlight **"rising stars"** – identifying up-and-coming researchers or clinicians who are gaining influence but might not yet be widely recognized (about:blank). This is particularly useful for medical affairs to get ahead in KOL development. H1 supports multiple use cases: medical (finding trial investigators, identifying advisors) and commercial (finding high-prescribing physicians who could be local champions) (about:blank). It also emphasizes connecting disparate data silos (for instance, linking a doctor's clinical outcomes or claims data with their research profile) to give a full picture (about:blank). Some pharma companies have used H1's tools for specific tasks like **conference planning** – e.g., before a major congress, the system can show which target KOLs will be attending and suggest who to meet, based on their recent activity. In one case study, a top 10 pharma company exceeded its conference engagement goals by using H1 to plan outreach to KOLs at the meeting (about:blank). In summary, H1 helps companies not only map and tier KOLs but also maintain up-to-date intelligence for field teams, so that MSLs always have the latest info on a given KOL's work.

- **Veeva Link (Key People):** Veeva Systems – known for its CRM widely used in pharma – offers a data product called **Veeva Link for Key People** (often referred to simply as Veeva Link, formerly Veeva Oncology Link for its oncology-focused segment). Veeva Link is essentially a curated, continually updated database of KOLs and digital opinion leaders, with extensive profiles of their **influence networks** (about:blank). Because it integrates directly with Veeva's CRM, it allows seamless access for sales reps and MSLs: when viewing a physician in CRM, one could see their KOL profile (publications, affiliations, connections, social media) without switching systems (about:blank). Veeva Link uses data science to map relationships – for example, identifying that Dr. X trained under Dr. Y (so Dr. Y influenced Dr. X), or that two doctors publish together often, etc., which can be invaluable in understanding a KOL's network. It also tags **digital opinion leaders** (like prominent healthcare bloggers or forum moderators) who might not appear in traditional academic lists. Companies leveraging Veeva Link can more easily segment KOLs by tier because they have a wealth of data at their fingertips and can filter by various metrics (e.g., sort experts by number of PubMed citations or by number of Twitter followers). In essence, platforms like **Veeva, Monocl, and H1 have moved KOL mapping from one-time consulting projects to continuous data-driven platforms with near real-time updates** (about:blank). This ensures that as soon as a KOL does something notable (publishes a new paper, gets a new grant, moves institutions), the information is captured – keeping the tiering and engagement approach accurate and up-to-date.

- **Medmeme:** Medmeme is a long-standing platform in the pharma industry known for its massive database of medical and scientific information. It has been described as **"the most comprehensive, continuously updated, and integrated online repository of disseminated medical science information"** (Med Affairs Building Up its Strategic Muscle). Medmeme historically focuses on capturing data from scientific publications, conferences, and other communications. For example, Medmeme tracks thousands of medical conferences and the abstracts presented there, as well as all PubMed-indexed journal articles, to build profiles of experts based on their publication and speaking history. Medical affairs teams have used Medmeme to identify which KOLs are actively talking about a disease at conferences, who is publishing on what topics, and even which KOLs often appear together (at events or in literature). In recent years, Medmeme launched a platform called **Medmeme Delta**, which uses proprietary algorithms to help measure the impact of medical communications and provide objective analytics for decision-making (Med Affairs Building Up its Strategic Muscle). While Medmeme may not have the same CRM integration as Veeva or the flashy network maps of Monocl, it is valued for the **depth of its content coverage** – ensuring no important publication or presentation by a potential KOL is missed. When segmenting by tiers, a company might use Medmeme data to set thresholds (e.g., Tier 1 KOLs = those who have >20 conference presentations + publications in the last 5 years, Tier 2 = those who have 5-20, etc., adjusting for context). Medmeme's data can also help validate KOL influence by showing how often an expert's work is cited or how frequently they speak at prestigious forums.

In addition to these, there are other notable tools and data sources: for example, **IQVIA's analytics platforms** (which leverage prescription and claims data alongside KOL data), specialized tools like **MDoutlook Lumineer** for certain domains, and social media analytics tools like **Symplur** for identifying digital KOLs in conversations. The key benefit across all these technologies is that they allow pharma companies to **use data to guide KOL tiering and engagement decisions**, rather than relying purely on anecdotal knowledge or manual research. By having a centralized, data-driven KOL platform, companies can quickly generate **scorecards**

for KOLs (covering all their metrics in one place) and even have algorithms suggest a tier ranking. This not only saves time but also supports compliance (since decisions can be backed by objective criteria). Moreover, technology platforms often include features to **track engagement** – e.g., logging interactions with KOLs, noting their preferences, etc. – which helps in refining the relationship and ensuring the right frequency of contact.

Best Practices and Compliance Considerations (U.S. Focus)

Implementing KOL tiering effectively requires following best practices in both strategy and compliance, especially given the regulatory environment in the United States. Below are some key guidelines:

1. Establish Clear, Objective Tiering Criteria: As discussed, define your criteria and scoring system for tiering before labeling KOLs. This could be a point system or threshold (for example, any KOL with X number of high-impact publications and a leadership position might automatically qualify as Tier 1). The goal is to make the process as **objective and auditable** as possible (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). Having clear criteria helps avoid bias (e.g. favoring someone just because they are personable or well-known to the team). An objective approach was highlighted in a recent solution by Baker Tilly, which developed a detailed **tiering methodology and algorithm** to evaluate KOLs' expertise and automatically assign tiers (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). This kind of transparency in how tiers are assigned is important not just internally, but also for compliance – you can demonstrate that KOLs are chosen for legitimate reasons (scientific stature, etc.) and not for undue commercial favoritism.

2. Regularly Update and Revalidate Tiers: KOL influence is not static. People win awards, publish breakthrough studies, move institutions, or conversely, they retire or become less active. A KOL tiering from two years ago may be outdated today. Best practice is to **review and update the tiering at least annually**, if not continuously. Many companies now use the aforementioned data platforms to keep an eye on changes. For example, if a Tier 2 KOL suddenly is senior author on a New England Journal paper, that might prompt a discussion to move them to Tier 1. Or if a Tier 1 KOL has taken a sabbatical or moved to a non-clinical industry role, you might downgrade their tier since their influence network might wane. Always incorporate fresh data – new publications, new trial roles, etc. – so the tiering reflects the current landscape (about:blank). In addition, solicit feedback from field teams: MSLs and sales reps can provide intelligence (perhaps a local doctor is now leading a big community physician network, making them more influential – something data might not immediately show).

3. Align Engagement Plans with Tier Definitions: Ensure that your **engagement frequency and type** are formally tied to the tier. This alignment should be documented in your SOPs (Standard Operating Procedures) or playbooks. For instance, a company might specify: *"Tier 1*

KOLs: global ad board 2x/year, MSL visit monthly, invite to speak at national congress symposia; Tier 2 KOLs: regional ad board 1x/year, MSL visit quarterly, invite as backup speakers; Tier 3 KOLs: maintain at least 2 touches per year, invite to local events." Having such guidelines prevents under- or over-engagement. It also helps field teams plan their time – for example, MSLs might each be given a list of Tier 1 and 2 KOLs in their region to focus on deeply, versus a broader list of Tier 3 to cover occasionally. As one report noted, instead of a flat approach of reaching everyone equally, segmentation enables **field force resource deployment** to be optimized – reps/MSLs focus more on high-priority physicians (Tier 1) and adjust call frequency accordingly (about:blank) (about:blank). By setting these standards, you ensure consistency across the organization in how KOLs are treated.

4. Cross-Functional Coordination: KOL tiering should be a collaborative effort between Medical Affairs, Commercial (Marketing/Sales), and sometimes Clinical Development. Different teams have different insights – medical may focus on scientific merit, commercial may focus on prescribing influence. Bringing these perspectives together (usually led by Medical to avoid purely sales-driven choices) will result in a well-rounded tiering. It also ensures that once tiers are set, all teams know the plan: e.g., Marketing knows which doctors to feature in speaker programs (likely Tier 1 or 2), Sales knows which doctors might be speakers or need special attention, and Medical knows whom to approach for clinical trial advice. A unified KOL engagement plan prevents duplication (e.g., two separate groups unknowingly reaching out to the same KOL without coordination) and ensures the KOL gets a cohesive experience with the company.

5. Compliance with the Sunshine Act and Transparency: In the U.S., the **Physician Payments Sunshine Act (Open Payments)** requires that pharmaceutical and device manufacturers **report virtually all transfers of value to physicians and teaching hospitals** (about:blank). This means any honoraria, consulting fees, meals, travel, or other payments provided to KOLs will become public record in the Open Payments database. Compliance best practice is to make sure that engaging a KOL (especially Tier 1 who may receive larger consulting fees for big projects) is done with full transparency and proper documentation. When tiering KOLs, it's wise to also cross-check the **Open Payments database** to see how much that KOL is already being paid by your company or others (about:blank). This can inform decisions: if a particular KOL has very high earnings from industry, you might be cautious about further engagements to avoid the appearance of a conflict of interest. Conversely, Sunshine data can highlight if a KOL has strong ties to a competitor (lots of payments from another company), which might affect whether you consider them neutral or not (about:blank). Always ensure that any compensation offered to KOLs is in line with **Fair Market Value (FMV)** (see next point) and that the arrangements are for legitimate services (advisory, speaking, etc.). All such interactions should be approved by compliance and ultimately reported as required by law.

6. Fair Market Value (FMV) and Anti-Kickback Compliance: Tiering KOLs and planning engagements must be done under the umbrella of U.S. anti-kickback statutes and related regulations. In practical terms, this means **never using KOL engagements as a reward for**

prescribing or as an inducement to prescribe. The OIG (Office of Inspector General) has scrutinized speaker programs and advisory boards for this reason. A robust tiering process with documented criteria helps demonstrate that KOLs are chosen for their expertise, not their prescription volumes. Additionally, each KOL interaction that involves payment should be compensated at a **fair market value rate** commensurate with the KOL's qualifications and the task. Many companies have FMV grids (hourly rates that depend on the physician's degree, experience, etc.) to ensure consistency. The Baker Tilly *kolNOW* tool, for example, integrates a database of pre-tiered HCPs with their FMV rates, so companies can quickly see the appropriate compensation for a given tier of KOL (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform) (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). This helps avoid overpaying a high-value KOL beyond what's defensible. It's also good practice to have a **cap on engagements per KOL** to prevent any one doctor from being excessively used/paid. Remember that anti-bribery/anti-corruption laws (FCPA, etc.) also require careful oversight if any KOLs are outside the U.S. or if the engagements could be seen as influencing government healthcare (many KOLs are academics at public institutions).

7. Screen KOLs for Compliance Risks: Part of tiering in the U.S. context is ensuring the KOLs you decide to engage (especially in higher tiers) don't pose compliance risks. This means doing due diligence: check if they have been **sanctioned by regulatory or medical boards**, had FDA warning letters, or any controversial public issues. The Baker Tilly solution explicitly includes verifying if selected HCPs have any regulatory sanctions as part of the tiering process (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). Engaging a high-tier KOL who later turns out to have undisclosed conflicts or prior misconduct can be damaging. Thus, best practice is to involve compliance/legal in vetting KOLs (especially new ones) – this might include background checks or at least an OIG exclusion list check. Also, maintain records of **contractual agreements** for all KOL engagements (outlining the services they will provide and payment, aligned with FMV). This ensures that if ever questioned (by auditors or investigators), the company can show a clear, fair process for KOL selection and compensation.

8. Respect Ethical Boundaries and Independence: Even as you engage KOLs closely, it's crucial to respect their scientific independence and credibility. KOL tiering should **not** lead to treating doctors as if they are part of your sales force. For instance, even if a Tier 1 KOL is very receptive, you must avoid pressuring them to advocate in ways that would be inappropriate. U.S. industry guidelines, like the **PhRMA Code on Interactions with Healthcare Professionals**, provide norms (e.g., prohibition of lavish gifts, quid pro quo arrangements, etc.) that apply to KOL engagements as well. One emerging best practice is to focus on **education and scientific exchange** in KOL interactions, not product promotion. This is especially true for medical affairs activities – they should be about science, with no off-label promotion (unless in response to unsolicited questions in a medical context). By keeping engagements medical in nature (for Tier 1 and 2 especially), you maintain compliance and also earn trust from the KOL, who will appreciate that the company respects scientific integrity.

9. Leverage Technology for Compliance Tracking: The same platforms that help identify KOLs can often assist in compliance tracking. For example, some CRM-integrated tools will log every meeting or action taken with a KOL. Use these to your advantage – track the dates and topics of interactions, and monitor if any KOL is being contacted too frequently or being asked to do too many paid activities. This oversight can prevent "overuse" of a single KOL which might raise flags. Additionally, technology can compile all the data needed for annual reporting (like Sunshine Act submissions). Ensuring accurate record-keeping is in itself a compliance mandate (for instance, the FDA requires that if any off-label info is discussed with a KOL, it should be documented via medical inquiry systems, etc.). So integrating compliance checks into the KOL management software or process is key.

10. Continual Training and Calibration: Finally, train your teams on both the **tiering methodology** and the compliance do's and don'ts. All field medical and commercial personnel should understand why Dr. Smith is Tier 1 and Dr. Jones is Tier 3, and how that affects their approach. Likewise, they should be trained on appropriate interaction types for each tier (e.g., what's okay or not okay to do with a KOL in a meeting). Training should also include refreshers on laws like the# KOL Tiering in the US Pharmaceutical Industry: Definition, Criteria, and Best Practices

Pharmaceutical companies in the United States heavily rely on **Key Opinion Leaders (KOLs)** – influential physicians and scientists – to inform and support their medical and commercial strategies. Given the vast number of experts in any therapeutic area, organizations use **KOL tiering** to prioritize who to engage and how to allocate resources. In simple terms, KOL tiering means categorizing these thought leaders into different levels (Tier 1, Tier 2, Tier 3, etc.) based on their influence and relevance. This in-depth article explains what KOL tiering is, why it's strategically important, how tiers are determined, and how engagement strategies differ by tier. It also provides real-world examples (in oncology and rare diseases), a sample tiering framework table, insights into technology platforms for KOL management, and best practices including U.S.-specific compliance considerations.

What Is KOL Tiering and Why It Matters

KOL Tiering is the practice of ranking or segmenting key opinion leaders into discrete levels of importance or influence. Typically, companies group KOLs into three tiers (Tier 1, Tier 2, Tier 3) – though some may use more nuanced categorization – with Tier 1 being the highest priority or most influential group (about:blank). The majority of pharmaceutical manufacturers favor a three-tier system for segmenting thought leaders (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...), reflecting a common industry approach to manage KOL relationships in a structured way. In essence, KOL tiering helps answer *"Who are our most important experts?"* and *"How should we engage each group differently?"*.

Strategic importance: Implementing a clear tiering strategy allows pharma teams to focus their efforts and resources where it counts most. Top-tier KOLs have broad influence on medical practice and policy, so engaging them can shape treatment guidelines, product perception, and adoption on a large scale. Lower-tier (but still important) KOLs often drive "grassroots" influence at the local level, impacting day-to-day prescribing and peer discussions. By segmenting KOLs, companies ensure that **global thought leaders** receive high-touch engagement for big-picture strategy, while **regional and local influencers** get appropriately tailored support for community-level impact (about:blank). This alignment of engagement with KOLs' level of influence leads to more efficient and effective medical affairs and marketing activities (about:blank) (about:blank). In fact, a data-driven tiering approach is seen as essential for successful product launches and ongoing education efforts, enabling teams to identify "the right experts to help achieve the team's goals" (about:blank).

Another reason KOL tiering is critical is **resource optimization**. Pharma companies have limited time and budget for KOL engagements (advisory boards, speaker events, one-on-one visits, etc.), so they must prioritize. For example, one survey noted that companies place especially high expectations on their Tier 1 KOLs and correspondingly devote significant engagement to them (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...). Without tiering, there's a risk of spreading efforts too thin or focusing on the wrong individuals. An organized tiering system brings clarity – **Tier 1 KOLs** are typically involved in key strategic decisions and major events, **Tier 2 KOLs** might be engaged for regional initiatives and periodic consultation, and **Tier 3 KOLs** are usually kept on the radar for local influence or future potential. This doesn't mean Tier 3 are unimportant – rather, their impact is more localized, and they can be cultivated over time. Ultimately, KOL tiering aligns the level of engagement (and investment) to each KOL's ability to impact the success of a drug or therapeutic area.

Typical Criteria for KOL Tiering

Pharmaceutical teams use a mix of **quantitative and qualitative criteria** to evaluate a KOL's influence. Tiering criteria are designed to measure a KOL's scientific contribution, reach among peers, clinical practice impact, and other relevant factors. Each company may have its own scoring system, but common **KOL tiering criteria** include (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL Tiering: Enhancing Targeted Outreach in Healthcare):

- **Scientific Contribution & Leadership:** Perhaps the most important factor is a KOL's academic and research impact (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). This includes the number and quality of **peer-reviewed publications** (especially in top journals), involvement in **clinical trials** (e.g. serving as a principal investigator in pivotal studies), contributions to **clinical practice guidelines or consensus statements**, and recognition by peers (such as awards or leadership positions in medical societies). A KOL who has authored landmark trial results or helped write national treatment guidelines wields significant influence and would likely be tiered higher (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). For example, a rare disease KOL who has published extensively and led patient registries would score high on scientific contribution (KOL mapping: Rare disease stakeholder engagement - Putnam).

- **Level of Influence (Sphere of Influence):** KOLs can be **international, national, regional, or local** in their reach. Companies assess whether a physician's influence extends globally or is more confined to a specific geography or institution (about:blank). **Global/National KOLs** (often Tier 1) are those who shape opinions across countries or an entire nation – they speak at international congresses, have widely cited research, and are known by specialists worldwide (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Regional KOLs** (Tier 2) might be highly respected within a country or region, leading local conferences or guidelines (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Local Thought Leaders** (Tier 3) may not publish much research, but they are the "go-to" experts in their community or institution whom other physicians turn to for advice (about:blank) (about:blank). The sphere of influence is a key qualitative measure – for instance, an institutionally influential physician who mentors others and shapes local practice might be considered a KOL even without global fame (about:blank).

- **Clinical Practice Impact (Prescribing Behavior & Patient Reach):** Especially in commercially driven analyses, companies look at how a KOL's own practice reflects influence. This can involve **prescribing behavior or patient volume** – e.g. is the physician a high prescriber of relevant therapies, indicating they treat a large number of patients in the disease area? A doctor who sees a high volume of patients or runs a renowned clinic can be an opinion leader through sheer clinical experience. However, volume alone doesn't make a KOL – it must be coupled with peer influence. As one guide notes, a practitioner with high prescription volume but low scientific contribution might be a "high-volume practitioner but not a thought leader" (about:blank). Thus, companies balance this factor: in a *crowded primary care field (e.g. diabetes)*, patient volume and community peer referrals might carry more weight, whereas in a *specialized rare disease*, volume is less important than research expertise (about:blank).

- **Geographic Relevance:** In the U.S., **geography matters** for practical reasons. A KOL's location can be crucial if a company is launching a product in specific regions or needs local advocates. Pharmaceutical field teams often map KOLs to **key markets or healthcare regions**, ensuring each important area has influential voices. For example, if a company needs to educate clinicians in the Northeast U.S., a highly influential doctor in Boston might be tiered higher for that region than an equally qualified doctor based elsewhere. Geographic relevance is often tied into the **tiering strategy** by labeling KOLs as global, national, or regional/local leaders (about:blank). Ensuring coverage across geographies is especially important for diseases that have regional centers of excellence.

- **Professional Authority & Peer Network:** This criterion looks at a KOL's roles and recognition among professional peers. It includes positions like **academic appointments** (e.g. professor at a top university), leadership roles in **professional societies or associations**, membership on **editorial boards of journals**, and invitations to serve on **regulatory or guideline committees**. These indicators show that the expert is respected and listened to by others. For instance, being the chair of an oncology department or the president of a specialty society confers influence beyond one's own practice. KOL mapping often combines such qualitative reputation indicators with quantitative metrics (about:blank). A local physician without titles might rank lower than one who heads a society committee – unless that local doctor has an exceptional informal following.

- **Digital Presence and Outreach:** In today's world, a KOL's **digital footprint** can greatly extend their influence (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). Many leading experts share insights on Twitter, LinkedIn, medical forums, or via blogs and podcasts. Companies assess the KOL's **social media reach** (number of followers, engagement levels) and contributions to **online medical education** (webinars, virtual panels) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). A KOL with tens of thousands of followers who actively discusses new research online can shape opinions far beyond their physical location – these individuals are sometimes called *Digital Opinion Leaders (DOLs)*. For example, a cardiologist who hosts a popular podcast on heart disease or is frequently cited on Twitter for commentary at conferences could be tiered higher due to digital influence. **Mentions in digital media**, participation in online Q&As, and general e-reputation are increasingly factored into tiering decisions (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare).

- **Collaborative History and Industry Engagement:** While not a pure indicator of influence, pharma companies may also consider a KOL's past interactions with industry. KOLs who have served on advisory boards, given paid talks, or consulted on research for pharmaceutical companies have a **collaboration history** that might make future engagement easier (or, if overdone, could raise conflict considerations). A track record of **positive collaboration** might bump a KOL into a higher tier as a known quantity. On the other hand, companies must ensure they include **emerging experts** ("rising stars") who haven't worked with industry before but have growing influence. Some firms formally score KOLs on openness or interest in collaboration (often gauged qualitatively via Medical Science Liaisons' feedback). In any case, having objective criteria – like those above – is crucial to keep tiering fair. An example framework from a consulting project in rare disease used a **matrix of metrics** (publications, trials, registries, leadership influence, society roles, key conference presentations, social media influence, and even data on research/speaking payments) to score and tier KOLs (KOL mapping: Rare disease stakeholder engagement - Putnam).

> **Note:** KOL tiering criteria can vary by company and therapeutic area. Some organizations use strict point-based algorithms (e.g. assigning weights to publications vs. presentations vs. prescriptions), while others allow qualitative judgment by medical affairs leaders (KOL Mapping Done Right - Climedo) (KOL Mapping Done Right - Climedo). Best practice is to define clear criteria upfront – for example, requiring a minimum number of publications or trials for someone to be considered a "KOL" in the first place (KOL Mapping Done Right - Climedo). This reduces subjectivity and ensures that tier assignments are grounded in evidence of influence. It's also important to update these criteria over time and re-assess

> KOLs annually or as new data emerges, because influence is dynamic (new experts rise, others retire or become less active) (about:blank).

Segmenting KOLs into Tiers (Tier 1, 2, 3) and Engagement Strategies

After evaluating KOLs on criteria like those above, pharma teams **segment the KOL list into tiers**. While the exact definitions can differ, a typical breakdown is:

- **Tier 1 KOLs:** The top-tier thought leaders – usually a select few (often a few dozen or less per therapeutic area in a country). These are the *elite influencers* who are nationally or internationally renowned in the field (about:blank). They often have prolific scientific output and hold positions that shape the direction of the specialty (e.g. guideline authors, lead investigators in pivotal trials, famous clinicians at leading institutions) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). **Tier 1 KOLs are the key strategic partners** for a pharma company. They are engaged in deep scientific dialogue, advisory boards, early product strategy, and are kept closely involved throughout a product's life cycle (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs). Because of their influence, Tier 1 KOLs lend credibility and can essentially champion a new therapy among the wider medical community.

- **Tier 2 KOLs:** The mid-tier influencers – a broader group (perhaps dozens to a hundred individuals) who have significant influence, typically at a national or regional level, but not quite the top handful. These could include respected **regional experts** (e.g. a well-known specialist in a particular state or cluster of states, or a prolific clinical trialist who isn't a household name beyond their network). They might be prominent at **major hospitals or regional health systems**, lead local chapters of medical associations, or be rising stars in academia. Tier 2 KOLs often have moderate publication records and some involvement in multicenter trials or speaking forums (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare). Pharma companies view Tier 2 KOLs as important **amplifiers and validators** – they can spread new information within their networks and often engage in two-way dialogue with Tier 1 KOLs. Engagement with Tier 2 tends to be focused on regional advisory meetings, speaker programs, and continued medical education events. They may be invited to national meetings as attendees or panelists, but not necessarily as keynote speakers (that's typically Tier 1 territory).

- **Tier 3 KOLs:** The third tier – usually the largest group (could be hundreds) – encompasses **local thought leaders and emerging influencers**. These are physicians who are influential in their **community or institution** but have limited wider recognition (about:blank) (about:blank). For example, a community oncologist who is the go-to person for difficult cases in a mid-sized city, or a young specialist who is very active on social media and starting to publish research. Tier 3 KOLs might not meet all the strict criteria of higher tiers (they may have few publications or not be on guideline panels), but they have frontline knowledge and the **ear of local peers**. They are often the "bridge" to the broader physician population – what they say in local forums or staff meetings can influence colleagues. Pharma companies consider Tier 3 KOLs as either **niche experts** (perhaps in a very specific subtopic) or **future KOLs** to cultivate. Engagement here is usually via Medical Science Liaisons (MSLs) making individual visits, inviting them to local roundtables, or including them in speaker training so they can present data to community physicians. Tier 3 KOLs might have limited industry exposure so far, but they hold *potential for future collaboration* as their careers progress (KOL Tiering: Enhancing Targeted Outreach in Healthcare).

It's worth noting that **tier definitions are not set in stone** – some companies might label only two tiers (e.g. "national KOLs" vs "regional KOLs"), or even four tiers if needed. The underlying concept is to stratify according to influence and **prioritize engagement intensity accordingly** (about:blank). Many organizations use a scoring system that results in a rank-ordered list of KOLs which they then break into approximately three groups (high, medium, low) – aligning with Tier 1/2/3 terminology. One industry survey found that a three-tier segmentation was the predominant approach among drug manufacturers for thought leader management (Pharma Companies Place High Expectations on Tier 1 Key Opinion ...).

How tiers guide engagement strategy: Once KOLs are tiered, pharma teams design different engagement plans for each tier. For example, **Medical Affairs leadership will devote more time to Tier 1 KOLs** – these top experts might be met by the **Head of Medical or Chief Medical Officer** periodically, involved in early advisory boards (even during pre-clinical or Phase 1 stages), and enlisted as principal investigators for clinical trials or as lead authors on important publications. A ZS Associates white paper emphasizes that Tier 1 KOLs should be **prioritized across the product life cycle, regardless of the type of asset** – meaning from pre-launch through launch and post-launch, these KOLs stay closely engaged (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs). For instance, when preparing a new drug launch, engaging Tier 1 KOLs who are academic researchers or trial investigators *early* (during Phase 2/3) is crucial so that they are knowledgeable and supportive by the time of launch (933508_Driving-agility-to-improve-productivity-in-medical-affairs).

By contrast, **Tier 2 KOLs** might be primarily engaged around launch and growth phases. Companies may host **regional advisory boards** for them (to gather feedback specific to certain areas or sub-populations) and involve them in speaker bureaus to educate physicians in their region. Tier 2 KOLs often serve as faculty for **regional Continuing Medical Education (CME)** events or as co-authors on secondary publications and posters. While Tier 1 KOLs are few and thus heavily utilized, Tier 2 KOLs can be more numerous and help extend outreach. These KOLs provide valuable feedback too – e.g. a regional KOL can tell the company about specific local

practice patterns or barriers to adoption in their area. They often interact mainly with MSLs or regional medical leads, who relay insights back to the central team.

Tier 3 KOL engagement focuses on **grassroots influence and future development**. A notable trend in recent years is an increased appreciation of local influencers. Pharma companies realized that relying only on big-name KOLs might miss the *"micro-influencers"* who quietly shape day-to-day practice in community settings. For instance, during an insulin launch, one company identified a network of local diabetes educators and physicians who were highly trusted in their cities – these weren't national figures, but by designating them as a **special tier of regional KOLs**, the company invited them to speaker training and equipped them to hold peer-to-peer education dinners (about:blank). This *"community KOL"* strategy led to better grassroots adoption, as local physicians often trust a respected peer from their area more than a distant famous professor (about:blank). Thus, Tier 3 KOL engagement can significantly improve **local uptake** of a therapy. It's a more decentralized approach: rather than a top-down message only from elite experts, it creates many touchpoints of influence throughout the healthcare community.

In summary, Tier 1 drives **broad policy and high-level endorsement**, Tier 2 drives **regional momentum and wider peer influence**, and Tier 3 drives **local adoption and practical feedback**. Companies align their **tactics** accordingly – for example, **advisory input** from Tier 1 is sought on clinical development plans, from Tier 2 on real-world challenges post-launch, and from Tier 3 on patient support needs or referral patterns. Even the **content** provided differs: Tier 1 KOLs might get very detailed unpublished data or be involved in scientific exchange meetings, whereas Tier 3 KOLs might receive more approved educational materials to share locally (about:blank). All tiers are important to a comprehensive engagement plan, but resources are weighted toward the higher tiers for maximum impact.

To visualize how KOLs might be segmented into tiers, below is an **example of a tiering framework** with illustrative metrics:

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
Tier 1 (Top KOLs)	*Global/National Thought Leaders*. These are the foremost experts who drive the field's direction. Often professors or department heads at major academic	– 30+ peer-reviewed publications in the specialty – Leadership on national guidelines or professional society boards – Principal	High-level strategic engagement: Advisory board membership, early access to data, one-on-one meetings with senior leadership. Speaking at major (inter)national events. Ongoing scientific collaboration (e.g. co-

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
	centers, guideline authors, lead investigators in pivotal trials.	Investigator on Phase III trials – Frequent speaker at international congresses and high citation count (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare) – Recognized by peers as a key authority (e.g. awards)	authoring papers). Engage at all stages of product lifecycle (933508_Driving-agility-to-improve-productivity-in-medical-affairs) (933508_Driving-agility-to-improve-productivity-in-medical-affairs).
Tier 2 (Mid KOLs)	*Regional or Emerging National Experts*. Influential within a country or region; may head a department at a big hospital or lead notable research in a sub-field. Known among specialists, though not the top global names.	– ~5-20 publications or significant research contributions – Participation in multicenter trials or regional treatment protocols – Leadership in local chapters or regional medical conferences – Serves as a	Targeted engagement: Regional advisory meetings to gather insights. Involvement in speaker bureaus for their area. Occasional consultation on company initiatives. Regular MSL visits (e.g. quarterly) to update on data. Invites to contribute to publications or case studies.

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
		referral expert for difficult cases in region – Moderate digital presence or known within specialist online communities	
Tier 3 (Low KOLs)	*Local Influencers and Niche Experts*. Respected at a community or institutional level. May be early in career (rising stars) or focused on patient care with little research, but colleagues value their opinion.	– Few (<5) publications, or primarily clinical practice-focused – Known as a skilled clinician in the community or runs largest local patient support group (about:blank) – High patient volume or high prescription rates locally (indicator of trust in community) (about:blank) – Active in local hospital committees or patient advocacy groups – Small but engaged network	Basic engagement and monitoring: MSL interactions to provide medical updates. Invitations to local educational events, speaker training sessions, or mentorship programs. Goal is to educate and build relationships. Identify those who could take on larger roles. Lower intensity contact (e.g. a few times per year).

Tier	Profile & Role	Example Metrics for Inclusion	Engagement Focus
		of peers (including on social media)	

Table: Illustration of KOL tiers with example characteristics, metrics, and engagement strategies. (Note that exact criteria and numbers will vary by company and therapy area.)

In practice, the **number of KOLs in each tier** will differ by the size of the field. For a broad disease like diabetes, there may be many Tier 2 and Tier 3 KOLs across the country; for a very rare disease, almost all the key experts might be Tier 1 by necessity (since only a handful of doctors specialize in it worldwide). A hypothetical example from one mapping guide output was a list of about **50 Top-Tier KOLs nationwide, 200 secondary influencers (Tier 2), and 5,000 target HCPs for sales** – each segment then gets a defined engagement strategy appropriate to their level (about:blank) (about:blank).

Engagement strategy differences by tier

A well-designed tiering system directly informs *how* a company engages each KOL segment. **Tier 1 KOLs** are treated as strategic partners: companies will **involve them early in development**, perhaps via investigator meetings or pre-launch advisory boards, to gain mindshare and insights (933508_Driving-agility-to-improve-productivity-in-medical-affairs). By the time of product launch, Tier 1 KOLs are often delivering scientific presentations on behalf of the therapy at conferences or acting as authors on key publications (e.g. presenting Phase III results at ASCO for an oncology drug). It's common in the U.S. for Tier 1 KOLs to be the primary speakers at **national launch events or disease awareness campaigns**, because their endorsement can carry significant weight. For example, an oncology company's disease awareness initiative on a rare cancer *"enlisted top oncologists from major cancer centers to present epidemiology data and patient stories,"* ensuring the campaign featured the **most respected voices** – the result was increased screening and diagnosis rates (about:blank). This illustrates how engaging top-tier KOLs can amplify a message and drive real-world impact.

Tier 2 KOL engagement is often about breadth and localized depth. These KOLs might be tapped closer to launch to help **educate regional peers**. A company might arrange a series of regional symposiums where Tier 2 KOLs present new clinical data to community physicians. They can also be invited to contribute to **publication programs** (for instance, writing review articles or case series about the new treatment in local journals). Tier 2 KOLs provide valuable feedback too – e.g. a regional KOL can share insights on specific local practice patterns or barriers to adoption in their area. They often interact mainly with MSLs or regional medical leads, who relay information back to the central team.

Tier 3 KOL engagement focuses on developing **grassroots support** and identifying future advocates. As described, involving local influencers can significantly boost uptake among community physicians. Companies might hold local peer-to-peer programs where a Tier 3 KOL (trained as a speaker) educates colleagues at a hospital dinner meeting. Also, tier 3 engagement is about **monitoring and nurturing**: the company keeps these doctors informed and gauges their interest; some may eventually become Tier 2 as their influence grows. For example, a young endocrinologist active in a diabetes Facebook group might be Tier 3 now, but with more publications or community projects could become a regional figure (Tier 2). By maintaining a relationship early, the company is well-positioned to support and collaborate with them as their career advances.

In all cases, **feedback loops** are important. KOL tiering is not just one-way (company to KOL outreach) but also about collecting insights: Tier 1s give high-level strategic input (e.g. trial design feedback), Tier 2s might give practical advice on things like referral patterns or formulary issues regionally, and Tier 3s might surface ground-level issues or success stories. Incorporating this feedback improves the strategy and also signals to KOLs that the company values their expertise, strengthening the relationship.

Real-World Examples: Oncology and Rare Disease KOL Tiering

To make these concepts more concrete, let's look at how KOL tiering plays out in two contexts: **Oncology** (a broad, highly scientific field with many KOLs) and **Rare Diseases** (niche fields with a small number of experts).

Oncology Example: Oncology is a therapy area where KOL influence is paramount – cancer treatments evolve rapidly, and oncologists look to thought leaders for guidance on new therapies. In oncology, **Tier 1 KOLs** typically include the few physicians who **steer national guidelines and lead major trials** in each cancer type. For instance, the doctors on the NCCN (National Comprehensive Cancer Network) guideline panels for lung cancer or breast cancer, or those who lead phase III trials that change the standard of care, would be Tier 1. These individuals often have dozens of publications and are frequent keynote speakers at ASCO, ESMO and other top conferences (KOL Tiering: Enhancing Targeted Outreach in Healthcare). They may also serve as advisors to the FDA or NIH on cancer research (KOL Tiering: Enhancing Targeted Outreach in Healthcare). A Tier 1 oncology KOL's endorsement can significantly shape oncologists' perceptions; as such, companies will involve them in trial design, get their feedback on study results early, and feature them in *Scientific Advisory Boards* around a new drug.

Example: For a new immunotherapy launch in melanoma, the company's Tier 1 KOLs might include professors from major cancer centers (e.g., MD Anderson, Memorial Sloan Kettering, Dana-Farber) – all globally recognized oncologists. These KOLs likely served as investigators in the pivotal trials and would present the data at a plenary session of ASCO. The company would

ensure they are well-versed in the product profile and perhaps have them co-author a journal article on the trial results. Meanwhile, **Tier 2 oncology KOLs** could include prominent oncologists who head oncology departments in other big hospitals or lead regional oncology societies. They might not be the ones defining global guidelines, but they run influential tumor boards in their networks. The company might invite these Tier 2 KOLs to regional advisory boards to discuss how the new immunotherapy could fit into local practice, or to lead **webinars** for community oncologists in their state. **Tier 3 oncology KOLs** could be experienced oncologists in community practice who aren't involved in research but treat many patients and whose opinions are respected by local peers. They might be engaged through MSL visits to ensure they understand the new therapy's data and to gather their feedback on patient management or insurance hurdles.

A real-world oncology case highlighting tiered engagement was an **awareness campaign for a rare cancer**. The pharma company identified the key opinion leaders (authors of the clinical guidelines for that cancer) and had them front and center in an educational initiative (about:blank). These top-tier KOLs gave talks and webinars on recognizing the cancer's symptoms and the importance of early diagnosis. Because these voices were highly credible, oncologists and other physicians paid attention, leading to measurable increases in screening and diagnoses (about:blank). This shows how leveraging Tier 1 KOLs (global experts) in oncology can drive change. At the same time, oncology companies often maintain a network of Tier 3 **community KOLs** (local oncology leaders) to ensure that information flows to every practice. For instance, if access to a star KOL is limited, companies will have influential community oncologists who can speak at local meetings – spreading the knowledge more broadly.

Rare Disease Example: Rare diseases present a very different scenario. By nature, rare diseases have far fewer patients and typically only a small cadre of physicians who specialize in them. Often, these experts all know each other and form a tight-knit global community. In such cases, the distinction between tiers can be less about *influence* (since all key specialists might be influential) and more about *roles*. Usually, in a rare disease there are a handful of **super KOLs** worldwide – often researchers who have dedicated their careers to the condition. These would be Tier 1 and likely the ones advising on the drug development. For example, in a rare neuromuscular disorder, Tier 1 might include the 3–5 physicians who run the largest clinical centers in the US or globally and who probably conducted the pivotal trials for the new drug. **Tier 2** might then include other specialists who contribute to research (perhaps investigators in smaller Phase II studies, or authors of important case series) or who lead major clinics in additional geographic areas. **Tier 3** could extend to doctors who see patients with the condition occasionally or are involved in patient advocacy groups, but are not research leaders.

Because rare disease KOLs are so few, companies often treat most of them as high priority. In fact, a "tiering" might still be done (to fulfill internal process) but engagement plans could be individually tailored per KOL since each one is critical. A consulting case study in a rare disease launch illustrates this: a large biopharma preparing to launch a rare disease drug asked for a

comprehensive stakeholder map. The solution involved developing **tiering criteria** to classify KOLs by overall expertise/influence and mapping potential roles for them (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL mapping: Rare disease stakeholder engagement - Putnam). The criteria spanned multiple domains – publications, clinical trials, patient registries, leadership in societies, key presentations, social media influence, and even research/speaking payments data – to ensure a 360° assessment (KOL mapping: Rare disease stakeholder engagement - Putnam). They **validated the mapping and tiering** with internal and external experts (including rare disease advocacy organizations) and ended up with a prioritized list of KOLs with validated tier assignments and specific recommended engagement roles (KOL mapping: Rare disease stakeholder engagement - Putnam) (KOL mapping: Rare disease stakeholder engagement - Putnam). The engagement plan for these rare disease KOLs was then based on the company's strategic needs and the unique capabilities of each KOL – for example, some top KOLs would spearhead evidence generation (like running an open-label extension study or writing disease state papers), while others might focus on physician education or patient community outreach (KOL mapping: Rare disease stakeholder engagement - Putnam).

In rare diseases, a company might decide *all* the top 10 experts globally are Tier 1 (because each has unique value – one might be the diagnostic expert, another the genetics research guru, another the clinical trialist, etc.). They will form a global advisory board that meets frequently. **Tier 2** in this context could include the next set of important physicians in key countries that will be launch markets (for instance, additional specialists in the U.S., and leading experts in Europe or Asia). **Tier 3** might include physicians who are not specialized in the disease but are likely to encounter and refer patients (for example, general neurologists in regions without a specialist center). Engaging those Tier 3 in rare diseases might involve providing them with education so they can identify patients and refer to the Tier 1 centers, rather than relying on them for research input.

One notable aspect of rare diseases is the importance of **evidence generation and community building**, since these conditions are not well known. KOL tiering in rare diseases often overlaps with building a *"Centers of Excellence"* network. Companies might facilitate collaboration among Tier 1 and Tier 2 KOLs to set up diagnostic guidelines, develop patient registries, or establish treatment protocols. For instance, a company might support an **expert consortium** led by Tier 1 KOLs to publish recommendations on managing the rare disease – with Tier 2 KOLs as co-authors – thereby quickly disseminating best practices. Tier 3 doctors then follow these guidelines in their local practice, improving patient care. In this way, even Tier 3 HCPs (who are not core KOLs) become part of the extended influence network via the work of Tier 1 and 2 KOLs.

To highlight criteria differences: the IntuitionLabs guide notes that for a *first-in-class rare disease drug*, **clinical trial experience and publication record** might be weighted most heavily to find KOLs who truly understand the innovative science (about:blank). In contrast, for a new drug in a common disease like diabetes (where many treatments already exist), **high patient volume and peer influence** might be weighted more, since the challenge is identifying clinicians

who can drive adoption in a crowded market (about:blank). This underscores how tiering criteria and strategy can flex based on context – in rare diseases, being a scientific leader is critical (otherwise one might not even encounter the disease), whereas in prevalent diseases, clinical reach and practical influence are also key.

In summary: In oncology, tiering helps manage a large, stratified pool of experts from world-famous oncologists (Tier 1) to community cancer doctors (Tier 3), aligning engagement from global congresses to local tumor boards. In rare diseases, tiering still occurs but given the small expert pool, nearly all key players might be high-tier; engagement is intensive with each of them to build the knowledge base and medical community for the disease. Both cases benefit from a structured approach: clarity on who the Tier 1 KOLs are (so they can be involved in every critical step) and who the extended network is (to disseminate information widely and ensure no region or patient population is left behind).

Role of Technology in KOL Tiering and Management

Identifying, profiling, and continuously updating information on KOLs can be an enormous task – especially in the U.S. with its large healthcare system. Fortunately, in recent years, specialized **KOL management and analytics software platforms** have emerged to assist pharma teams. These tools aggregate vast amounts of data (publications, conference presentations, clinical trial databases, prescription/claims data, social media, and more) to help discover KOLs and assess their influence objectively. They also provide interfaces to **segment KOLs into tiers** and track engagement. Below are some of the commonly used platforms: **Monocl, Veeva Link, H1, and Medmeme**.

- **Monocl (Definitive Healthcare's Monocl Expert Suite):** Monocl is a comprehensive KOL intelligence platform now part of Definitive Healthcare. It maintains a database of over **15 million global experts** across therapeutic areas (about:blank). Users can search for experts and view **detailed profiles** that include each expert's publications, clinical trial involvement, conference talks, affiliations, and even social media impact (about:blank). One of Monocl's strengths is its data visualization – it can generate **dynamic maps** of KOL networks, showing how experts connect to each other (e.g. co-authorship, institutional collaborations) and where they are located geographically (about:blank). Monocl also offers modules like *ExpertInsight* (for deep profiling), *ExpertConnect* (CRM integration for engagement tracking), and *ExpertClaims* (linking KOL profiles to healthcare claims data) (about:blank). For example, using Monocl, a company's medical affairs team could quickly find the top 20 oncology KOLs in California, see each person's latest research, who they collaborate with, and which conferences they've spoken at (about:blank). Platforms like Monocl have essentially transformed KOL mapping from a labor-intensive one-time exercise into an ongoing, data-driven practice – they are continuously updated as new information comes out (e.g. if a KOL publishes a new paper or a physician moves institutions) and even send alerts about important KOL activities. This allows companies to keep their tiering current and actionable (about:blank).

- **H1 (HCP Universe by H1):** H1 is another leading data platform that provides a **360° view of healthcare providers and KOLs**. It aggregates both public and proprietary data: clinical history, scholarly work, trial participation, and even info on patient populations served (about:blank). H1 markets its system as an "AI-powered KOL mapping & engagement" tool (about:blank). It uses algorithms to highlight **"rising stars"** – identifying up-and-coming researchers or clinicians who are gaining influence but might not yet be widely recognized (about:blank). This is particularly useful for medical affairs to get ahead in KOL development. H1 supports multiple use cases: medical (finding trial investigators, identifying advisory board members) and commercial (finding high-prescribing physicians who could be local champions) (about:blank). It also emphasizes connecting disparate data silos (for instance, linking a doctor's clinical outcomes or claims data with their research profile) to give a full picture of their impact (about:blank). Some pharma companies have used H1's tools for specific tasks like **conference planning** – e.g., before a major congress, the system can show which target KOLs will be attending and suggest who to meet, based on their recent activity and collaborations. In one case, a top 10 pharma used H1 to exceed conference engagement goals by identifying which KOLs to engage at the event (about:blank). In summary, H1 helps companies not only map and tier KOLs but also maintain up-to-date intelligence for field teams, so that MSLs always have the latest info on a given KOL's work.

- **Veeva Link (Key People):** Veeva Systems – known for its CRM widely used in pharma – offers a data product called **Veeva Link for Key People** (often referred to simply as Veeva Link, formerly Veeva Oncology Link for its oncology-focused segment). Veeva Link is essentially a curated, continually updated database of KOLs and digital opinion leaders, with extensive profiles of their **influence networks** (about:blank). Because it integrates directly with Veeva's CRM, it allows seamless access for sales reps and MSLs: for example, a rep can pull up a doctor's profile and see their key publications, trial participation, affiliations, and even connections to other experts, all within the CRM interface (about:blank). Veeva Link provides deep data on experts (publications, affiliations, social media) and can surface connections between KOLs (e.g., showing that two doctors trained together or frequently co-author papers). Companies leveraging Veeva Link can more easily segment and target KOLs by seeing who the true leaders are in a given field and how they interact. In essence, platforms like **Veeva, Monocl, and H1 have moved KOL mapping from one-time consulting projects to continuous data-driven platforms with near real-time updates** (about:blank). This ensures that as soon as a KOL does something notable (publishes a new study, speaks at a major conference, etc.), the information is captured – keeping the tiering and engagement approach accurate and up-to-date.

- **Medmeme:** Medmeme is a long-standing platform in the pharma industry known for its massive database of medical and scientific information. It has been described as **"the most comprehensive, continuously updated, and integrated online repository of disseminated medical science information"** (Med Affairs Building Up its Strategic Muscle). Medmeme historically focuses on capturing data from scientific publications, conference presentations, and other medical communications. For example, Medmeme tracks thousands of medical conferences and indexes the abstracts presented, as well as virtually all PubMed-indexed journal articles, to build profiles of experts based on their publication and speaking history. Medical affairs teams use Medmeme to identify which KOLs are actively talking about a disease at conferences, who is publishing on relevant topics, and even how often each KOL's work is cited or mentioned. Recently, Medmeme launched a platform called **Medmeme Delta**, which uses proprietary algorithms as an objective solution to validate decisions and measure results of medical activities (Med Affairs Building Up its Strategic Muscle). While Medmeme may not have the same CRM integration as Veeva or the network visualization of Monocl, it is valued for the **depth of its content coverage** – ensuring no important publication or presentation by a potential KOL is missed. When segmenting by tiers, a company might use Medmeme's analytics to set thresholds (e.g., Tier 1 KOLs = those who have ≥X conference presentations and ≥Y publications in the last 3 years) or to find "hidden gems" (someone who hasn't been on the radar but has a sudden spike in relevant publications). Medmeme's data can also help validate KOL influence by showing how widely their research has been disseminated.

In addition to these, there are other notable tools and data providers: for example, **IQVIA's** KOL offerings (which leverage large healthcare databases and graph analytics (about:blank)), specialized tools like **MDoutlook Lumineer** (focusing on certain specialties and combining expert human analysis with data), and social media analytics tools like **Symplur** (to identify digital KOLs via healthcare hashtags and online engagement). The key benefit across all these technologies is that they allow pharma companies to **use data to guide KOL tiering and engagement decisions**, rather than relying solely on anecdotal knowledge or manual research. By having a centralized, data-driven KOL platform, companies can quickly generate **scorecards for KOLs** (covering all their metrics in one place) and even have algorithms suggest a tier ranking. This not only saves time but also supports compliance (since decisions can be backed by objective criteria). Moreover, technology platforms often include features to **track interactions** – e.g., logging each touchpoint with a KOL – which helps in analyzing engagement effectiveness and ensuring appropriate frequency per tier.

Best Practices and Compliance Considerations (U.S. Focus)

Implementing KOL tiering effectively requires following best practices in both strategy and compliance, especially given the regulatory environment in the United States. Below are some key guidelines:

1. Establish Clear, Objective Tiering Criteria: As discussed, define your criteria and scoring system for tiering before labeling KOLs. This could be a point system or threshold (for example,

any KOL with X number of high-impact publications and a leadership position might automatically qualify as Tier 1). The goal is to make the process as **objective and auditable** as possible (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). Having clear criteria helps avoid bias (e.g. favoring someone just because they are personable or well-known to the team). An objective approach was highlighted in a recent solution by Baker Tilly, which developed a detailed **tiering methodology and algorithm** to evaluate KOLs' level of expertise and continuously assign them to tiers (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). This kind of transparency in how tiers are determined is important not just internally, but also for compliance – you can demonstrate that KOLs are chosen for their scientific or clinical merit, not for unrelated commercial reasons.

2. Regularly Update and Revalidate Tiers: KOL influence is not static. People win awards, publish breakthrough studies, move institutions, or conversely, they retire or become less active. A KOL tiering from two years ago may be outdated today. Best practice is to **review and update the tiering at least annually**, if not continuously. Many companies now use the aforementioned data platforms to keep an eye on changes. For example, if a Tier 2 KOL suddenly is senior author on a New England Journal paper, that might prompt moving them to Tier 1. Or if a Tier 1 KOL has taken a non-clinical job (reducing their direct influence on practice), you might downgrade their tier since their network impact might wane. Always incorporate fresh data – new publications, new trial roles, new social media trends – so the tiering reflects the current landscape (about:blank). In addition, solicit feedback from field teams: MSLs and reps can provide on-the-ground intelligence (perhaps a local doctor is now leading a big multi-hospital consortium, making them more influential – something not obvious from publication metrics). Regular calibration ensures your engagement efforts remain directed at the right people.

3. Align Engagement Plans with Tier Definitions: Ensure that your **engagement frequency and type** are formally tied to the tier. This alignment should be documented in your SOPs (Standard Operating Procedures) or playbooks. For instance, a company might specify: *"Tier 1 KOLs: global advisory boards 2×/year, MSL visit monthly, invite to speak at national congress symposia; Tier 2 KOLs: regional advisory board 1×/year, MSL visit quarterly, include in speaker bureaus for local events; Tier 3 KOLs: MSL touchpoints 2×/year, invite to local educational meetings."* Having such guidelines prevents under- or over-engagement. It also helps field teams plan their time – for example, MSLs might each be given a list of Tier 1 and 2 KOLs in their region to focus on deeply, versus a broader list of Tier 3 to cover occasionally. As one report noted, segmentation enables **field force resource deployment** to be optimized – reps/MSLs focus more on high-priority physicians and adjust call frequency accordingly (about:blank) (about:blank). By setting these standards, you ensure consistency across the organization in how KOLs are approached.

4. Cross-Functional Coordination: KOL tiering should be a collaborative effort between Medical Affairs, Commercial (Marketing/Sales), and often Clinical Development. Different teams bring different insights – medical may focus on scientific leadership, commercial may focus on prescribing influence, and clinical might identify investigators. Bringing these perspectives

together (usually led by Medical Affairs to maintain a scientific focus) results in a well-rounded tiering and a unified **KOL engagement plan**. It ensures that once tiers are set, all teams know the plan: e.g., Marketing knows which doctors to feature in speaker programs (likely Tier 1 or 2), Sales knows which doctors might be key targets or speakers in their territory, and Medical knows whom to approach for clinical trial collaborations or deep scientific discussions. A unified approach prevents duplication (such as multiple people reaching out to the same KOL separately) and ensures the KOL experiences one coherent relationship with the company. Many companies have **KOL management teams or committees** that meet periodically to review tiering and coordinate outreach across functions.

5. Compliance with the Sunshine Act and Transparency: In the U.S., the **Physician Payments Sunshine Act (Open Payments)** requires that pharmaceutical and device manufacturers **report virtually all transfers of value to physicians and teaching hospitals** (about:blank). This means any honoraria, consulting fees, meals, travel, or other payments provided to KOLs will become public record in the Open Payments database. Compliance best practice is to make sure that engaging a KOL (especially Tier 1 who may receive larger consulting fees for big projects) is done with full transparency and proper documentation. When tiering KOLs, it's wise to also cross-check the **Open Payments database** to see how much that KOL is already being paid by your company or others (about:blank). This can inform decisions: if a particular KOL has very high earnings from industry, you might be cautious about further engagements to avoid the appearance of undue influence. Conversely, Sunshine data can highlight if a KOL has strong ties to a competitor (lots of payments from another company), which might affect whether you consider them neutral or how you differentiate your engagement approach (about:blank). Always ensure that any compensation offered to KOLs is in line with **Fair Market Value (FMV)** (see next point) and that the arrangements are for legitimate services (advisory, speaking, etc.). All such interactions should be approved by compliance and ultimately reported as required by law. Keeping a clean record in Open Payments (i.e., payments that are reasonable and for bona fide services) helps maintain trust and avoid regulatory scrutiny.

6. Fair Market Value (FMV) and Anti-Kickback Compliance: KOL tiering and engagement planning must be done under the umbrella of U.S. anti-kickback statutes and related regulations. In practical terms, this means **never using KOL engagements as a reward for prescribing** or as an inducement to prescribe. The OIG (Office of Inspector General) has scrutinized speaker programs and advisory boards for this reason. A robust tiering process with documented criteria helps demonstrate that KOLs are chosen for their expertise and influence, not their prescription volumes. Additionally, each KOL interaction that involves payment should be compensated at a **fair market value rate** commensurate with the KOL's qualifications and the task. Many companies have FMV grids (hourly or daily rates based on the physician's specialty, experience, and credentials) to ensure consistency. The Baker Tilly *kolNOW* tool, for example, uses a **pre-tiered database of HCPs with FMV rates**, so companies can quickly verify that a given KOL's compensation is appropriate (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform) (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). This helps avoid overpaying a high-value KOL beyond what's defensible. It's also good

practice to have a **cap on engagements per KOL** to prevent any one doctor from being excessively used/paid, and to rotate speakers or advisors when possible. Remember that anti-bribery/anti-corruption laws (like the FCPA) also require careful oversight if any KOLs are outside the U.S. or if the engagements involve government-employed HCPs. Industry experts frequently emphasize understanding the various anti-kickback, anti-corruption, and anti-bribery regulations that affect the KOL tiering and compensation process (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform) and designing engagement processes accordingly.

7. Screen KOLs for Compliance Risks: Part of tiering in the U.S. context is ensuring the KOLs you decide to engage (especially in higher tiers) don't pose compliance risks. This means conducting due diligence: check if they have been **sanctioned by any regulatory or medical board**, if they are debarred or excluded from federal programs, or if they have any public controversies (e.g. malpractice issues, disciplinary actions). The Baker Tilly solution explicitly includes verifying if selected HCPs have any regulatory sanctions as part of the tiering process (Baker Tilly Solves Time-consuming KOL Tiering Process With New Online Platform). Engaging a high-tier KOL who later turns out to have undisclosed conflicts or a tainted reputation can be damaging to a company's image. Thus, best practice is to involve compliance/legal in vetting KOLs (especially new ones) – this might include background checks or at least an OIG exclusion list check and a review of their Open Payments records. Also, maintain records of **contracts and agreements** for all KOL engagements (outlining the legitimate services they will provide and the payment). This ensures that if ever questioned (by internal audit or external regulators), the company can show a clear, fair process for KOL selection and compensation.

8. Respect Ethical Boundaries and Independence: Even as you engage KOLs closely, it's crucial to respect their scientific independence and credibility. KOL tiering should **not** lead to treating doctors as if they are part of your sales force. For example, do not pressure a KOL to publicly advocate your product in exchange for being considered "Tier 1" – that would be inappropriate and could backfire. Instead, the relationship should be mutually respectful: you provide information and opportunities; the KOL provides insights and perhaps education to peers, but always based on their honest opinion. U.S. industry guidelines like the **PhRMA Code** on interactions with HCPs provide boundaries (e.g., no extravagant gifts or entertainment, content of exchanges must be informational, etc.) that apply to KOL engagements as well. Particularly for Tier 1 KOLs who may be heavily involved, ensure there are **firewalls between commercial influence and scientific exchange**. For instance, a Tier 1 KOL might be giving input on a clinical trial (a scientific engagement) – marketing teams should not misuse that setting to push marketing messages. Maintaining this professionalism preserves the KOL's trust and reputation. It's often said that KOL engagement is a two-way street; by respecting their expertise and avoiding any quid pro quo implications, you build a genuine partnership rather than a transactional relationship.

9. Leverage Technology for Compliance Tracking: The same platforms that help identify KOLs can assist in compliance tracking. For example, many CRM-based KOL tools will log each

interaction (date, type, attendees) with a KOL. Utilize these to maintain an **engagement log**. Regularly review the log for each Tier 1 and 2 KOL: Are we within our interaction frequency guidelines? Have we documented the topics discussed? Is there any pattern of potential concern (e.g., an MSL straying into off-label discussions without proper context)? Some systems can also integrate with Sunshine Act reporting, making it easier to aggregate all transfers of value for each KOL. Additionally, technology can help ensure **material review** processes are followed – for instance, if an MSL wants to use a new slide deck with a KOL, they should only use approved materials; tracking tools can flag if non-approved content is being shared. By embedding compliance into the workflow (e.g., mandatory fields to fill after a meeting, or alerts if a KOL is being approached too often), you reduce the risk of human error or oversight.

10. Continuous Training and Calibration: Finally, train your teams on both the **tiering methodology** and the compliance do's and don'ts. All relevant staff (Medical Science Liaisons, medical directors, marketing managers, sales reps who work with speaker programs, etc.) should understand why Dr. Smith is Tier 1 and Dr. Jones is Tier 3, and how that affects their approach. This prevents scenarios like an MSL ignoring a Tier 3 rising star who should actually get some attention, or a rep inadvertently giving too much focus to a lower-tier HCP who isn't a priority. Training should also reinforce compliance guidelines specific to KOL interactions – for example, appropriate ways to invite a KOL to an event, rules for providing meals or travel, and how to handle unsolicited questions about off-label uses (typically by referring to Medical Information). Role-playing exercises can help MSLs practice how to engage in a scientific yet compliant way. It's also useful to train on **cultural expectations**: e.g., in the U.S., HCPs expect transparency about why you're meeting and what the follow-up is, so make sure field teams always clarify the purpose (education, seeking advice, etc.) and avoid any perception of pushing for prescriptions.

In conclusion, **KOL tiering is a powerful strategic tool** for pharma companies to effectively engage the medical experts who drive opinion and practice. By defining clear tiers (Tier 1, 2, 3) based on objective criteria, organizations can tailor their engagement – ensuring the most influential KOLs inform high-level strategy while also fostering a broad base of support through regional and local influencers. When supported by robust data (via modern KOL analytics platforms) and executed with strong compliance oversight, KOL tiering leads to more efficient use of resources, deeper relationships with experts, and ultimately better outcomes in product adoption and patient care (about:blank). In the U.S. pharmaceutical market – with its unique regulatory and healthcare landscape – following best practices in KOL tiering and engagement is essential for success, helping companies advance scientific dialogue and achieve commercial goals in an ethical, compliant manner.

Sources: This article integrates insights from industry analyses and case studies on KOL mapping and engagement, including references from IntuitionLabs (2025) (about:blank) (about:blank), Aissel's thought leadership on KOL tiering (KOL Tiering: Enhancing Targeted Outreach in Healthcare) (KOL Tiering: Enhancing Targeted Outreach in Healthcare), consulting case examples in rare diseases (KOL mapping: Rare disease stakeholder engagement - Putnam)

(KOL mapping: Rare disease stakeholder engagement - Putnam), and technology platform descriptions (Monocl, H1, Veeva, Medmeme) (about:blank) (about:blank), among others. These sources reinforce the concepts of tiered KOL segmentation, criteria used in practice, and the importance of compliance in KOL management in the U.S. market.

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