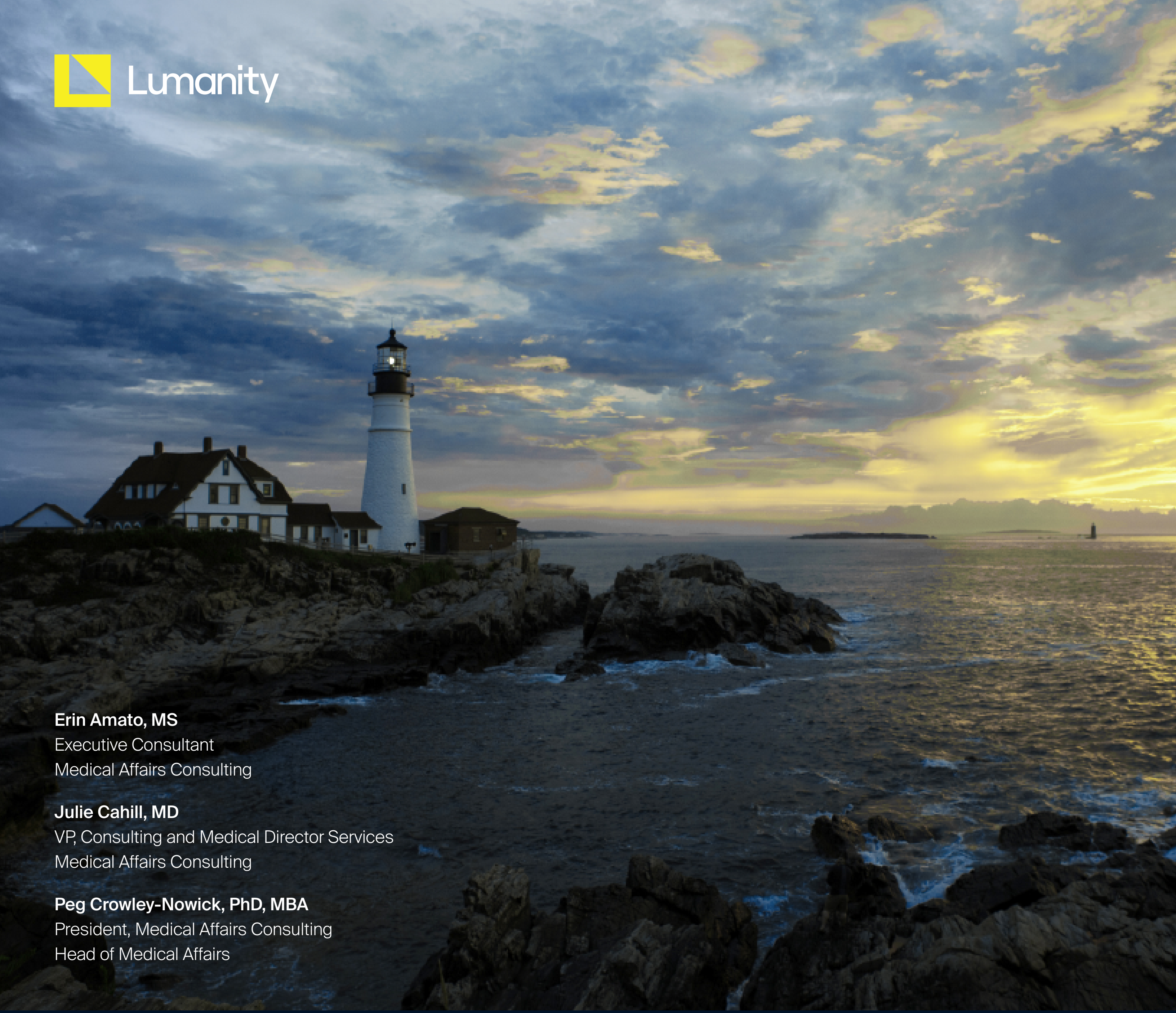

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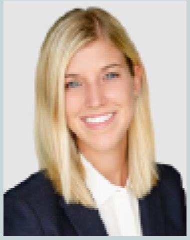
Advancing Clinical Development

by Strategically Leveraging Advisory Boards



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One of the biggest challenges in the biotech and pharmaceutical industry today is achieving market expectations for a new approved therapy.

Clinical development teams are laser focused on regulatory approval. However, it is possible to gain approval and still experience a less than optimal commercialization due to changes in the therapeutic landscape, a lack of data for payer access or a patient-averse regimen. Early incorporation of external advice into the development program decision process can reduce this risk and potentially improve commercialization.

External advice serves as an integral tool to formally validate internal decisions. A well-designed advisory board will strengthen partnerships, provide advice to support clinical trial design, and deliver perspective on trends in the real-world clinical landscape. The advice gained may shape strategy and inform decisions to accelerate development and commercialization of an investigational therapy.

Our Medical Affairs Consulting team at Lumanity focuses on early and late development advisory meetings as well as Medical Affairs specific meetings. We focus on delivering insights that are focused, aligned with the objectives, and can immediately be translated into action in your program. Over the past 15 years we have engaged many clients and shared tips on how to design, plan, and develop an effective advisory board. We are sharing this information broadly now to advance the industry and support strategic advising programs.

1. Agenda

A well thought out agenda with defined objectives can set the course.

Clearly identifying the goals of the meeting and what should be accomplished will set the foundation and help focus the advisors to ensure enough time is devoted to the discussion and garner key insights.

Some questions to consider when developing the agenda:

- Are presentations needed? If so, in what capacity? How will each presentation inform a productive discussion that meets our objectives?
- How can we streamline the content so there is less of a didactic-focus and more time for engaging discussion?
  - We recommend limited slides that contain only the essential information necessary to tell the story and initiate an informed discussion. Presentations should be 10 minutes or less.
- Would a pre-read be beneficial so the advisors can refresh on their own prior to the meeting?
  - Additional detailed or technical information can be provided as part of a pre-read for advisors to prepare for the meeting and reduce presentation time.
- How can we structure the session topics and overall meeting design to ensure we ask the appropriate questions?
- Would interactive technology support the objectives we are trying to achieve?
  - For example: posing questions as a quick anonymous poll during the meeting can gauge perceptions without influence from their peers, allow everyone's voice to be heard, and stimulate a group discussion around the polling results.

Defining the rationale and potential impact of holding an advisory board is critical. Asking the simple questions, "What is the purpose of holding this meeting?" and "How does this align with our strategy? Our business needs?" will ensure that the advisory board will provide a meaningful impact and demonstrate the value Medical Affairs teams provide, rather than simply checking a box.

2. Chairperson

An external advisor chairing the meeting brings independent thinking to the program and can support engagement of the advisors to enhance discussion.

An external chair can set the tone for the meeting, allow advisors to feel comfortable sharing their knowledge and expertise among their peers, and facilitate a sense of community. Creating a dialog and developing a sense of community can be a challenge if an industry member is the main moderator.

Some factors to consider when choosing a chair:

- **Experience and Expertise:** Is this advisor a true expert or leader in the therapeutic area or topic(s) of interest? What is the rationale for selecting them as chair for this meeting? Does the company have a relationship with them? Are they well known among the scientific and medical community? Do they sit on the guidelines? Have they published recently? Are they plugged into the digital space?
- **Communication and Personality:** Is this advisor engaging? Do they have a demonstrated ability to facilitate group conversations? Have they presented at a conference recently that either generated strong engagement or resonated well with the audience?
- **Advocacy and Scientific Partnership:** Is this advisor a known partner or scientific advocate for your company? Are they familiar with your drug / have they participated in your clinical trials? Has the company engaged with them in a similar role previously?

Choosing a chair that a panel of advisors, as well as the internal company team, respects is important. The chair may even inspire a higher invitation acceptance rate from the prospective advisors. Additionally, selecting a chair that is comfortable, engaged, and aligned with the key strategic questions for the meeting is critical, as they will ultimately drive and facilitate discussion across the panel. In addition, the chair will help steer or focus the conversation as needed, to ensure the advisory board stays the course and reaches the defined objectives as set in the agenda.

3. Audience

Who is sitting at the table can significantly influence the outcome of your advisory board meeting.

Your agenda, topics of interest, and key questions should influence, guide, and drive who you select as an advisor. Having a renowned thought leader who may even be a scientific partner for the company may not be the top priority if the focus of the advisory board is beyond their main area of interest / expertise.

Some questions to consider for identifying external attendees:

- Do these advisors have the appropriate expertise to answer your questions? Would inclusion of other disciplines or other practitioner types be beneficial?
- Do you have a diverse and well-balanced panel? Is geographical distribution (either regional or global representation) important for the meeting?
- Do you have community representation or is the panel predominantly academic? Are your questions more research-focused or are you looking to capture insights on real-world experience?

In addition to the advisors, careful selection of the internal panel is equally as important.

Ensuring the right people from the company are present will not only allow the advisors to feel at ease and comfortable that their questions can be addressed but also *allow them to feel heard.*

Some questions to consider for identifying internal attendees:

- Is global representation needed or is this a region-specific meeting?
- Do you have clinical development team members present who are highly knowledgeable of the study design as well as any relevant preclinical or clinical data?
- Are there key decision-makers that will be in attendance? If not, should there be?
- Are there any program leads or disease state experts that would be able to contribute to the conversation?
- Are biomarkers or translational research a core component on the agenda that would warrant team members with this expertise?
- Would having field team members present be important for follow-up discussions?
- Will the attendees feel comfortable engaging, responding to questions or asking follow-up questions to drive a deeper discussion?

4. Internal Speakers

Internal speakers with polished presentations can set the tone.

Short, concise sessions with limited slides that display focused information designed to enhance the conversation are recommended, as the meeting should primarily be discussion-based.

Some best practices for effective presentations:

- **Short and Concise:** Keep the slides and timing of the presentations to a minimum (i.e., 10 min in length). Follow the 80:20 rule for the design of the meeting (80% discussion and 20% presentation) to maximize insight gathering potential.
- **Simplify the Visual:** The intent is not to have the audience read the slides but rather for the slides to complement the speaker. The slides should focus on the top takeaways with easy-to-discern content, such as legible data tables, figures, and study designs.
  - *Reminder:* If there is a strong need to show several slides, consider sending a pre-read that may also contain the planned presentation slides for the advisors to review on their own ahead of time.
- **Speaker Meetings:** This can't be emphasized enough. Not all of the internal speakers may be on the medical team leading this project; therefore, taking the time to get the team members up to speed and create an opportunity to receive their input can make a huge difference in the end product. Prior to slide development, meet with each of the speakers and talk them through the planned agenda, the attendees, and the overall objectives / expectations. Use this time to gain their feedback, outline the next steps, and provide firm deadlines as to when you need content with ample time for review.
  - In addition to the internal speaker call with the medical affairs project lead, consider inviting them to join the pre-meeting chair call as well to hear their perspective and create an opportunity for engagement ahead of the meeting day.
- **Slide Review:** Rehearse, rehearse, rehearse. This may seem obvious, but devoting time to fully walk through the presentation a few days prior to the advisory board allows for any last-minute slide rearrangement or updates, section transitions, and clear roles and responsibilities when it comes to facilitation. Including the chair on this meeting is also a core component of the slide review.

5. Discussion Guide

A focused, strategic discussion guide will optimize insight capturing and in turn, help to maximize impact.

Advisory boards are an opportunity to ask your external stakeholders those "big questions" and inspire innovative thinking that can foster new ideas and potential development strategies. A discussion guide serves as an integral tool to help cultivate those insights by highlighting your top questions to ask.

Some aspects to consider when developing a discussion guide:

- Build out your discussion guide by agenda topic; what are the questions medical, clinical development, or any other key internal stakeholder needs answered?
- It's imperative to include the specific questions you need but also consider weaving in some future-looking or "big picture" ones as well, making sure to frame all questions in a strategic manner.
- Prioritize the nonnegotiable questions in each section. Include the top 3 or so that you must ask the panel on a slide and incorporate these into the presentation deck for a focused discussion.
- Allow for input from the broader team, especially the team members selected as internal speakers, as the discussion guide should have full alignment with the teams participating.

This curated, comprehensive list of prioritized questions, organized by agenda topic can act as a "north star" for the moderators of the meeting (e.g., the external chair and the internal project lead). Finally, development of the discussion guide should be a cross-functional effort and be aligned with the overall objectives and business needs.

6. Reporting

The value of an advisory board is enhanced when the insights are shared in a simple and objective-driven report.

A concise document that highlights the overall key take aways and defined action items from the meeting will help medical effectively communicate the insights provided by the advisors.

To kickstart this process, a post-meeting debrief immediately following conclusion of the advisory board will help ensure the key takeaways and action items are aligned with the internal medical team from the start, and establish a solid structure for the report. A core goal of the executive summary report is to synthesize the insights collected in a strategic manner with enough context that will allow the audience, regardless of whether they attended, to immediately grasp the most important aspects of the advisory board on page one of the report. From there, other pertinent details supporting those top points can be included along with the recommended actions for the company to consider.

Following the executive summary, a detailed report is generated that captures the specificity of what was discussed, which includes individualized comments and anecdotes during the meeting.

This reporting approach allows the medical team to quickly communicate the impact and value of the insights collected, validate what was heard by their external stakeholders and allow for swift action as needed, to the broader team.

Summary

Executing on these top tips will equip you with the tools needed to successfully lead and develop impactful advisory boards that are aligned with both the medical strategy and business objectives of the organization. Our medical affairs experts draw from our foundation of scientific knowledge, regulatory expertise, and industry experience to develop medical strategy, cross-functional communication plans, and programs to engage patients and providers. Success in these areas allows the medical team to provide leadership and demonstrate maximum value to your brand and organization. Our clients also benefit from broader capabilities and expertise across commercial, market access, real world evidence HEOR, and communications. Lumanity is here to advance your program.

Contact us at Lumanity.com for more information.

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