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Global Medical Affairs / Scientific Strategy

Best Practices for Planning an Effective Medical Advisory Board
**Medical Affairs** is the broad term that describes the department within a pharmaceutical or medical device company that interacts with physicians and other healthcare professionals who utilize or are involved with research related to the companies' products.

**3 Central Areas of Medical Affairs.**
What is an Advisory Board?

“An advisory board is a body that provides non-binding strategic advice to the management of a corporation, organization, or foundation”

- A meeting that comprises an appropriate number of appropriately selected medical advisors who provide the company with relevant advice
- Run for the benefit of the company, not the attendees
- An agenda that will optimise time spent with advisors and provide key insights
Some examples of Medical Advisory Board (MAB) include:

- Advise on the long-term strategy of the product
- Perform research gap analysis
- Proposals for new research programs, investigator competitions, and grants programs
- The scientific achievements and future potential of current investigators, including the evaluation of whether an investigator's term of appointment should be renewed
- Other matters concerning scientific programs and performance upon which the president requests advice and recommendations
Start with the End in Mind!

What is your meeting objective?

- Critiquing data
- Informing about medical strategy
- Competitor/Issues management
- Gap analysis
- Understanding the clinical landscape
- Clinical protocol studies
What can be Discussed?

- Legitimate exchange of medical and scientific information
- Can be pre-launch/pre-licence

What might make it promotional?

- Use of brand names in invite, slides, materials
- Use of branding, or branding colors
- An agenda that does not allow adequate time for advice to be given (suggested 70/30 discussion/presentation)
- Having sales colleagues present
- Disproportion of Medical Advisors to company representatives at the MAB.
Implementing an Effective Advisory Board

Key Points to Consider

1. Understand your environment, challenges and opportunities
   Define the objectives, knowledge gaps and desired outputs

2. Make careful choices about who to invite and how to engage them to ensure objectives are reached
   A meeting agenda that will optimize time spent with advisors and provide key insights

3. Detailed briefings, effective chairing, create ample opportunity for discussion

4. Briefly capture the core insights and areas of consensus in an output format that meets the needs
Choosing Participants

- Define the purpose of the meeting to define the criteria for choosing experts
- Ensure representation from key regions
- Ensure a diversity of views are represented
- Level of contribution by the participants
- Consider any historical or interpersonal dynamics
Selecting a Chairperson

Choosing a chairperson

• The most senior opinion leader is not always an effective chair

• The **ideal chair** is:
  ▪ collaborative
  ▪ able to maintain control of discussions to keep the meeting on target
  ▪ encourages interaction
  ▪ credible
  ▪ knowledgeable
  ▪ impartial
  ▪ goal-oriented
Briefing the Chairperson

Briefing the chairperson

• Assess interest in chairing the meeting
• Prior to the meeting: review objectives, draft agenda, and desired outputs
• Immediately prior to meeting, a full run-through of the agenda and desired outputs
• Develop a short “Chair’s Guide” to assist the chair

The case for a co-chair

• Can aid the effectiveness of advisory boards
• Co-chair from the company can help ensure exactly the information the company needs is obtained in the meeting

Balancing stimuli vs discussion

• A major pitfall is including too many presentations and allowing too little time for discussion
• Discussion time should be balanced with the need to present information
Ensuring All Voices are Heard

- Another major pitfall is allowing the discussion to be dominated by 2–3 voices
- Variety of mechanisms to ensure this is avoided
  - Chair briefed to obtain information from each expert in turn
  - Room choreography
  - Asking the chair to request opposing views
Briefing and Facilitating

For break-out sessions:

1. Always include a facilitator
2. Always provide printed, clear instructions
3. Allow adequate time for feedback/advice
Recording and Sharing Proceedings

- **Acknowledge recorder** at start of meeting – electronic and writer

- Agree in advance what needs:
  - to be shared with advisors following the meeting
  - to be kept on file

- **Agree with Stakeholders** how they would like to review meeting proceedings/outputs
Post-meeting Materials

The importance of post-meeting engagement

- Prepare template thank you letters in advance, for rapid distribution following the meeting
- Where possible, share a summary/minutes with advisors
- Share the minutes with other internal stakeholders

• Optimizing the post-meeting report
- Two report formats can work well:

**Option 1: Summary report** in Microsoft Word, typically with an Executive Summary condensing the key outcomes into one page followed by ~10 pages of key supporting discussion points

**Option 2: PowerPoint report** containing an Executive Summary, summary of discussions in response to key meeting questions, incorporating key slides from the actual meeting with callout boxes to emphasise key observations
Advisory Board Planning – Project Timelines
A Medical Advisory Board is nothing less than a Project with a “temporary endeavor undertaken to create a unique product, service or result. A project is temporary in that it has a defined beginning and end in time, and therefore defined scope and resources.

A project is unique in that it is not a routine operation, but a specific set of operations [tasks] designed to accomplish a singular goal.”

Project governance is the framework which ensures that the project has been correctly initiated and is being executed in accordance with best project management practice.
Advisory Board Planning – Project Timelines

Triple constraint

Time

Cost

Quality

Scope

Compliance
## Advisory Board Planning - Timeline*

*Timeline assumption: you have appropriate internal and cross-functional resources available to execute on this advisory board

<table>
<thead>
<tr>
<th>July</th>
<th>August</th>
<th>September</th>
<th>October</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4 weeks</strong></td>
<td></td>
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<tr>
<td><strong>2 weeks</strong></td>
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<td><strong>2 weeks</strong></td>
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<tr>
<td><strong>3–4 weeks</strong></td>
<td></td>
<td><strong>8 weeks</strong></td>
<td></td>
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<tr>
<td><strong>2 weeks</strong></td>
<td></td>
<td><strong>3 weeks</strong></td>
<td><strong>2 weeks</strong></td>
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<tr>
<td><strong>1 week</strong></td>
<td><strong>12 weeks</strong></td>
<td></td>
<td><strong>2 weeks</strong></td>
</tr>
</tbody>
</table>

### Activities
- Confirm budget, draft AB objectives/questions, confirm HCP availability (collect HCP CVs), determine AB location, venue
- Compliance: activity approval
- Compliance: venue approval
- Vendor contract: Procurement & Legal
- Slides: technical content development
- Compliance: KOL CVs/FMV/honorarium
- Compliance: Govt./VA/CDC approval
- Draft KOL Consulting Agreements with Legal; KOL feedback/revisions
- Material approval (MLR)
- Compliance close-out/final reconciliation/executive summary

### Timeline Phases
- **Initiation**
- **Planning**
- **Execution**
- **Close-Out**
- **Monitoring & Controlling**
RACI (Responsible, Accountable, Consulted, and Informed) Matrix for Medical Advisory Boards

<table>
<thead>
<tr>
<th>Task/Deliverable</th>
<th>Suggested Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GMH</td>
</tr>
<tr>
<td>Send internal SAVE the Date for AB, Slide Review and Dinner</td>
<td></td>
</tr>
<tr>
<td>Confirm vendor and negotiate proposal/budget</td>
<td></td>
</tr>
<tr>
<td>Complete due diligence</td>
<td></td>
</tr>
<tr>
<td>Liaise with consultants</td>
<td></td>
</tr>
<tr>
<td>Address terms of reference for invitations</td>
<td></td>
</tr>
<tr>
<td>Finalize invitation (include est. for attendance)</td>
<td></td>
</tr>
<tr>
<td>Conduct presentations</td>
<td></td>
</tr>
<tr>
<td>Develop draft meeting agenda</td>
<td></td>
</tr>
<tr>
<td>Obtain KOL CVs (if available), and schedule and facilitate meetings with vendors and weekly in the</td>
<td></td>
</tr>
<tr>
<td>Coordinate and host initial meeting to determine business need, strategy, goals and preliminary details (location, congress, venue, dates, advisors, home country of KOLs, slide review, faculty dinner, vendor, etc.)</td>
<td></td>
</tr>
<tr>
<td>Complete Meeting Planner Form and confirm Global Meeting Planner (GMP) availability</td>
<td></td>
</tr>
<tr>
<td>Identify Core Team (CT) and internal presenters</td>
<td>R/A</td>
</tr>
<tr>
<td>Confirm internal availability and finalize date(s)</td>
<td>A</td>
</tr>
<tr>
<td>Identify vendor(s) and request proposals (for content support, KOL management, logistics, transcription, executive summary, security, etc.). Decide what capacity you are utilizing vendor(s.)</td>
<td>A/R</td>
</tr>
<tr>
<td>Set up Project SharePoint Site</td>
<td></td>
</tr>
</tbody>
</table>
Risk Management - is a process for dealing with uncertain events that have the potential to negatively impact the project. A risk management plan encompasses identification, response planning, and ongoing monitoring of risk.

**Issues** = Has happened or will happen

**Risks** = May or may not happen
Project Risk Management is:

• The management of anticipated events that could impact the project in a negative way

• Logical steps taken to minimize the negative consequences of the risks

• Action to respond to risk events
1. **Identify Project Risks**
   - Brainstorming, Delphi Technique, Ishikawa (aka. Fishbone) Diagram
   - Interviews/Subject Matter Experts (SME’s)/Risk Breakdown Structure (RBS)/Historical Retrieval

2. **Assess Project Risks**
   - Probability - (H/M/L) or another scale
   - Impact - (H/M/L) or another scale
   - Overall Threat – (Probability x Impact)

3. **Develop a Response Plan**
   1) **Accept the Risk** (Ac) or
   2) **Manage the Risk** (ATM)
      - **Avoid the Risk**
      - **Transfer the Risk**
      - **Mitigate the Risk**
   3) **Develop Contingency Plans**
      - Evaluate the **Risk Management Plan**

4. **Define Contingency Triggers**
   - Weak Trigger – Not clear or timely
   - Strong Trigger – Very Clear … Data available
## Risk Management / Risk Register

<table>
<thead>
<tr>
<th>Risk Identification</th>
<th>Qualitative Rating</th>
<th>Risk Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Description</td>
<td>Probability (P) 1–5</td>
<td>Impact (I) 1–5</td>
</tr>
<tr>
<td>Risk Category</td>
<td>1–5</td>
<td>1–5</td>
</tr>
</tbody>
</table>
Advisory Board Planning – Project Management Tools
Risk Management / Risk Register

• **Risk Description:** The risk stated in a complete sentence which states the cause of the risk, the risk, and the effect that the risk causes to the project.

• **Risk Category:** Categorization of risks by area of project affected, source of risk or other useful category.

• **Probability:** The likelihood that a risk or opportunity will occur (on a scale from 0 to 5 with 5 being the highest).

• **Impact:** The impact of the risk on the project if the risk occurs (scale from 0 to 5 with 5 being the highest).

• **Risk Score:** Determined by multiplying probability and impact (scale from 0 to 25).

• **Risk Ranking:** A priority list which is determined by the relative ranking of the risks with the number one being the highest risk score.

• **Risk Response:** The action which is to be taken if this risk occurs.

• **Trigger:** Something which indicates that a risk is about to occur or has already occurred.

• **Risk Owner:** The person who the project manager assigns to watch for triggers, and manage the risk response if the risk occurs.

• **A-T-M:** Avoid - Transfer - Mitigate
### Risk Management Likelihood Scale

<table>
<thead>
<tr>
<th>Score</th>
<th>Very low 1</th>
<th>Low 2</th>
<th>Moderate 3</th>
<th>High 4</th>
<th>Very high 5</th>
</tr>
</thead>
</table>

### Risk Management Impact Scale

<table>
<thead>
<tr>
<th>Objective</th>
<th>Very low 1</th>
<th>Low 2</th>
<th>Moderate 3</th>
<th>High 4</th>
<th>Very high 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>Insignificant cost increase</td>
<td>&lt;10% cost increase</td>
<td>10-20% cost increase</td>
<td>20-40% cost increase</td>
<td>&gt;40% cost increase</td>
</tr>
<tr>
<td>Time</td>
<td>Insignificant time increase</td>
<td>&lt;5% time increase</td>
<td>5-10% time increase</td>
<td>10-20% time increase</td>
<td>&gt;20% time increase</td>
</tr>
<tr>
<td>Scope</td>
<td>Scope decrease barely noticeable</td>
<td>Minor areas of scope affected</td>
<td>Major areas of scope affected</td>
<td>Scope reduction unacceptable to Sponsor</td>
<td>Project end item is effectively useless</td>
</tr>
<tr>
<td>Quality</td>
<td>Quality degradation barely noticeable</td>
<td>Only very demanding applications are affected</td>
<td>Quality reduction requires Sponsor approval</td>
<td>Quality reduction unacceptable to Sponsor</td>
<td>Project end item is effectively useless</td>
</tr>
</tbody>
</table>
## Advisory Board Planning – Project Management Tools
### Risk Management

<table>
<thead>
<tr>
<th>Risk ID</th>
<th>Risk Description</th>
<th>Risk Category</th>
<th>Probability (P)</th>
<th>Impact (I)</th>
<th>Risk Score (P × I)</th>
<th>Risk Rank</th>
<th>Accept / Manage</th>
<th>Risk Response</th>
<th>Trigger</th>
<th>Risk Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>External vendor that manages AB logistics has limited financial capability to cover suddenly increased operating expenses</td>
<td>Planning</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>2</td>
<td>M</td>
<td>Initiate PO# increase approval</td>
<td>Communi</td>
<td>PM</td>
</tr>
<tr>
<td>1.1</td>
<td>Ad Board venue selection is at risk of not being secured on time when no external vendor is used</td>
<td>Planning</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>1</td>
<td>T</td>
<td>Consider use of experienced internal planning group</td>
<td>Venue not contracted 2+ months out from the AB Date.</td>
<td>PM</td>
</tr>
<tr>
<td>1.2</td>
<td>KOL consulting contracts not executed on time per the GMA AB SOP</td>
<td>Execution</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>3</td>
<td>A c</td>
<td>Finalize as soon as possible at the AB meeting</td>
<td>Consulting agreement not finalized by the AB date.</td>
<td>PM</td>
</tr>
</tbody>
</table>

Ac = Accept  
T = Transfer  
M = Mitigate  
A = Avoid
Conclusion - Final Tips

- **Start with the end in mind**
- Allow **plenty of time** to plan and give lots of notice
- Know your **advisors** – if possible
- Ensure a **diversity** of views are represented
- Don’t be overly ambitious in terms of agenda
- Ensure that your data expert IS an **expert**
- Think carefully about **pre-work**
- **Brief tasks/workshops** using simple language
- Try to ensure that **everyone contributes**
- **Rehearse** the opening and closing of the meeting
- **Preparation! Preparation! Preparation!**
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References


Thank you

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Questions?