Covering a medical advisory board meeting and creating the report or publication: The role of the professional medical writer

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Abstract
Medical advisory board meetings are an integral part of the healthcare and, in particular, the pharmaceutical landscape. These meetings serve to identify knowledge gaps in a specific therapeutic area and to suggest measures that could be implemented and followed to bridge the identified gaps. Although the preparation and hosting of these meetings and the creation of the meeting reports and publications are tasks often assigned to medical writers, there are no standard guidelines or templates on how to accomplish these tasks. In this article, we report our experiences with medical advisory board meetings and the processes that we follow to get the most out of these meetings.

Introduction
A medical advisory board is a group of healthcare professionals, headed by a chairperson who directs the meeting to discuss the available literature according to a predefined agenda and to come up with a consensus or guidelines and/or an agenda for the next meeting. The meetings are normally conducted in an informal and flexible manner and issues that were not included in the initial agenda may also be discussed.

Medical advisory boards have been a part of the pharmaceutical landscape for a long time. They provide a robust, market-informed view of unmet medical or healthcare needs. They are a good platform to combine and compare the experience and expertise of practicing healthcare professionals (HCPs) and key opinion leaders

(KOLs) with the available literature to ultimately come up with region-specific and practical solutions for healthcare issues. The organisation of medical advisory board meetings is a reliable way by which pharmaceutical companies can gain the insights required to achieve a better understanding and interpretation of the various medical benefits of their pharmaceutical products.

Other ways in which pharmaceutical companies engage with HCPs and patients are: the support of scientific congresses, data generation (pre- and post-marketing studies), implementation of educational programs for HCPs and patients, promotional material review, and by providing answers to product-related medical inquiries. Out of all the above-mentioned strategies, medical advisory boards are considered to be of the greatest value to pharmaceutical companies, as the exchange of scientific knowledge between the members leads to non-binding but informed guidance on various business aspects.

The preparation of the medical advisory board meeting, meeting attendance, and the preparation of the meeting report are tasks often assigned to professional medical writers. The present review aims to guide the medical writers through the process of conducting a medical advisory board meeting and to help them gain a better understanding of the basic composition and functioning of a medical advisory board, the various roles of the medical writer, and the development of a scientific report that can later be published or circulated among the scientific community.

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Composition of a medical advisory board

A medical advisory board consists of KOLs in the respective field along with a chairperson who moderates the meeting and steers the panel members to a conclusion. As a rule, the KOLs are selected by the pharmaceutical company, however in some cases representatives of medical societies (related to a pharmaceutical product or a disease state) are also engaged as KOLs. Discussions at medical advisory board meetings are usually facilitated by a chairperson who is unanimously selected by the board's members.

Although the majority of medical advisory boards are initiated by pharmaceutical companies, they are sometimes organised by publication companies or other third parties, such as sponsored or non-sponsored medical societies or by medical communication companies.

To ensure a productive and ethical discussion, a specific code of conduct and a stringent protocol is followed throughout the medical advisory board meeting. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, 2012, is an elaborate code of conduct for pharmaceutical companies' engagements with HCPs providing consulting services, such as scientific consulting, market research, and medical advisory board participation.[1] In addition, in recent years many national codes have been updated to provide a pre-set code of conduct for running medical advisory board meetings, including those from the UK (Association of the British Pharmaceutical Industry, ABPI), the US (Pharmaceutical Research and Manufacturers of America, PhRMA), Canada (Research-Based Pharmaceutical Companies), and Australia (Medicines Australia).[2-5]

Purpose of medical advisory board meetings

All medical advisory board meetings are objective-driven with the purpose to identify unmet needs in a field of medicine. It is important for the medical writer to understand the purpose and objective of the meeting before he or she initiates the assignment. As mentioned above, the primary goal of a medical advisory

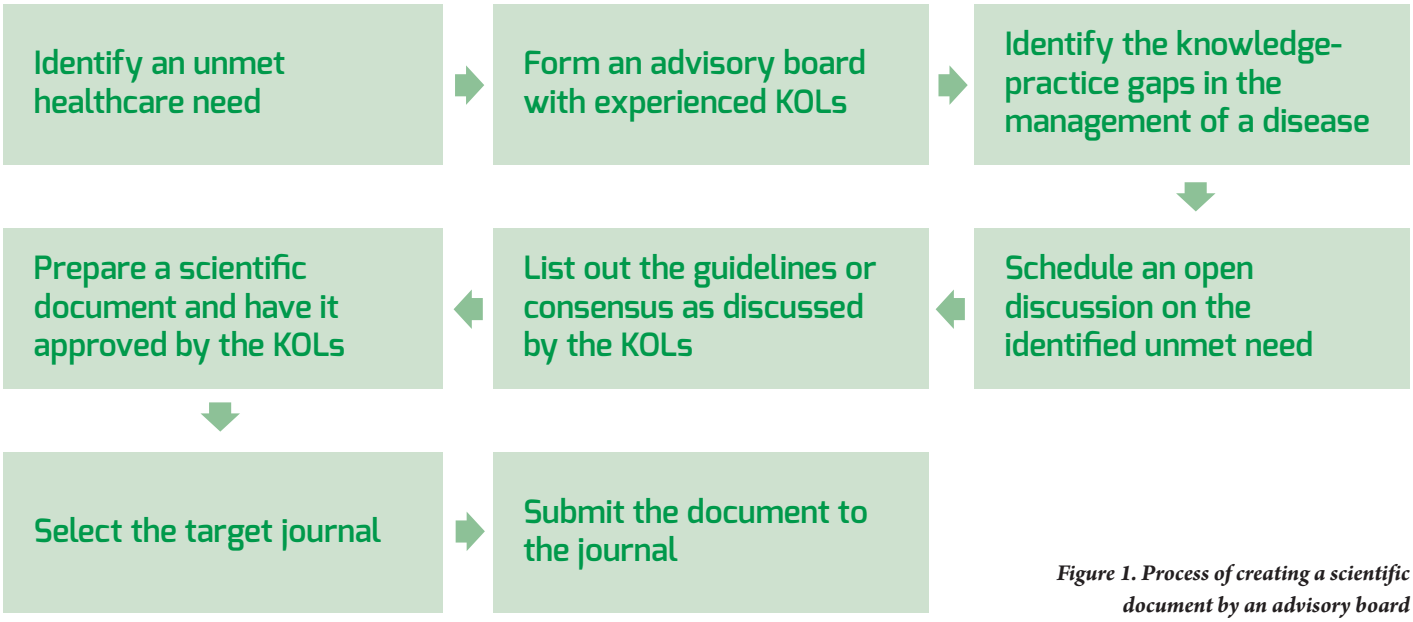

Figure 1. Process of creating a scientific document by an advisory board

board meeting is to gather insights on possible research opportunities, including guidance on the clinical development and trial protocols, as well as unmet health care needs that might drive future clinical strategies. Usually, the information collected during a medical advisory board meeting is later shared with peers and other healthcare stakeholders to achieve better patient outcomes (Figure 1). However, in some cases, if 'no consensus' is achieved after the meeting, then pharmaceutical companies might keep the information to themselves, or share it with participating KOLs only.

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Role of the professional medical writer

The medical writer may accompany a medical advisory board from the preparation/conception stage through to the execution and finally to the writing and publishing of the report. The medical writer might be assigned various responsibilities depending on the nature and objectives of the meeting. These responsibilities may include, but are not limited to, engaging KOLs for a medical advisory board, preparing questionnaires, conducting online surveys (with the aim of understanding unmet needs), preparing a pre-meeting report to be shared with KOLs, preparing an executive summary, preparing presentations for the medical advisory board meeting, hosting a medical advisory board, capturing the minutes of the meeting, preparing the meeting report, and modifying the report into a publication-ready document (if applicable). The roles and responsibilities of a medical writer change as per the requirements of the organising body and stage of the meeting (Figure 2). Hence, as a medical writer, it is important to have a comprehensive discussion with the organising body at the start of the project in order to understand their needs and expectations.

Pre-meeting stage

Medical writers may be asked to perform multiple duties during a medical advisory board meeting, and it is, therefore, necessary that they prepare themselves well before attending the meeting. A few things that medical writers should consider are:

1. **Communication:** Clear communication with the organising body is essential for understanding the objectives of the meeting and the nature of the deliverables, i.e. it is important to know why this particular medical advisory board meeting is being conducted, what unmet needs are to be addressed, and what kind of deliverable is expected at the end of the meeting. The medical writer might also assist the organising body in selecting the KOLs for the meeting.
2. **Invitation:** The organising body might ask the medical writer to assist with sending invitations to the KOLs, along with an introductory email for the advisory meeting, if required.
3. **Getting acquainted and collecting information:** The next important step is to get acquainted with the therapeutic area to be discussed at the meeting. The medical writer should do a thorough literature search and read about the therapeutic area for which the meeting is to be conducted. For instance, if the medical advisory board has been organised to develop a set of clinical practice guidelines for a particular disease in a particular region, the writer should acquaint himself/herself with the current scenario of the disease in that region, the clinical practice guidelines followed (if any), knowledge gaps among the HCPs of that region, and global practice guidelines for that disease. This process will help the medical writer gain a better understanding of the therapeutic area to be discussed. This also familiarises the writer with the medical terminology or jargon that KOLs

Pre-meeting Stage

- Assist the sponsor in selecting key opinion leaders (KOLs) and chairpersons
- Send invites to KOLs and chairpersons
- Research the KOLs thoroughly
- Participate in discussions with sponsor/KOLs/chairperson to understand the objectives of the meeting
- Discuss the nature of deliverable after the advisory board meeting
- Perform a literature search
- Prepare questionnaire/survey questions
- Selection of target journal
- Prepare the presentation or first draft of the proposed meeting

Meeting Stage

- Reach the meeting venue with time to spare
- Dress in business attire
- Introduce himself or herself to all participating members
- Arrange for audio/visual recording
- Listen carefully and document all relevant points
- Conclude the meeting and inform the participants about the timelines for the development of the deliverable

Post-meeting Stage

- Prepare and share minutes of the meeting with the participants
- Update the executive summary according to the comments and suggestions made by the panel members
- Initiate the drafting of the publication document
- Share the final draft for approval by KOLs and sponsor
- Submit the final, approved manuscript draft to the desired journal

Role of the professional medical writer at an advisory board meeting

might use during the discussion, thereby making it easier for the writer to capture the minutes of the meeting.

It is also important that medical writers familiarise themselves with the KOLs who might attend the meeting. If permissible, it is useful to have a discussion with the participating KOLs in advance of the meeting, in order to gain an understanding of their perspectives and expectations for the meeting. This can also help the writer identify the critical points to be captured during the meeting.

If the medical advisory board meeting is an extension of one or more previous meetings, the medical writer should request the minutes and reports of the previous meetings from the organising body. This is yet another important set of information that can help the medical writer stay focused on the key points that are to be discussed.

4. **Questionnaires, presentations, and reports:** Particularly in the case of an opening meeting, the organising body may ask the medical writer to prepare a pre-meeting survey questionnaire or a presentation or reports about the unmet needs and objectives of the meeting. Hence, the medical writer needs to understand the requirements of the organising body and prepare the document as desired.

5. **Executive summary:** In some cases, the organising body may also ask the medical writer to prepare an executive summary of the problem statement, proposals, and the key discussion points to be covered during the meeting. The executive summary is intended to aid the KOLs in decision making and help them arrive at a consensus.

Meeting stage

Medical writers should reach the meeting venue well in advance. They should also be professionally dressed and carry their business cards, which will help them introduce themselves to other participants. The capturing of the minutes of the meeting is the most important duty of a medical writer at an advisory board meeting. It is relatively difficult to capture all the important information manually; hence the medical writer might have to rely on audio-visual aids to effectively capture the meeting minutes. It is therefore important that the medical writer asks the organising body to provide technical support during the meeting. This not only facilitates the collection of information, but also ensures that any information relevant to the topic is not missed. The medical writer should be prepared with an outline of the meeting with the sessions written out in his/her notes to capture the minutes of the meeting. It is important that the writer pays extra attention to the discussions; in the case of disagreement, the opinions of both sides have to be captured. The organising body might ask the medical writer to conclude the meeting and inform the participating members about the prospective timelines for sharing the minutes of

the meeting and also the updated executive summary report.

Post-meeting stage

1. **Minutes of Meeting:** Minutes of Meeting (MoM) is the first and an essential document that the medical writer has to deliver after attending the medical advisory board meeting. The medical writer is usually asked to deliver the MoM to the organising body and to the participating KOLs within 48 hours of the meeting. The MoM not only provides an overview of the meeting but also helps to lay the foundation on which the final report will be developed. There is no standard format in which an MoM is to be prepared and the medical writer should ask the organising body if they require the MoM in a specific format. Ideally, an MoM should include particulars about the meeting, information about the organising body and the participating KOLs, background information about the unmet need that was discussed, the objective of the current meeting, highlights of the discussion, and future directions (as suggested by the KOLs).
2. **Update the executive summary:** The next step is to update the executive summary (that was prepared prior to the meeting) in accordance with the comments and suggestions provided by the participating KOLs.
3. **Final report:** Once the MoM is approved by the organising body and the KOLs, the medical writer should start preparing the final report. The content of the report may vary according to the type of publication document desired by the organising body. In general, the meeting report contains detailed information about the subject discussed during the meeting and the outcomes of the meeting. Although there is no fixed format for writing the report, it is expected that the report is centred on the objective. An ideal report includes detailed background information on the therapeutic area for which the meeting was conducted, highlights the unmet needs/knowledge-practice gaps among the HCPs, contains the objective of the meeting, discusses the insights provided by the KOLs and compares them with the currently available medical literature, and mentions possible future directions. The meeting report often acts as a guide on possible research opportunities, including guidance on the clinical development and trial protocols in that therapeutic area. It should therefore be written in a manner that allows it to add value to the existing literature.
4. **Publication support:** Once a consensus is achieved, the final report is formatted as per the requirements of the selected journal and the medical writer submits the article for publication/sharing with the scientific community. However, if the meeting does not arrive at any consensus then the final report is retained by the organising body for their future reference.

Key Messages

- Advisory board meetings are an integral part of the pharmaceutical and healthcare landscape, which are used for sharing knowledge among various stakeholders.
- The medical writer should understand the objective of the advisory board meeting.
- Some of the medical writer's key responsibilities are:
  - To have a detailed discussion with the organising body and key opinion leaders (KOLs) to understand their expectations, nature of the final report, and timelines
  - To carry out a comprehensive literature search well in advance of the meeting
  - To listen carefully and document all relevant points
  - To share the minutes of meeting (MoM) within 48 hours of the meeting
  - To prepare the final report and have it approved by the KOLs
  - To submit the final approved draft (if the meeting reaches the stage of consensus) to the desired journal for publication

Acknowledgements

The authors would like to acknowledge the clients who gave them the opportunity to work on various medical advisory board projects and to develop their processes, as well as the team of medical writers at Turacoz Healthcare Solutions.

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