Regulatory Matters

SECTION EDITORS

Clare Chang
clarechangphd@gmail.com

Zuo Yen Lee
zuoyen.lee@gmail.com

Editorial

The briefing document is one of the many types of documents that a medical writer prepares during a clinical development programme. It is an essential document for facilitating interactions between pharmaceutical companies and health authorities, mainly to seek scientific advice for drug development. There are different guidelines provided by health authorities to guide companies in preparing the meetings/interactions and the briefing documents. In this article, Clare Chang helps us understand what a briefing document is and the medical writer's role in preparing the document.

Zuo Yen

Briefing documents: Facilitating health authority interactions

Clare Chang
AstraZeneca
clarechangephd@gmail.com

doi: 10.56012/ucdt2648

Abstract

Briefing documents, essential for facilitating interactions between pharmaceutical companies and health authorities like the US FDA and EMA, provide critical information necessary for obtaining scientific advice throughout drug development. These documents encompass product background, development status, regulatory interactions, and specific questions from Sponsors, significantly influencing regulatory decision-making. The complexity of briefing documents varies based on development stages, requiring detailed preparation by medical writers to ensure clarity and relevance. Successful interactions rely on effective collaboration, flexibility, and thorough documentation of outcomes, enabling Sponsors to make informed decisions and continuously refine their clinical development programmes based on health authority feedback.

Introduction

Briefing documents, also known as briefing packages or briefing books, are documents developed by pharmaceutical or biotechnology company that help to facilitate their interaction with the intended health authority. These interactions, such as meetings or written responses, may happen at different stages of drug development and the intention is often to obtain scientific advice on development that would eventually shape product and clinical development through to market authorisation and beyond. Product development includes those for new molecular entities and new therapeutic biological products, biosimilars, and generics. Here, the focus will be preparing briefing documents for new molecular entities and new therapeutic biological products.

Different health authorities around the world have their own guidelines on the types of interactions and the contents of briefing documents.

Overview of the type of meetings with the US FDA and EMA

Different health authorities around the world have their own guidelines on the types of interactions and the contents of briefing documents. The types of meetings available with the US FDA and the EMA are listed in Table 1. The latest guidance for regulatory meetings with the US FDA was recently updated per July 17, 2024.[1]

Content of the briefing document

In general, the structure and content of briefing documents are similar for the US FDA and EMA with some regional differences.[2] The US FDA provides general guidance on topics to be included depending on the meeting type or purpose without a strict structure, whereas the EMA provides templates for the specific interactions.[3]

General content of briefing documents include:

1. Product background information (e.g., proposed indication and other relevant background information including for the targeted disease)
2. Current development status and plans (chemistry, manufacturing and controls, non-clinical, clinical)
3. Regulatory status and regulatory interactions
4. Purpose of meeting
5. List of questions and company's rationale and positions (including scientific data to support position)
6. Meeting attendees (role and function)

Table 1. Type of Health Authority Interactions with the FDA and EMA

Meeting type examples	Timing and logistics
US FDA [a,1]	
Type A Development stalled; urgent FDA input required (e.g., important safety issue)	Response to request: 14 days Meeting package receipt: With meeting request Preliminary responses: No later than 2 days before meeting Meeting date: Within 30 days from request Meeting minutes receipt: 30 days after meeting
Type B Pre-IND, pre-EUA, pre-BLA/NDA, overall development of Breakthrough Therapy Designation, regenerative medicine and advanced therapy	Response to request: 21 days Meeting package receipt: No later than 30 days before meeting or WRO Preliminary responses: No later than 2 days before meeting Meeting date: Within 60 days from request Meeting minutes receipt: 30 days after meeting
Type B (EOP) Meeting EOP1 (for products that will be considered for market approval), EOP2/Pre-Phase 3	Response to request: 14 days Meeting package receipt: No later than 50 days before meeting or WRO Preliminary responses: No later than 5 days before meeting Meeting date: Within 70 days from request Meeting minutes receipt: 30 days after meeting
Type C Others, not A, B, C, D, or INTERACT. Can be about product development or review	Response to request: 21 days Meeting package receipt: No later than 47 days before meeting or WRO Preliminary responses: No later than 5 days before meeting Meeting date: Within 75 days from request Meeting minutes receipt: 30 days after meeting Note: for consultation on new surrogate endpoints, logistics may differ
Type D Focuses on a narrow set of issues (<2 topics)	Response to request: 14 days Meeting package receipt: With meeting request Preliminary responses: No later than 5 days before meeting Meeting date: Within 50 days from request Meeting minutes receipt: 30 days after meeting
INTERACT For very novel products and development programmes (e.g., pre-IND)	Response to request: 21 days Meeting package receipt: With meeting request Preliminary responses: No later than 5 days before meeting Meeting date: Within 75 days from request Meeting minutes receipt: preliminary responses are annotated and resent within 30 calendar days if advice provided changes as a result of the meeting
EMA [3,4,5]	
Scientific advice and protocol assistance Advice at any stage of drug development (e.g., consult about appropriateness of study designs and robustness of data)	The EMA typically follows a timeline for their procedures. It is recommended to check the procedure date being followed for the respective applications. • Scientific advice and protocol assistance: Usually written response only. Meeting only when discussion is required. • PRIME: In exploratory clinical trial phase with preliminary clinical evidence. Early PRIME entry is available for academia and small medium enterprises. Pre-submission support is available to assess eligibility. • Orphan designation: Pre-submission meeting is recommended (at least 2 months before the planned submission date) to increase success rate.
PRIME Priority medicines, similar to FDA Breakthrough Therapy Designation (special support provided)	
Orphan designation	

Abbreviations: BLA, biologic license application; EOP, end of phase; EUA, emergency use authorisation; IND, investigational new drug; INTERACT, Initial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs; NDA, new drug application; WRO, written response only

[a] The FDA has a number of meeting types based on the drug products such as biosimilar, generics, and prescription drugs. This table only shows the interaction for prescription drugs.

Medical writer's role in briefing documents and what to expect

Depending on the stage of development, complexities in the product's development programme, and the project teams' dynamics, briefing documents can range vastly in their complexity. As a medical writer, it is important to do some "research" and get to know the programme and its history before kicking off the project. This preparation helps not only to get the medical writer up to speed with the project, but it also sheds light on the current problem the project team is facing and hence the reason for the interaction.

In the content listed above (items 1-6), the core of the briefing document is item 5 – List of questions and company's rationale and positions (including scientific data to support said position). Besides item 5, the other sections are relatively straightforward and could be drafted well in advance of the kick-off if all the relevant background information can be provided ahead of time.

Consequently, important information to request includes documents related to the drug product (e.g., investigator's brochure and the study design or protocol) and documents related to prior interactions (e.g., briefing documents and meeting minutes from prior interactions). The information will help the writer understand the development history and understand what the intended health authority currently understands about the development program. This is important while developing the briefing document as the writer can help the team be mindful of gaps between the last interaction and the current one when developing the background and framing the questions/company positions.

The last and most important piece of content to ask for are the Sponsor's questions and preliminary company position (item 5). Oftentimes, it is not possible to obtain granular details on these, and during the briefing document's development, the most time will be spent on this content. Nonetheless, it is good to touch base with the team on a general direction so the writer can prepare a starting position and take things from there.

Another aspect is the logistics. Depending on the type of interactions, the logistics and timing differ and the feedback from the health authority need to fit into the Sponsor's clinical development programme. Table 1 provides an overview of logistics and timing and is useful in developing the briefing document's development timelines.

In general, it is good to obtain the information or background information described above from the project team prior to the kick-off meeting so that the team can agree on the proposed timelines and the preliminary content.

Briefing document kick-off

If time permits, the above preparations can be done ahead of the kick-off and a preliminary draft or a skeleton can be developed for the kick-off meeting. Working with the team, below is a checklist for the kick-off:

1. Background and rationale for the briefing document (usually led by the team).
2. Outline and agree on the logistics (how document development will work, timing of each step, who else will contribute content directly, who the reviewers and approvers are). This is best led by the medical writer.
3. Agree on the structure of the document (e.g., important sections to keep and the amount of detail). This is also best led by the medical writer.
   a. Background: Ideally the background would be in good shape at this point, provided the background materials were available ahead of the meeting. That being said, some further background may be required to support the company position, and these will need to be discussed and highlighted.
   b. Questions: A good amount of time should be spent on the list of questions. In a clinical programme there are often overlaps in topics and it is important to develop the logic and rationale of whether certain questions should be standalone questions or better placed as a subset of another question (e.g., Question 1 by itself or Question 1a and 1b).
   c. Company position: Each question would also contain a company position with the Sponsor's proposal for tackling the question asked. Again, a good amount of time should be allocated to this to obtain the team's thoughts and overall position.

Briefing document development

Depending on the complexity of the briefing document, the development process can be smooth or quite turbulent. If the briefing document is a very standard procedure and all the functions are prepared with their questions and their position, then the process can be quite smooth. On the contrary, there are times when the strategy continuously changes, and new information arises. Therefore, it is important to be flexible and be mindful of working with a lot of ambiguity.

As mentioned, the questions and company positions are the most important parts in the briefing document. Therefore, it is an art to frame the questions appropriately. It is recommended to frame the question in a positive light and in a way that can ascertain a clear answer. For example, one way of asking is, "Does the Agency agree that …?" rather than "What do you think about…?". Similarly, when framing the company position in relation to the question asked, it is important to back up the recommendation from the company with good scientific justifications.

The questions and company positions are the most important parts in the briefing document. Therefore, it is an art to frame the questions appropriately. It is recommended to frame the question in a positive light and in a way that can ascertain a clear answer.

A simple example of a question is as follows:

Question: Does the US FDA agree that a 4-month safety update is not required and can be waived for Drug A's proposed supplemental new drug application (sNDA) for the XXX indication?

Company Position: The clinical development programme for Drug A to support the XXX indication includes three clinical studies: one pharmacokinetic study (study 1); one long-term safety study (study 2); and one pivotal efficacy and safety study (study 3). All three studies will be provided in the sNDA to support the proposed indication. There are no further clinical studies that are ongoing following the proposed sNDA application. Therefore, a 4-month safety update report is not warranted.

Meeting preparations

On some occasions, the medical writer may also attend meetings with the health authorities. Regardless of whether medical writers attend or not, it is often beneficial to participate in the meeting rehearsals along with the team. Important discussions around potential questions and gaps in information submitted that may be challenged could arise. These discussions are important in understanding the rationale and proposed responses, which are important to further understand the project.

After the interaction

Once the interaction has taken place, the health authority often provides the Sponsor with the outcome of the meeting in the form of meeting minutes. These agreements are stored as part of the history of the clinical development programme. The Sponsor is often recommended to implement the suggestions but depending on the suggestion and the overall programme, the Sponsor may or may not implement all the recommendations due to the company's plans. If the medical writer continues the project, they will be able to work with the team and implement the required changes to relevant documents seamlessly.

Conclusion

In conclusion, briefing documents serve as crucial tools for facilitating interactions between pharmaceutical/biotechnology companies and health authorities. The medical writer plays a vital role in preparing these documents by understanding project history, identifying gaps, and formulating well-reasoned questions and positions. Effective collaboration and flexibility during the document development process enhance the likelihood of positive outcomes. At the end of the day, these documents help Sponsors make informed decisions regarding implementation of suggestions and recommendations for future clinical development.

Acknowledgements

Clare Chang would like to thank Zuo Yen for her patience and review of this article.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author is employed by AstraZeneca. The author declares no conflicts of interest.

References

1. US FDA. Formal Meetings and Requests for Feedback for CBER-Regulated Products. 2024 [cited 2025 Apr 04]. Available from: https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/formal-meetings-and-requests-feedback-cber-regulated-products.
2. Trilogy Writing and Consulting. How to streamline regulatory authority meetings. 2022 [cited 2025 Apr 04.]. Available from: https://trilogywriting.com/document/how-to-streamline-regulatory-authority-meetings/.
3. EMA. Scientific advice and protocol assistance. 2023 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-advice-and-protocol-assistance
4. EMA. PRIME: priority medicines. 2025 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines.
5. EMA. Applying for orphan designation. 2015 [cited 2025 Apr 04]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/research-and-

Author information

Clare Chang is a clinical regulatory writer at AstraZeneca with experience in both early and late-stage clinical development. She has been an EMWA volunteer since 2018 mostly involved with the journal. She enjoys coffee, hiking, travelling, reading, and gaming.