Best Practices for Meeting Minutes: Content and Format Considerations to Enhance Process

FDA-Industry IVD Roundtable Meeting
May 15, 2013

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Pre-Submissions and Meetings

- A sponsor or applicant may request a meeting as the preferred mechanism of feedback for a Pre-Sub.
- The intent of this meeting is for FDA staff to provide feedback on specific questions identified in the Pre-Sub
- Should include specific questions regarding review issues relevant to a planned marketing application
- Your meeting request should be concise, yet contain sufficient information to allow FDA to address the focused questions in your meeting request.
- Our advice will be guided by your questions and may not identify all submission requirements

Pre-Submissions and Meetings

Good questions:

- Is the selected study population for this trial appropriate?
- Do you have any concerns about whether the proposed follow-up period is adequate for the proposed clinical study?

Bad questions:

- How large should the sample size be?
- Does the FDA agree that the proposed clinical study protocol is adequate to support the safety and effectiveness of the device in a marketing application?
- Does the FDA agree that the clinical results provided in the background package for the meeting are sufficient to support the safety and effectiveness of the device in a marketing application?

Pre-Submissions and Meetings

- At least 3 business days prior to the meeting, FDA will provide initial written responses to the applicant's questions and FDA's suggestions for additional topics for the meeting, if applicable.

- The written response may be a complete response to the applicant's questions, or may consist of some initial feedback and note the need for further discussion in the meeting.

- If all of the applicant's questions are addressed through prior written responses to the applicant's satisfaction, FDA and the applicant can agree that a meeting is no longer necessary and the written responses provided by email will be considered the final written feedback to the Pre-Submission.

Pre-Submissions and Meetings

- Following the meeting or teleconference, the sponsor should develop draft minutes and provide the draft minutes to FDA within 15 calendar days of the meeting.
- The minutes should summarize the meeting discussions, document how questions were answered, and include any action items.
- FDA will provide any edits to the draft minutes to you via email in a timely manner (generally within 30 days).
- These minutes will become final 15 calendar days after you receive FDA's edits (unless you indicate that there is a disagreement, which would then be resolved)

Meeting Minutes

- The quality of meeting minutes received by OIR from Sponsors varies significantly
- Common to receive minutes from sponsors that require significant time and resources to edit
  - Contain incorrect information
  - Do not contain major meeting conclusions
  - Are prepared more like transcripts than summary minutes of the meeting

Meeting Minutes

Sponsors should:

- Focus on the answers to the Pre-Sub questions
- Think “Big picture”, and not “word-for-word”
- Remember, not *everything* that is said during the meeting needs to be captured
- Focus on specific proposals, agreements and action items

There’s no harm in asking the FDA to summarize their point of view for you at the meeting to ensure that you get it right

Meeting Minutes

Focus on the answers to the Pre-Sub questions:

- Responses with concise explanations, important discussion points, and conclusions per question
- Indicate owner of comments (FDA or sponsor, not by individual)
- Note agreements and disagreements per topic/question.
- The minutes should clearly indicate if no discussion was needed on a particular question and that the sponsor accepted FDA's preliminary response

Example

RECORD OF MEETING

Submission Number:
Product Name:
Sponsor:
Meeting Date/Time:
Meeting Format: (e.g., teleconference, face-to-face)
FDA Attendees:
Sponsor Attendees:

Background:

Questions/Answers Discussed:

Action items:

Attachments/Handouts:

Example

Background: Preliminary responses to the questions included in Q139863 were sent to the sponsor on June 5, 2013. The sponsor had no need for follow-up discussion for questions 1-3 and question 6. The sponsor requested additional discussion regarding FDA's responses to questions 4 and 5 during the meeting.

Questions/Answers Discussed:

4. *Is the selected study population for this trial appropriate?* – The sponsor clarified that the intended use of the device was … and that they chose this study population because of …. The FDA stated ….. After discussion, the FDA recommended that the sponsor include …. types of patients in their study.

5. *Do you have any concerns about whether the proposed follow-up period is adequate for the proposed clinical study?* – The FDA clarified that they were concerned the study period would be too short to allow for adequate numbers of positive cases to be collected. The sponsor stated that based on their analysis, they would achieve the necessary number of positive and negative patients to meet their study endpoints. The FDA reiterated their advice that the sponsor should ensure that their design was sufficient to collect an adequate distribution of results to enable robust estimates of device performance.

Discussion