SOPP 8101.1 Appendix 5 Official Meeting Summary Template

Date:

Meeting ID # [CRMTS]
Application type and number (if applicable)
Product name (if applicable)
Sponsor
Meeting type (A, B, C)
Meeting category (e.g., Pre-IND, End-of Phase 2, Pre-BLA/NDA)
Meeting date & time
Meeting format (e.g., face-to- face, telecom)
Meeting Chair/Leader
Meeting Recorder

Attendees (sponsor/applicant & FDA), titles, affiliations

Background and Objectives

a. Brief history of events leading up to the meeting
b. Cite who requested the meeting (FDA or sponsor/applicant)
c. Reference the meeting request and information package submission by date
d. Context of product development
e. Purpose of the meeting

Discussion

a. Sponsor/applicant questions
b. FDA responses with rationale
c. Key discussion points
   i. Summary of discussion points
   ii. Indicate owner of comments (FDA or sponsor/applicant)
   iii. If no discussion is needed, the minutes should clearly indicate that there was no discussion of the topic by FDA or the sponsor/applicant
d. Discussion of pediatric plan (or deferral/waiver request with rationale) including timeline for conducting pediatric studies, study design, pediatric populations to be evaluated and pediatric formulation to be studied

Decisions/agreements reached

a. Agreements and disagreements should be noted regardless of length of discussion
b. When writing about agreements, disagreements, issues for further discussion, and action items ownership should be acknowledged not as "he said, she said" but as whether the item was conducted by FDA or the sponsor/applicant in general. Action items also should include

dates for follow- up. There should be a record of when discussions occurred and when there was no discussion.

c. Discussion of pediatric plan or whether deferral/waiver was granted, if applicable

Issues requiring further discussion

Action items

a. Description of action
b. Ownership (FDA or Sponsor)
c. Due date or timeline
d. When writing about agreements, disagreements, issues for further discussion, and action items ownership should be acknowledged as to whether the item was raised by FDA or the sponsor in general. Action items also should include dates for follow-up. There should be a record of when discussions occurred and when there was no discussion.

Attachments/Handouts

Copy of materials (e.g. slides) used during discussion at the meeting
PREA Compliance Checklist (for administrative record only)

Chronology

Meeting Minutes Drafted/Author
Meeting Minutes Finalized/Author

[Complete all CRMTS entries upon issuance of the minutes to the sponsor.
Run a CRMTS incomplete data entry report to ensure that all information has been entered.]