Effective Use of the FDA Pre-Submission Process: An Industry View

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FDA FEEDBACK OPTIONS DURING PRE-MARKET REVIEW[1]

What types of FDA feedback?

- Brief clarification questions
- Proposed protocol prior to conducting a major (clinical or animal) study to address a deficiency
- Discussion of deficiencies identified during premarket review of a 510(k), de novo, IDE, HDE, PMA, IND or BLA application or CLIA Waiver by Application

What is are options?

- Brief questions: Teleconferences or e-mails, when communications can be handled by Lead Reviewer or Management review not needed
- Protocol proposal: Pre-Submission
- Deficiency discussions: Submission Issue Meeting

[1] FDA Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff ; Section III.E.

PRE-SUBMISSION PROCESS DURING FDA PRE-MARKET REVIEW

What is it?

- Same title, different purpose

What is its purpose?

- To obtain FDA reviewer(s) feedback on new or revised study design plans, acceptance criteria, subject population, etc.
- Specific to FDA request for additional studies
- Not needed for minor “tweaks” to plans

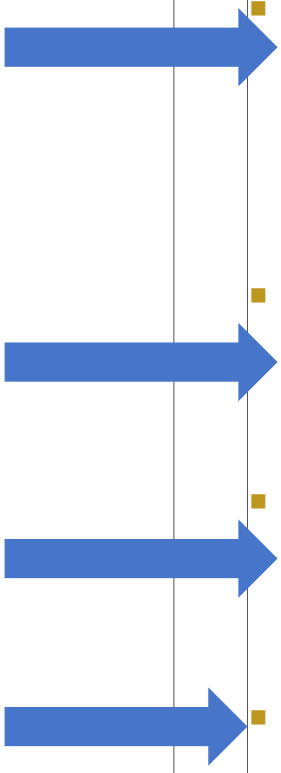
When is it used?

- Infrequently
- After receipt of written FDA review comments on pre-market submission
- After pre-market submission is placed on hold pending receipt of additional requested information and/or data from sponsor

PRE-SUBMISSION CONTENT DURING FDA PRE-MARKET REVIEW

Prior to Pre-Market Submission

- Device Description
- Proposed Intended Use/Indications for Use
- Previous Discussions or Submissions
- Analytical Study Plans
  - Acceptance Criteria
- Clinical Study Plans
  - Acceptance Criteria
- Specific Questions



During Pre-Market Submission

- Proposed Intended Use/Indications for Use
- New Analytical Study Plans
  - New Acceptance Criteria
- New Clinical Study Plans
  - New Acceptance Criteria
- Specific Questions

PRE-SUBMISSION TIMING DURING FDA PRE-MARKET REVIEW

- Not a defined process
- FDA review and feedback timing based on number and complexity of new proposed studies
- 20 days, but within the hold time
- Feedback by e-mail, letter, or teleconference

INDUSTRY EXAMPLES/RECENT EXPERIENCE CASE #3

- Sponsor submitted 510(k) for complex product
- Based on review of data, FDA provided detailed feedback on required new studies and additions to current studies.
- FDA information was communicated in a formal Hold Letter, with the suggestion that the Sponsor may submit proposed new and/or modified studies in a Pre-Submission to FDA for review prior to testing
  - e.g., …you may want to submit a pre-submission…so that we can provide feedback on your proposed plans…
- Sponsor submitted study plans in Pre-Submission and obtained rapid real-time feedback from FDA.
- Both Sponsor and FDA agreed that this process provided transparency on the planned studies, with a positive impact on review times.

Thank you!

For further questions:

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