Pre-Submission/Pre-IDE Recent Experiences

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Recent Pre-Submission/IDE Experiences

- Case Study 1
  - A company submitted a pre-IDE that was comprehensive and complete, and requested a meeting in advance of the questions.
  - The meeting took approximately 4 weeks to schedule.
  - The meeting was productive and both the company and Agency agreed on the actions.
  - Other than a few rounds to get the minutes agreed upon, the process went well.
  - So far, the company is satisfied with the process.

Recent Pre-Submission/IDE Experiences

- Case Study 2
  - A company submitted a pre-IDE for a “refreshed” version of a previous product with minimal “new” technology
  - The pre-IDE focused on representative assays for the new analyzer.
  - Initial response was received within 60 days, however there were an additional 60-90 days of Q&A.
  - It did take multiple rounds of Q&A to reach agreement, with discussions around statistics (methods and experimental power), analytical testing (protocols and data analysis), and clinical studies (involving pediatric subsets when no specific pediatric claims are being made).
  - Overall, the company was satisfied with the process.

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- Case Study 3
  - A company submitted a pre-IDE and held a meeting with FDA to confirm 510(k) requirements. The pre-IDE process seemed quick and comprehensive.
  - Within 6 months the 510(k) was submitted to the agreed upon content.
  - After submission, the company received a letter with numerous questions and additional data requirements.
  - FDA told the company these items are new requirements they were implementing.
  - The company is concerned about the pre-IDE process as they believed the "agreement" from the meeting reflected current Agency thinking, and they were not notified of potential changes.

Recent Pre-Submission/IDE Experiences

- Case Study 4
  - A company submitted their pre-IDE for a new device. The interactions with the Agency went well for the company and were timely.
  - When the 510(k) review began, the company received a number of questions indicating the Agency viewed the device as one that could potentially be used in a Point of Care (POC) environment.
  - The company was upset as this concern was not raised during the pre-IDE discussion.
  - The company believes they made their *intended use* clear in the pre-IDE documentation, discussion, and meeting. The Agency was asking for additional data and experiments even though the company was willing to add labeling to disclaim POC use.

Recent Pre-Submission/IDE Experiences

- Case Study 5
  - The company submitted a pre-IDE with complete content, and had a meeting prior to the 510(k) submission.
  - The company had a very productive and informative meeting and believed they had agreement on clinical studies and data analysis.
  - When the 510(k) questions were received, the Agency asked for method comparison data analysis by alternate methods (Bias at Medical Decision Levels, Bland-Altman & Passing-Bablok) in addition to the Deming regression discussed during the pre-IDE meeting. They also asked for all line-listing (raw data) files.
  - The company was concerned as these alternate statistical methods were not discussed in the pre-IDE, are not required as part of CLSI EP9, and added weeks to their 510(k) clearance.

Recent Pre-Submission/IDE Experiences

- Case Study 6
  - A company submitted a pre-IDE for a product type that has been in the market for years and has a guidance document.
  - The pre-IDE meeting was productive and the company prepared it's 510(k) centered around requirements in the product-specific guidance document and meeting.
  - After submission, the company received a letter outlining several new requirements. Many involved new studies, data generation, and data analysis. The company had to put their submission on an extended hold.
  - The company's concern is that the Agency did not share during the pre-IDE meeting that the guidance document being used was under revision, and that new requirements were coming. If the Agency would have shared the new requirement up front, costly new studies and 510(k) delays could have been avoided.

Recent Pre-Submission/IDE Experiences

- Case Study 7
  - A company submitted a pre-IDE for a flu test that they would like to be CLIA waived as well.
  - The first round of questions was received within a month after pre-IDE submission.
  - Both the company and Agency agreed to a “series” of pre-IDE meetings as the product development and CLIA waiver study design progressed.
  - The company is pleased with the discussions so far, but knows the interaction will be every 2-3 months until the product is submitted. They are optimistic that this product will clear and that CLIA waiver will be successful.

Recent Pre-Submission/IDE Experiences

- Case Study 8
  - A company submitted a pre-IDE for a new biomarker utilizing molecular technology.
  - They received written feedback from FDA within 50 days and held a conference call to clarify questions and points
  - The pre-IDE focused on the clinical plan, and the company and Agency agreed the company would submit supplemental questions on analytical testing via an amendment to the initial pre-IDE at a later date.
  - The company was pleased with the interaction as they were able to finalize clinical plans and adjust enrollment requirements.

Recent Pre-Submission/IDE Experiences

- Case Study 9
  - The company submitted a pre-IDE and received written feedback received in 60 days
  - During the pre-IDE teleconference, FDA provided examples of the reference methods, recommended the use of a flow chart for sample collection, preparation, and testing.
  - They also provided guidance on analytical testing and the appropriate use of test panels as a guidance document for this assay is not available.
  - They also provided advice on discordant sample analysis and expected statistical analyses.
  - FDA also provided their minimum acceptance criteria for sensitivity and specificity.
  - The company is satisfied with the interaction and process.

Recent Pre-Submission/IDE Experiences

- Case Study 10
  - A company submitted a pre-IDE for a new product.
  - The pre-IDE reviewer notified the company early on to let them know he was the reviewer and would be in touch.
  - Within 60 days, questions were received and all issues were resolved within a single round.
  - Most of the dialogue was centered around the predicate device's clearance requirements versus those outlined by FDA for their similar product.
  - The company was satisfied with the experience and will be submitting their 510(k) soon.