Tips for communicating with FDA

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Product

Idea

Learning Objectives

- What's the right time and way to communicate with FDA?
  - How do you know you are ready to talk to the FDA?
  - How do you know you are NOT ready to talk with the FDA?
- Are there common errors investigators make when communicating with FDA?
  - Are there fatal errors? How do I recover?
- What kind of responses can I expect from FDA?

What's the right time and way to communicate with FDA?

- The minute you think you've got a new medical product?
- Just before you get funding for your final clinical study?

- After you've done your homework, when you have questions only FDA can answer.
- Different tolerance for early interactions at
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
  - Center for Devices and Radiological Health (CDRH)

What is homework?

- Develop a likely regulatory path based on what's already on market.
  - Similar route of administration
  - Same molecular class
  - Same metabolic pathway
  - Similar/same target population
  - Similar design or manufacturing elements
  - Online info such as the NHLBI Small Biz Hangouts
    - https://www.youtube.com/playlist?list=PL_ntiNjc6GvlvOEcAmciE3MEkvs-jX7ea

!!!Validate your plan before spending lots of money!!!

	Small Business Office Name	Email contact	Website
CBER	Manufacturers Assistance and Technical Training Branch	Industry.Biologics@fda.hhs.gov	https://www.fda.gov/vaccines-blood-biologics/resources-you-biologics/industry-biologics
CDER	Small Business and Industry Assistance Office	CDERSBIA@fda.hhs.gov	https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia
CDRH	Division of Industry and Consumer Education	DICE@fda.hhs.gov	https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice

Common errors when communicating with FDA

- Please be my consultant….
- What do you want?
- I haven’t heard from you today, AKA do you still love me?
- How do I recover if I realize I’ve overreached?

What kind of responses can I expect from FDA?

- **Thorough**
  - FDA typically provides as much information as possible in their written responses
  - Many times there will be links to guidance documents or similar resources
  - Initial responses may look boilerplate, check to see if more information is expected
- Non-binding
  - FDA reserves the right to modify their expectations even though they are giving you their best current opinion
  - Long lag times between meeting and submission, evolving regulatory field (nanotech, gene and cell therapy)
- Binding
  - FDA intends to commit to what they have agreed to unless additional knowledge emerges (i.e. red cell aplasia, cytokine storm)

Suggested approach and FDA requests

- Guidance documents provide “suggested approaches” – what if I want to do something different?
  - Propose a different approach
  - Defend it scientifically

- FDA is requesting “something”
  - Can I ignore FDA requests? (sometimes)

What to know about visiting FDA

- In-person meeting attendees names must be submitted in advance (with meeting request letter)
- All attendees must have valid government issued ID
  - Seriously! I know someone who had to call in to his meeting **from the parking lot** at White Oak because his drivers license had expired
- Meetings will start and end on time – no overage!
- Spend your time where it matters most
- Summarize your take-aways while in the room with FDA
- Debrief immediately with your team
- Send draft meeting minutes to FDA promptly

Thanks!