# TIP Sheet

## FDA PRE-SUBMISSION ADVICE FOR INVESTIGATIONAL MEDICAL DEVICES

### Tip #1: What is the Pre-Submission Program?
- The FDA encourages IDE sponsors to contact them prior to submission of their IDE applications. These pre-submission meetings can be very beneficial to new sponsor-investigators.

### Tip #2: How do I request a pre-submission meeting with the FDA?
- Submit a formal written request to the FDA for a meeting or teleconference to discuss the new submission.
  - Feedback from these meetings should be documented in meeting minutes
- Your request must include specific questions regarding review issues relevant to a planned IDE or marketing application

### Tip #2: What are the general considerations for the Pre-Submission meeting?
- These meetings may be very beneficial when preparing a submission for a new device that does not clearly fall within an established regulatory pathway
- These meetings may be very beneficial prior to initiating long term preclinical studies
- These meetings may be beneficial when planning a study that does not require an IDE
  - Studies outside of US
    - Exempt or Non-Significant Risk devices
- These meetings may be beneficial before the submission of an IDE
  - Discuss non-clinical data and clinical study design
- These meetings may be beneficial before submission of a marketing application
  - As the sponsor-investigator you can apprise the FDA review team on specifics of the device and clinical study if there have been changes since initiation of the IDE
  - Obtain feedback on preferred data presentation
  - Gain insight into the potential hurdles for approval or clearance

### Tip #3: What are specific considerations for In-Vitro Diagnostic (IVD)?
- These meetings may be beneficial to Sponsor-Investigators who plan to conduct clinical, nonclinical, or analytical studies or submit a marketing application for a new IVD that:
  - Is a multiple device capable of simultaneously testing a large number of analytes
  - Contains a new technology
  - Has a new intended use
  - Includes a new analyte
  - Presents new clinical questions
  - Presents complex data/statistical questions
  - Use a predicate or reference method that is unclear or uncertain

### Tip #4: What documentation must be submitted as part of the FDA’s Pre-Submission process?
- Cover letter that includes the following:
  - Designation of meeting request type (Q-Sub type) (i.e. Pre-sub, Submission Issue etc) Reference this document for further detailed guidance: [http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf](http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf)
  - Sponsor-Investigator contact information
  - Device name
- Q-submission (CTRC template)
**Tip #5: What are the requirements for the package submission?**
- 1 eCopy and 1 hard copy are required
- An electronic copy (eCopy) is defined as an exact duplicate of the paper submission, created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive.
- An eCopy is accompanied by a paper copy of the signed cover letter and the complete paper submission.
- The cover letter signature may be a wet (i.e., ink) signature or a valid digital signature

**Tip #6: What is the current mailing address for this pre-submission meeting and review process?**
- Food and Drug Administration
- Center for Devices and Radiological Health
- Document Control Center – WO66-G609
- 10903 New Hampshire Avenue
- Silver Spring, MD 20993-0002

**Tip #7: What are the Pre-Submission Process Steps and Timelines?**
1. Sponsor submits to the Document Control Center
2. FDA conducts acceptance review (14 days)
3. Meeting/Teleconference requested:
   a. FDA works with sponsor to schedule the meeting/teleconference (21 days)
   b. FDA provides preliminary feedback via email (at least 3 days prior to the meeting/teleconference)
4. FDA provides feedback (75-90 days)
5. After Meeting/Teleconference held:
   a. Sponsor provides draft minutes to Document Control Center (15 days)
   b. FDA reviews/edits minutes (30 days)

**Tip #8: For more information, go to:**
- [http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf)
- or call the Clinical Research Support Center at (303) 724-1111