### Tip 1: As the Sponsor-Investigator and IDE holder, what are my reporting responsibilities to the FDA?

- As the Sponsor-Investigator and holder of an **IDE of a significant risk device**, you are required to submit progress reports to the FDA on a regular basis but no less than once each year.
- As the Sponsor-Investigator of a treatment IND is required to submit progress reports on a semi-annual basis to all reviewing IRBs and FDA until the filing of a marketing application. These reports must be based on the period of time since initial approval of the treatment IDE and shall include the number of patients treated with the device under the treatment IDE, the names of the investigators participating in the treatment IDE, and a brief description of the sponsor’s efforts to pursue marketing approval and/or clearance of the device.

### Tip 2: When is the Progress Report due to the FDA?

- IDE progress reports must be submitted to the FDA Division overseeing the IDE within 60 days of the IDE’s anniversary date.
- The reporting period for the first report starts on the date the IDE went into effect. The date the IDE went into effect is the date when the FDA approved the IDE in writing. This is also knowns as the IDE’s anniversary date.

### Tip 3: Suggested Format for the IDE Progress Report

1. **Basic Elements**
   - IDE Number
   - Device name and indication(s) for use
   - Sponsor’s name, address, phone number, and fax
   - Contact person
2. **Study Progress** (Data from beginning of the study should be reported, unless otherwise indicated.)
   - Brief summary of the study progress in relation to the investigational plan
   - Number of investigators/investigational sites (attach list of investigators)
   - Number of subjects enrolled (by indication or model)
   - Number of devices shipped
   - Brief summary of results
   - Summary of anticipated and unanticipated adverse effects
   - Description of any deviations from the investigational plan by investigators (since last progress report)
3. **Risk Analysis**
   - Summary of any new adverse information (since the last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
   - Reprints of any articles published from data collected from this study
   - New risk analysis, if necessary, based on new information and on study progress
4. **Other Changes**
   - Summary of any changes in manufacturing practices and quality control (including changes not reported in an IDE supplement)
   - Summary of all changes in the investigational plan not required to be submitted in an IDE supplement
5. **Future Plans**
Progress toward product approval/clearance, with projected date of PMA or 510(k) submission

Any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices (NOTE: Actual proposals for these changes should be made in a separate IDE supplement).

Tip #4: How do I prepare the information package for shipment to the FDA?

- Use one of these fonts: Times New Roman or Courier (11 point)
- Print area for all pages should fit on 8.5 by 11 inches paper □
  - Allow margin of 1.5 “ on the left side of page (to avoid obscuring information when the pages are subsequently printed and bound) and 3/8 “ on the other sides.
  - Header and footer information can appear within these margins as long as it is not within 3/8 “ of the edge (to avoid text is lost when pages are subsequently printed and bound)
- When the materials can be securely held together with a standard office staple, then there is no need to place the report in any type of binder.
- When using a binder, indicate on the binder front that the submission is for a Progress Report (you can use an extra copy of the Cover page for this).
  - In the report, begin each section on a new page, use index tabs to mark each section of the submission packet. Don’t use colored paper to separate sections.
  - Provide a table of contents
- Use sequential page numbers
  - For pages in landscape orientation, allow ¾ “ at the top to allow more information to be displayed legibly on the page.
- Use single sided copies
- Keep the copy of the shipping form/air bill for your files

Tip #5: How many copies of the Progress Report do we submit to the FDA?

- Submit 3 sets of documents to the FDA (1 original and 2 copies)
  - Make and keep an extra copy for your own records, additional copies for other parties if needed (e.g. outside funding entity or company providing the investigational drug for the study),
  - Scan a copy of the entire package including shipping form/air bill to the Clinical Research Support Center

Tip #6: Where do I send Progress Reports?

☐ Check your IDE approval letter for details and instructions.
- Unless otherwise noted, all Progress Reports are mailed to:

  Food and Drug Administration
  Center for Devices and Radiological Health
  Document Mail Center - WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, Maryland 20993-0002

Tip #7: For more information, go

to:  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm

or call the Clinical Research Support Center at (303) 724-1111