FDA INSIGHTS

IDE Progress Reports

Understanding and adhering to these guidelines will go a long way in streamlining the review process.

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The progress reports required to accompany Investigational Device Exemptions applications (IDEs) serve several important purposes, although not all are explicitly stated in the regulations: (1) to monitor the progress and conduct of the study; (2) to provide justification for the continuation of the study; and (3) to educate reviewers. Submission of incomplete reports is a common occurrence that, frankly, consumes resources that could be better spent on other projects. Common deficiencies in addressing these three purposes follow.

MONITOR THE PROGRESS AND CONDUCT

(In other words, neither you nor we want to wait until an FDA investigator shows up at your door to find out you have not been adhering to the investigational plan and properly monitoring your study. Equally unsatisfactory for all is finding out at the time of PMA submission.)

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There is a document entitled, *Suggested Format for IDE Progress Reports*, which can be found at http://www.fda.gov/cdrh/dsma/311.html. Although this document does not explain exactly how to put together a report, it does list the type of information that is necessary for every IDE report, that is, for both manufacturer- and investigator-sponsored IDEs. Very often we receive reports that do not contain all of the listed information, requiring us to ask for something we have essentially already asked for through this document. In summary, the following headers should show up in every progress report:

- Basic Information (device and sponsor information and IDE number);
- Study Progress (summary of enrollment, results, adverse events, progress of study, device accountability, deviations from the investigational plan);
- Risk Analysis (new information that could affect the

		Patient follow-up # (%)			Patients with adequate imaging to assess the parameter # (%)				Events occurring before next visit # (%)			
Time of visit	Eligible for visit	Followed	CT	X-ray	Size increase	Endoleak	Migration	Fracture	Conversion	Death	LTF	Not due for next visit
Periop			N/A	N/A	N/A							
30 day												
6 month												
1 year												
Additional years												

Figure 1. An example of a table illustrating patient follow-up accountability information.

risk analysis, reprints of articles from data collected from the study, a new risk analysis, if necessary);

• Changes (to manufacturing or quality control and the investigational plan); and

• Future Plans (projected date of a marketing application submission, any plans to submit future supplemental applications to change the investigation).

As an example, the reporting of protocol deviations is frequently minimal at best, requiring us to pry information out of the sponsor. Given that this is an area of great focus by FDA investigators and during a PMA review, this section should be taken quite seriously. With respect to compliance to the follow-up requirements outlined in the study protocol, we have often sent the following deficiency to sponsors:

Please identify any deviations from the investigational plan. Include in your response patient accountability information, with the following information for each follow-up interval: number due for follow-up; number not yet due for follow-up; number followed; number that missed follow-up; number lost to follow-up or withdrawn; and number deceased. In addition, please specify the number eligible, the number with data for each key parameter (eg, endoleak, migration, integrity, aneurysm size change) at each follow-up interval. (Figure 1 may be of use in addressing this concern.)

JUSTIFYING CONTINUATION OF THE STUDY

(In other words, could we see some data, please? Oh, and could you please put it in a format that allows us to review the information in less than the approximately 175 working hours we have before the response due date?)

One of the sections of every progress report is the summary of the results. Please note that this summary should not consist of case reports for each patient, in the absence of summary data. "Why not?" you might ask. Shear volume. Every IDE requires a report. For endovascular grafts alone, that means we review about 70 such reports each year. We need the summary data to evaluate whether the achieved results are consistent with the expectations for the study. This can only be done by looking at compiled data. The following is a deficiency we have sent out to many sponsors of endovascular graft IDEs that suggests what is commonly submitted and what is needed:

Please provide a summary of your results and adverse device effects. Although the patient line listings you have provided contain the raw data, composite results must also be provided. (Figures 2 and 3 may be useful in addressing this concern.)

In addition, please include definitions for size increase,

	First Year # (%)	Separate column for each additional year # (%)	Total # (%)
Total Number			
Technically Successful Implant			
Perioperative			
Conversion			
Death			
Serious AE			
Endoleak			
Type I			
Type II			
Type III			
Type IV			
Follow-up			
Conversion			
Death			
Rupture			
Serious AE			
New Endoleak			
Type I			
Type II			
Type III			
Type IV			
Continuing Endoleak			
Type I			
Type II			
Type III			
Type IV			
Size Increase			
Migration			
Loss of Device Integrity			

Figure 2. Example of a table presenting data from entire study duration. Data are separated by year of patient enrollment. The sponsor should highlight new data/reports from the latest reporting interval either in this table, a separate table, or in the narrative.

	Conversion # (%)	Death # (%)	Rupture # (%)	Serious AE # (%)	Endoleak # (%)	Size Increase # (%)	Migration # (%)	Loss of Device Integrity # (%)
Perioperative						N/A		
30 days – 6 months								
6 months – 1 year								
Other Intervals								

Figure 3. Another example of a table illustrating data from entire study duration, organized by follow-up interval of observation. The sponsor should highlight new data/reports from the latest reporting interval either in this table, a separate table, or in the narrative.

migration, and serious adverse events; a separate table for serious adverse events; and individual case reports for each death, rupture, and conversion.

Although this example is specific to endovascular grafts, comparable tables could be constructed for all types of devices. Of note is that data should be provided from the beginning of the study.

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EDUCATE REVIEWERS

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One of the best perks of working for the FDA is learning about new technology as it develops and helping to optimize collection of useful information while protecting patient safety. Sharing insights learned during studies through progress reports not only keeps us abreast of patient outcomes, but also gives us the opportunity to refine our recommendations regarding study design and conduct. For example, when we learned of the difficulties encountered when attempting to randomize patients during early endovascular graft studies, we considered the need for alternative study designs.

Investigator-sponsored IDEs often involve broad application of novel devices and provide a source of useful and unique information. Through comprehensive progress reports, we have learned of important patient selection considerations and challenges in applying new technology to more complicated patient populations.

SUMMARY

IDE progress reports are a useful tool in sharing important information and in ensuring on a regular basis that the investigational plan is being followed. Submission of complete reports will avoid the sometimes multiple interactions that can be required to satisfy the reviewers. Ideally, sponsors should use the suggestions in this article to set up a template for reporting to optimize the use of resources by the Agency, as well as themselves. ■

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