Live Case Presentations in IDE Studies – FDA Draft Guidance

04-17-14 • alert • katherine leibowitz

FDA recently released draft guidance on the use of live case presentations in IDE studies. With this draft guidance, FDA intends to improve the quality of information that sponsors submit in IDE applications or supplements, and to reduce the need to submit an IDE supplement solely to conduct a live case presentation after an IDE has been approved. This draft guidance represents an effort by FDA to shift evaluation of the use of live case presentations to a one-time prospective protocol review at the time the original IDE is submitted.

FDA expects few IDE investigations to have a need for live case presentations. When appropriate, live case presentations can increase awareness of the study for potential investigators and facilitate subject recruitment, but care must be taken to avoid violating the FDA regulatory prohibition on promoting investigational devices. The draft guidance explains what to include in the IDE application (or supplement), factors the IRB should consider, what to include in the informed consent (which must be separate from the main study ICF), risk analysis, and data collection and analysis. The draft guidance includes checklists to help sponsors comply.

• • •

If you have any questions or would like more information about these developing issues, please contact the following:

KATHERINE LEIBOWITZ
1-610-896-5788
Katherine.Leibowitz@LeibowitzLawTeam.com