

In view of the careful and systematic work of the CONSORT group, medical writers should read and contemplate the guidance provided by this group.

VIII. MEETINGS WITH THE U.S. FOOD AND DRUG ADMINISTRATION

a. Introduction

The most important meetings with the FDA are the pre-IND meetings, end-of-Phase II meetings, pre-NDA/BLA meetings, advisory committee meetings, and labeling meetings, as summarized below (101,102):

- **Pre-IND meetings.** The sponsor presents data on non-clinical test data on efficacy and safety, data on the characterization and manufacturing of the drug, and the proposed Clinical Study Protocol. The goal is to acquire feedback from the FDA, in an effort to place the clinical trial on “active status,” rather than on “hold.”
- **End-of-Phase II meetings.** After completing the Phase II trial, the sponsor provides proof of concept for the drug or medical device, through data on efficacy from Phase I and Phase II trials, and from non-clinical data. Phase III trial designs are discussed, including information on indications, doses, safety, and manufacturing, suitable for the NDA or BLA.
- **Pre-NDA/BLA meetings.** The sponsor and FDA discuss how the application (NDA or BLA) will be organized.
- **Advisory Committee meetings.** These meetings take place after submitting an NDA or BLA, and are conducted when the FDA needs advice from external experts and thought leaders about the approvability of an application. Advisory Committee Meetings are open to the public. Advisory Committee members discuss the benefits and risks of the drug, and vote on whether to recommend it for FDA approval. The FDA is not required to follow the recommendations of its Advisory Committees, but it usually does. An Advisory Committee is used for about one third of new drugs (103).
- **Labeling meetings.** Labeling meetings are held after an NDA or BLA is submitted and prior to the FDA approval of a drug. These meetings occur at the end of the NDA review process, when the FDA and the sponsor meet to agree on writing that informs physicians of the indications the product has been approved for, the dosages, and adverse drug reactions.

¹⁰¹ U.S. Dept. of Health and Human Services. Food and Drug Administration. Guidance for Industry. Formal meetings with sponsors and applicants for PDUFA products. February 2000 (13 pages).

¹⁰² Grignolo A. *Meeting with the FDA in FDA Regulatory Affairs*. 2nd ed. In: Pisano DJ, Mantus DS, eds. New York, NY: Informa Healthcare, Inc.;109–123.

¹⁰³ Lurie P. Financial conflicts of interest are related to voting patterns at FDA Advisory Committee meetings. *MedGenMed*. 2006;8:22 (1 page).