TIMETABLE

Organizational Meeting _____ (date)
First DMC Meeting _____ (date)
Second DMC Meeting _____ (date)

CONTACT INFORMATION

_____
_____
_____
DMC chairperson
_____
_____
_____
DMC member
_____
_____
_____
DMC biostatistician
_____
_____
_____
PharmaDrug, *Inc*., Chief Medical Officer
_____
_____
_____
PharmaDrug, *Inc*., Director of Drug Safety

APPENDIX A (Synopsis of Clinical Study Protocol)

XXII. CONCLUDING REMARKS

The issue of drug safety can be divided into a handful of topics. The topic of medical manifestations of adverse events is readily appreciated by any layperson, as these often include nausea, vomiting, and low blood cell counts. The topic of definitions is more subtle, as these definitions reflect definitions set forth by regulatory agencies. In addition to definitions, adverse events can fall into other categories, such as classifications created by statisticians, for example, ITT analysis versus PP analysis of adverse events, categories requiring clinical judgment, and categories requiring a knowledge of pharmacology and biochemistry. The above-mentioned topics are a prerequisite for understanding the following topics, that is, the topics of data management and process in clinical trials, as it applies to drug safety. Data management and process encompasses use of various tools for capturing drug safety data, such as case report forms, MedWatch forms, Yellow Card forms, and CIOMS I forms. Data management and process also encompasses tools for transmitting safety data to regulatory agencies, and to nonregulatory agencies, such as the Sponsor and to the DSMC. FDA's Guidance for Industry document on good pharmacovigilance practices provides an indispensable overview, and recommendations, on many of the above topics (413).

[413]Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Good pharmacovigilance practices and pharmacoepidemiologic assessment; March 2005 (20 pp.).