SPONSOR'S DECISIONS AND ANNOUNCEMENTS

In the event that any significant development results from DMC recommendations, *PharmaDrug*, *Inc.*, will be responsible for notifying investigators, regulatory agencies, ethics committees, and institutional review boards (IRBs). The DMC will not make any public announcements without prior written permission from *PharmaDrug*, *Inc.*

TIMETABLE

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

CONTACT INFORMATION

_____
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DMC chairperson
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_____

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

XI. 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