

PERIODIC REPORTS TO THE DMC

Summaries of SAE data will be provided to the DMC members on a monthly basis. Blinded SAE listings will be distributed to the DMC at the first day of each month. DMC members will acknowledge the receipt of, and their review of, these listings, by way of e-mail to the Independent Reporting Statistician and DMC project administrator. If any safety concerns arise, DMC Chair may request the DMC to schedule an ad hoc teleconference as soon as possible. Serious, unexpected AEs will be distributed immediately to all DMC members with summaries and narratives. The Chair may communicate with other members of the DMC, and vice versa, should any safety concerns that may arise.

UNSCHEDULED MEETINGS

PharmaDrug, Inc., reserves the right to request unscheduled meetings of the DMC, for example, in the event of notification of SAEs. Any such request will be made in writing to the DMC Chair. The DMC may request additional meetings with *PharmaDrug* and these requests must be made in writing by the DMC Chair directly to *PharmaDrug*. If the DMC decides to hold an unscheduled meeting, it must notify *PharmaDrug* immediately after the DMC has made the decision to hold this meeting.

DMC RECOMMENDATIONS

At each DMC meeting, the DMC will evaluate the nature and frequency of adverse events, decide on unblinding of safety data, and (if unblinded) evaluate whether there are significant differences in drug safety between the various study arms. The DMC will also evaluate safety issues in individual subjects and determine whether adverse events or laboratory abnormalities represent dose-limiting toxicity.

The DMC may make a recommendation regarding any aspect of the conduct or design of the study, including early termination for safety reasons, dose reduction, dose escalation, change in number of subjects in the trial, termination of a subgroup, or any other modification of the Study Protocol. The DMC Chair will communicate recommendations to sponsor within _____ days of the DMC meeting.

Final decision-making authority regarding the study belongs to the sponsor. If the DMC recommends stopping or modifying the trial, the sponsor may, at its discretion, meet immediately with the DMC to review the available data and recommendations. The sponsor may also seek advice from regulatory bodies or from external experts. The sponsor will make a decision to accept or reject the DMC's recommendation, to accept or reject recommendations from outside experts or regulatory bodies, and will relay its decision to the DMC and to relevant regulatory bodies.

In the event that the sponsor decides to stop, extend, or otherwise modify the trial, it will inform all investigators and the relevant regulatory bodies. The DMC will not make any information public without prior approval from the sponsor.

OUTSIDE EXPERTS

Where an issue cannot be resolved by way of a teleconference, the DMC should convene by way of a face-to-face meeting. The DMC is free to consult outside experts in the event of an impasse, after acquiring written permission from the sponsor. The