- A Closed Session for discussing blinded safety data (if still blinded) and unblinded safety data (if unblinded), and for arriving at recommendations for the Sponsor.
- A Wrap-Up Session for communications between the DMC and the sponsor.

PARTICIPANTS

The Open Session and Wrap-Up session will be open to DMC members and to *PharmaDrug*. Other individuals identified by *PharmaDrug* may also participate in the Open and Wrap-Up sessions. The closed meeting will be for voting members only, optionally with a non-voting Independent Reporting Statistician. It is recognized that including further non-voting members may introduce bias.

REVIEW MATERIALS

Before each scheduled DMC meeting, *PharmaDrug* will prepare a packet of summary materials for the Board's review. These review materials will be sent to DMC members at least one week before each scheduled meeting. The DMC will keep an accurate minute of their discussions. Separate sections will be required for the open and closed sessions. The DMC Chair will sign off any minutes or notes. A sealed copy will be sent to the independent statistician.

The following concerns closed sessions. All DMC members should meet face-to-face in order for the DMC to make any formal recommendations regarding stopping or modifying the study. In the event that a timely face-to-face meeting cannot be held, members of the committee may confer by teleconference. Closed session participants will review information that includes, but not limited to, the following. In closed DMC sessions can consider data summarized by treatment arm (treatment arms coded as A and B), or unblinded data if needed. The following topics may be discussed:

- Safety related data, including adverse events (AEs) and serious adverse events (SAEs).
- Number of deaths and life-threatening events.
- Adverse events, or possible indications of drug toxicity, presenting as hematological values, serum chemistry, urinalysis, and the like.
- Events leading to discontinuation or withdrawal.

Open session materials will summarize results within the study. The following information will be summarized:

- Enrollment, including enrollment exceptions, subject accrual and drop-out rates, and deviations from the Clinical Study Protocol.
- Subject demographics, including demographics of subgroups in the subject population, and baseline characteristics.
- Study drug dosing information.
- Safety data, including adverse events or lab abnormalities that may represent dose limiting toxicities.
- Missing data, including identification of specific study sites that are lagging in providing data, and the frequency of non-reported safety data.

At open sessions, the above material should be discussed in aggregate, not separately by study arms.