

## **DSMB meeting proceedings**

Each DSMB meeting will consist of the following three sessions: Open Session, Closed Session, and Open Executive Summary Session.

### **Open Session**

This will begin with an introductory session that consists of introductions, a roll call, a quorum assurance, a reminder that the proceedings and related documentation are confidential, and a review of conflicts of interest for each and every DSMB member. The introductory session will be followed by the open session of the DSMB. The meeting's open session may be attended by any members of the study staff. The following people will be present: the DSMB members, the DSMB secretary, the PI, the study statistician, and study personnel that work in biostatistics, project management, site monitoring, and data management.

An overview and update of the study will be provided during the open session. The PI or designee will be called upon to report the status of the study and any known pertinent findings. Others with specialized knowledge or concerns about safety may also be called upon to present. The meeting will offer a venue for information sharing between the different teams working on the study. The DSMB members will have an opportunity to ask questions regarding the study and request any further information that they feel is pertinent to the data review from the project team. Topics that have come up during the safety data review may be discussed. During the open session, only masked data—combined of all treatment arms—will be examined and/or discussed.

### **Closed Session**

The DSMB members and the interim analysis statistician (if invited by the DSMB Chair) will meet in closed session after the open session to review treatment level grouped safety data, discuss findings, formulate recommendations, and settle on voting procedures. All matters concerning the safety of the subjects will be covered during this session. Members of the DSMB may request that data be unmasked at this time. A priori planned interim efficacy analysis will be discussed in the closed session. A formal vote and a review of the recommendations the DSMB wants to make to the are also included in closed sessions.

### **Open Executive Summary Session**

The DSMB chair may call an executive summary session following the closed session and invite those present at the open session. High-level conclusions and suggestions discussed by the DSMB will be verbally presented by the chair without disclosing any confidential information from the closed report. The DSMB report will contain the specific recommendations made in detail.