



Cancer and Leukemia Group B
Central Office of the Chairman

230 W. Monroe Street, Suite 2050
Chicago, IL 60606-4703
TEL (773) 702-9171
FAX (312) 345-0117

www.calgb.org

Trini Ajazi
Group Administrator

MEMORANDUM

Date: October 14, 2005

To: CALGB Principal Investigators and Lead CRAs

From: Trini Ajazi, Group Administrator

Re: Data and Safety Monitoring Board (DSMB) Statements

Attached, please find the listing of DSMB recommendations released after the June 17, 2005 DSMB meeting.

You may submit the DSMB statements to your IRB per local IRB guidelines.

CALGB DSMB Recommendations June 2005

Leukemia Committee

9710

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 9710 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

19808

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 19808 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

10201

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 10201 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

GI Committee

80101

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80101 during a meeting on June 17, 2005. The DSMB recommended closure due to the slower than expected accrual rate. No toxicity concerns were identified.

Action: Following a discussion with the leadership of NCI and CALGB, the recommendation was not accepted. A protocol amendment will be prepared to modify the required sample size. The amendment will be distributed by the Central Office once all necessary approvals have been obtained.

80203

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80203 during a meeting on June 17, 2005. The trial was closed to accrual on January 15, 2005 based on a prior DSMB recommendation. The DSMB recommended 1) Generate a letter to all stakeholders reporting the closure; 2) Release the study data to the study team and the GI Committee after the stakeholders have been notified.

Action: Recommendation accepted. A sample letter for patient notification will be forthcoming from the Central Office.

80303

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80303 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

Breast Committee

49907

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 49907 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring. However, the DSMB is not prepared to approve the proposed amendment concerning the use of Herceptin until the amendment also addresses a revision of the statistical section of the protocol to reflect study accrual history to date as well as the current accrual goals.

Action: The Breast Committee has revised the proposed amendment and it has been resubmitted to the DSMB for its review.

40101

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 40101 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring. The amendment to allow Herceptin therapy was accepted but the Board suggested that the 6 month post chemotherapy window for initiation of Herceptin for patients who have already completed chemotherapy be reconsidered.

Action: After consideration of the DSMB's comments, the Breast Committee has elected to retain the 6 month window for initiation of Herceptin in patients who have completed chemotherapy. The protocol amendment will be forthcoming from the Central Office once all necessary approvals have been obtained.

GU Committee

90104

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90104 during a meeting on June 17, 2005. The DSMB recommends 1) Closure now; 2) Generate a letter to all stakeholders reporting the closure; 3) Release the study data to the study team and the GU Committee after the stakeholders have been notified.

Action: The study was closed to accrual on July 15, 2005. A sample letter for patient notification will be forthcoming from the Central Office.

90202

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90202 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring with the implementation of the plan for expanded access proposed by the study team.

Action: Recommendation accepted.

90206

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90206 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

Transplant Committee

100104

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 100104 during a meeting on June 17, 2005. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.