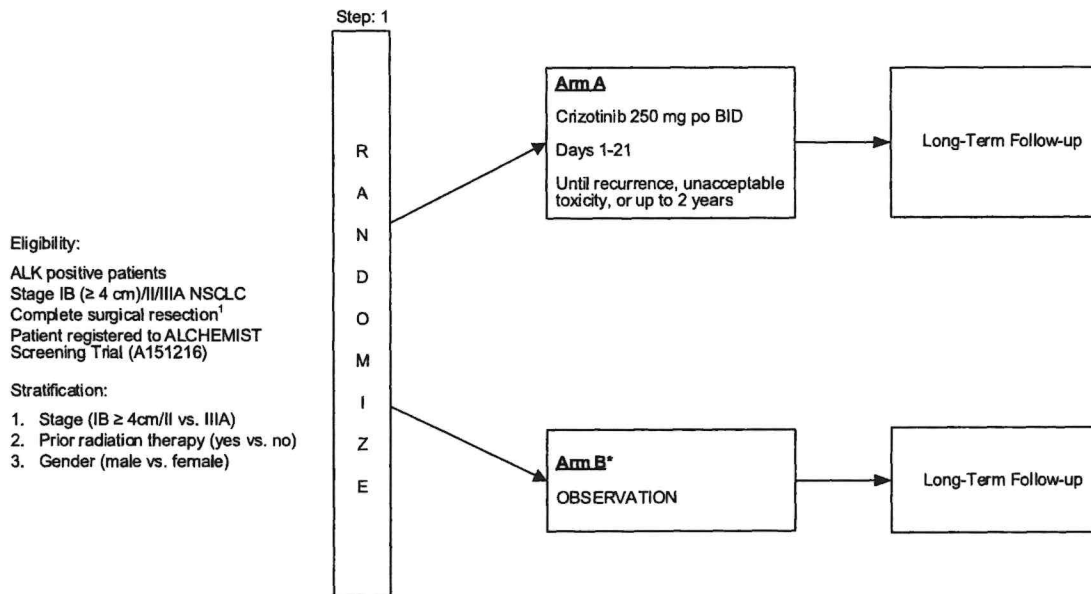


Rev. 6/17
Rev. Add10
Rev. Add12

Schema



Accrual Goal: 168 patients
Cycle= 3 weeks (21 days)

1. Patients must have completed any prior surgery 4 or more weeks prior to randomization and be adequately recovered at time of randomization. Maximum time between surgery and randomization is 4 months if no adjuvant chemotherapy was administered, 9 months if adjuvant chemotherapy was administered, and 11 months if adjuvant chemotherapy and radiation therapy were administered.

*Prior to activation of Addendum 8, Arm B patients were receiving placebo

*Patients enrolled on previous addendums will have been enrolled based on AJCC v7 and patients enrolled after amendment #12 and on will be based on AJCC v8