

SCHEMA

Registration



*Screening blood draw prior to first dose of first-line chemotherapy



Chemotherapy may be initiated while waiting for CTC result



<5 CTC/7.5 mL blood
Arm A (Low Risk)



**Follow-up for OS and PFS
No further blood draws

≥5 CTC/7.5 mL blood



← 2nd blood draw
at Day 22

<5 CTC/7.5 mL

Arm B (Moderate Risk)



≥5 CTC/7.5 mL

Arm C (High Risk)



Randomization



***Arm B ***Arm C
Maintain Current Therapy Group

Arm C2
Switch Therapy Group



- * Patients must be registered prior to initiation of testing (no more than one working day prior to initial CTC submission).
- ** Patients in the Low Risk Group (Arm A) may enroll in other clinical trials while being followed for OS and PFS on S0500.
- *** Patients in Arms B and C1 and their physicians will be blinded to which arm they are by study design. Protocol requirements are the same for these two arms.