NSABP CLINICAL TRIALS OVERVIEW

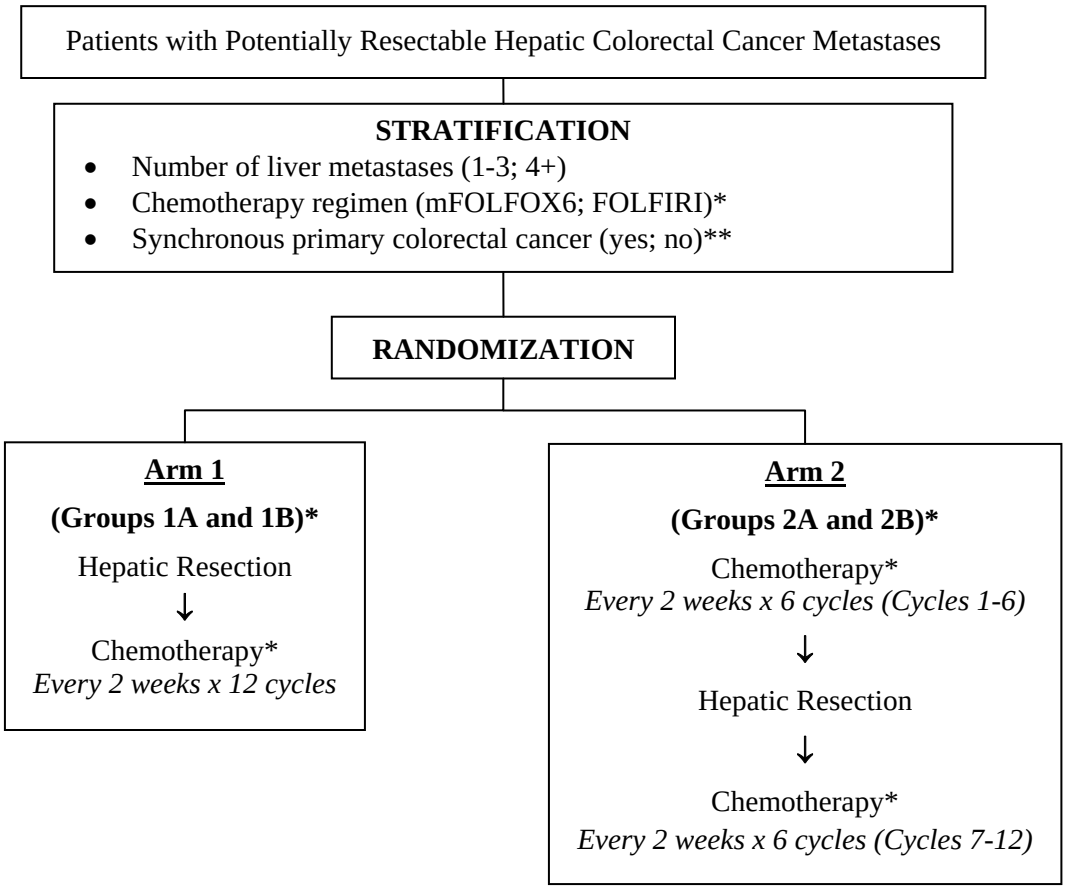
PROTOCOL C-11

A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases

Specific Aim

To evaluate the difference in recurrence-free survival (RFS) between those patients receiving perioperative (preoperative plus postoperative) adjuvant chemotherapy and those receiving only postoperative adjuvant chemotherapy following liver resection for colorectal metastases.

NSABP C-11 Schema



* *The chemotherapy regimen will be determined by the patient's previous exposure to oxaliplatin.*

- **Chemotherapy regimen A for Groups 1A and 2A:** The chemotherapy regimen for patients who have not received previous treatment with oxaliplatin is **mFOLFOX6**.

  oxaliplatin 85 mg/m^2 IV + leucovorin 400 mg/m^2 IV + 5-FU 400 mg/m^2 IV bolus + 5-FU 2400 mg/m^2 IV over 46 hours

- **Chemotherapy regimen B for Groups 1B and 2B:** The chemotherapy regimen for patients who have received previous treatment with oxaliplatin is **FOLFIRI**.

  irinotecan 180 mg/m^2 IV + leucovorin 400 mg/m^2 IV + 5-FU 400 mg/m^2 IV bolus + 5-FU 2400 mg/m^2 IV over 46 hours

** *Synchronous is defined as the detection (by imaging) of suspicious liver metastases within 90 days before or after the date of histologic diagnosis of the primary colon or rectal cancer.*