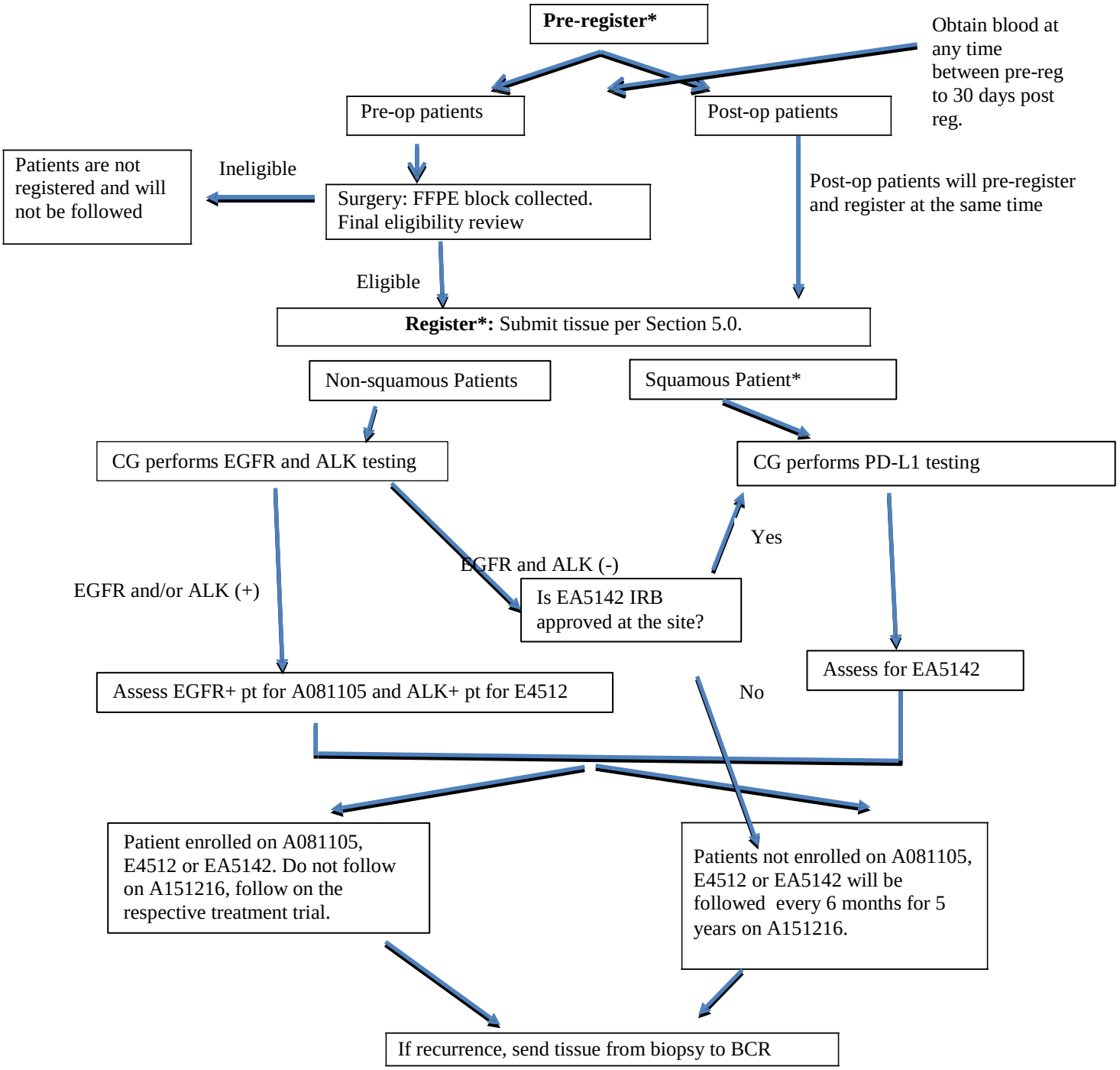
Schema



* Patients with squamous cell carcinoma are able to pre-register to A151216 only when the enrolling site has the EA5142 trial IRB approved.

3.0 PATIENT PRE-REGISTRATION/REGISTRATION ELIGIBILITY CRITERIA

3.1 Patient Pre-registration Eligibility Criteria

For pre-surgical patients

- Suspected diagnosis of resectable non-small cell lung cancer. Patients with squamous cell carcinoma are eligible only if the registering site has EA5142 IRB approved.
- Suspected clinical stage of IIIA, II or large IB (defined as size ≥4cm)

For post-surgical patients

- Completely resected non-small cell lung cancer. Patients with squamous cell carcinoma are eligible only if the registering site has EA5142 IRB approved.
- Pathologic stage IIIA, II or IB (defined as size ≥4 cm)

For all patients

- ECOG Performance Status 0-1
- Age ≥ 18 years
- No patients who have received neoadjuvant therapy (chemo- or radio-therapy) for this lung cancer
- No prior or concurrent malignancies within 5 years, except non-melanoma skin carcinoma or in situ carcinomas. A secondary primary lung cancer is considered a concurrent malignancy and would make a patient ineligible for A151216.
- No prior treatment with agents targeting EGFR mutation, ALK rearrangement, and PD-1/PD-L1/CTLA-4.
- No patients known to be pregnant or lactating
- Patients who have had local genotyping are eligible, regardless of the local result.
- No patients with recurrence of lung cancer after prior resection.

Note: Post-surgical patients should proceed to registration immediately following pre-registration.

3.2 Patient Registration Eligibility Criteria

- Completely resected NSCLC. Patients with squamous cell carcinoma are eligible only if the registering site has EA5142 IRB approved.
- Pathologic stage IIIA, II, or large IB (defined as size ≥ 4cm)
- Tissue available for the required analyses (either clinical tissue block or slides and scrolls, see Section 5.1)
- In order to allow for time for central genotyping and eligibility for the ALCHEMIST treatment trial, patients must register within the following eligibility windows, depending on the adjuvant treatment approach:
  1. If no adjuvant therapy, register patient within 75 days following surgery.
  2. If adjuvant chemotherapy only, register patient within 225 days following surgery.
  3. If adjuvant chemotherapy and radiation, register patient within 285 days following surgery.