The detection of ctDNA after cancer surgery with curative intent may indicate the presence of minimal residual disease and a higher risk for relapse. The Addario Lung Cancer Medical Institute (ALCMI) has launched a multi-center study to evaluate the presence of minimal residual disease and a higher risk for relapse. The Addario Lung cancer residual disease (MRD) personalized assay is used to detect tumor-specific variants in plasma DNA from patients with NSCLC.

**INTRODUCTION**

The study will enroll 500 patients across three cohorts. Patients must be older than 18 with surgical resection planned for stage II or IIIA NSCLC. There are three cohorts:

- **Cohort #1: Neoadjuvant Therapy** - enrollment prior to initiation of treatment based on radiographic staging
- **Cohort #2: Pre-Surgery** - enrollment within 30 days of planned surgery, based on surgical pathology
- **Cohort #3: Post-Surgery** - enrollment occurs prior to adjuvant therapy, based on surgical pathology.

We will conduct an initial evaluation of ctDNA results after enrollment of 100 eligible patients. All patients will be followed for survival and recurrence for a maximum of 60 months from the date of surgery. The primary objective is to correlate the presence of ctDNA following complete surgical resection with disease-free survival. Secondary objectives are to evaluate the changes in ctDNA after complete resection at pre-specified intervals and correlate the presence of ctDNA with overall survival.

**ASSAY**

The assay begins with a list of tumor variants and associated variant allele fractions (VAFs). The VAF is the fraction of molecules of DNA at a particular locus that contain the variant. The list of tumor variants derives from next-generation sequencing (NGS) of the initial liquid biopsy. The tumor variants and associated VAFs are input into a proprietary algorithm which outputs a multiplex PCR design that targets up to 48 variants. The multiplex PCR assay is performed on cell-free DNA isolated from a patient's peripheral blood sample taken at a time point of interest. Proprietary algorithms are used to analyse the resulting sequencing data and determine whether circulating tumor DNA is detected. As circulating tumor DNA has a half-life of around one hour its detection gives real-time assessment on whether residual tumor remains (Wan et al. 2017).

**ELIGIBILITY AND PROTOCOL**

**ELIGIBILITY**

- **Inclusion criteria**
  - Patients with histologically confirmed stage IIA, IIB, or IIIA NSCLC
  - Patients aged over 18 years
  - Patients with a histologically proven NSCLC with no evidence of distant metastasis
  - Patients with a Karnofsky performance status of at least 60
  - Patients with no prior treatment for NSCLC

**Exclusion criteria**

- Patients with a history of prior malignancy
- Patients with a history of a second primary tumor
- Patients with a history of another malignancy
- Patients with a history of a second primary tumor
- Patients with a history of another malignancy
- Patients with a history of a second primary tumor
- Patients with a history of another malignancy

**STUDY OVERVIEW**

The study is currently open at the following sites and additional sites are being actively recruited:

- Orange Coast Memorial Medical Center, Fountain Valley, California
- Saddleback Memorial Medical Center, Laguna Hills, California
- Long Beach Memorial Medical Center, Long Beach, California
- Northside Hospital, Atlanta, Georgia
- Rush University Medical Center, Chicago, Illinois
- Dana Farber Cancer Institute, Boston, Massachusetts (Pending)
- Saint Louis Cancer Care, Bridgetown, Missouri
- Washington University School of Medicine, St. Louis, Missouri
- Vanderbilt University Medical Center, Nashville, Tennessee
- Baptist Memorial Hospital, Memphis, Tennessee

**STUDY CONTACTS**

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