PROSPECT Lung

A non-small cell lung cancer trial

PI/SITE FAQs

What is the PROSPECT-Lung trial?

The **PROSPECT-Lung trial** (CTIU2317-A082304-S2402), co-led by the Alliance for Clinical Trials in Oncology and the SWOG Cancer Research Network, is the first trial to open through the recently formed **NCI Clinical Trials Innovation Unit (CTIU)** that was launched in February 2023 to advance innovative science, trial designs, and operational efficiencies for high-priority clinical research needs. The CTIU was created in recognition of the need to accelerate clinical testing of new cancer prevention, diagnostic, treatment, and survivorship approaches. The PROSPECT-Lung trial aims to compare perioperative and adjuvant immunotherapy-based treatment in patients with resectable non-small cell lung cancer (NSCLC) to help define the best treatment strategy for these patients.

What are the standard treatments for resectable non-small cell lung cancer?

At this point in time, **upfront surgical resection** to be followed by chemotherapy and immunotherapy to reduce the possibility of cancer coming back (adjuvant approach) and giving chemotherapy and immunotherapy before surgical resection to be followed by one year of immunotherapy after surgery (perioperative approach) are both acceptable, standard of care options for treatment of this patient population. There is no study to compare these two approaches. PROSPECT-Lung is addressing the question of which approach is better for our patients.

Why is this trial important scientifically?

- Despite curative treatments, the **5-year overall survival** (OS) rates for patients with resectable non-small cell lung cancer (NSCLC) remain low, ranging from 41% in stage IIIA to 65% in stage IIA.
- While adjuvant cisplatin-based chemotherapy has shown some benefits, **data on neoadjuvant therapy** is more limited, and there is no clear evidence favoring neoadjuvant over adjuvant chemotherapy.
- The **success of monoclonal antibodies** against PD1 and PD-L1 in metastatic tumors has led to their evaluation in resectable NSCLC. Preliminary studies suggest that neoadjuvant immunotherapy might be more effective than adjuvant immunotherapy.
- There are **no direct comparisons** among neoadjuvant, perioperative, and adjuvant chemoimmunotherapy approaches in resectable NSCLC. This trial aims to fill this gap by comparing adjuvant and perioperative chemoimmunotherapy.

Who is eligible to participate?

Patients who have newly diagnosed non-small cell lung cancer and are evaluated by a thoracic surgeon and deemed to **have a potentially resectable tumor** are eligible to participate in this study.

Why is this trial important for the patient?

Patients enrolled on this study will receive a **standard of care**, FDA approved approach to treat their cancer, and will be monitored carefully while on the study. Results of this study will help to determine which of these standard of care approaches are better for this patient population.

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What is the treatment schedule in brief?

Patients will be randomized to one of two arms:

Arm 1 - Adjuvant: Patients will proceed to surgical resection to be followed by up to four cycles of adjuvant platin-based chemotherapy to be followed by adjuvant immunotherapy for up to one year.

Arm 2 - Perioperative: Patients will receive up to four cycles of platin-based chemotherapy and immunotherapy to be followed by surgical resection to be followed by up to one year of adjuvant immunotherapy.

Patients will be followed clinically and with surveillance scans after completion of therapy per national guidelines.

What are the potential benefits of this trial for the patient?

Patients enrolled on the study will receive a standard of care approach for treatment of their cancer based on the stage of the disease. Considering it is a pragmatic study, there are no extra visits of lab testing involved in this study.

What are the potential benefits of this trial for the site?

- This is a **pragmatic study** and there are innovative aspects of trial design and conduct.
- Treating oncologists can **select the treatment regimens** according to the standard of care at the time of enrollment.
- There are **dual endpoints** of real-world event-free survival (rwEFS) and overall survival (OS).
  - rwEFS definition refinement to align with Checkmate 77T
- **Streamlined data collection** aligns with the electronic medical record (EMR), when possible.
  - Protocol Document: 29 pages; CRF Packet: 13 forms (143 total fields)
  - No required Response Evaluation Criteria In Solid Tumor (RECIST) use for evaluation of response.
  - Adverse event reporting is minimal, making it easier on research teams in sites/centers where the study is open.
- This is an NCI study so the site/center will receive **credit for enrolling patients per NCI regulations**.

Who should I contact with questions?

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