Do you have advanced non-small cell lung cancer and are aged 70 or older?

If so, you may be able to participate in this study of a new treatment approach.

Chemotherapy Combined with Immunotherapy vs. Immunotherapy Alone for Older Adults with Advanced Lung Cancer

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating lung cancer.
- The usual approach for older patients with non-small cell lung cancer (NSCLC) (i.e., the care these patients would get if not in a study) is a combination of immunotherapy and chemotherapy, or sometimes immunotherapy alone.
  - Additional treatment with surgery, radiation therapy, or chemotherapy may be recommended.
- EA5221/ACHIEVE aims to find out if adding chemotherapy to immunotherapy helps older patients with lung cancer live longer while also maintaining a good quality of life.

WHAT does this study involve?

- If you decide to take part in this study, your doctor will review your medical history with you, and give you a general physical exam. You will also get an MRI and/or CT scans to determine if this study is an option for your care.
- Then, you will complete a geriatric assessment, which includes physical function, nutrition, thinking skills, and quality of life components.
- Next, you will be assigned by chance (randomized) to one of two groups. You will be told which group you are in.
  - **Group 1:** You will get the standard immunotherapy used to treat NSCLC, called pembrolizumab.
    » You will receive pembrolizumab by vein (intravenously) every 3 weeks for 4 cycles. After this, you and your doctor may choose to change the pembrolizumab dosing to be given once every 6 weeks for up to 2 years.
  - **Group 2:** You will receive chemotherapy, plus immunotherapy (pembrolizumab).
    » You and your doctor will choose from several possible chemotherapy options (pemetrexed, carboplatin, paclitaxel, or nab-paclitaxel). You will get one or more of these medications intravenously either once weekly or every 3 weeks, along with pembrolizumab, for 4 cycles. After this, you will receive pembrolizumab alone, and your doctor may change your schedule to receive pembrolizumab every 6 weeks.
    » Pemetrexed may be continued with pembrolizumab, per your doctor’s decision. You will continue to receive pembrolizumab for up to 2 years.
• After you finish treatment, your doctor will continue to follow your condition every 3 months for 2 years, then every 6 months for the next 3 years (5 years total).

**WHO will take part in this study?**

• Approximately 304 older adults (70 years of age or older) diagnosed with advanced NSCLC will take part in EA5221.
• You can decide to stop taking part in the study at any time, even after you have enrolled.

**WHAT are the costs of taking part in this study?**

• Just as you would if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for some or all the costs of medical care you get as part of EA5221/ACHIEVE. Check with your insurance company to find out what they will pay for.
  – You/your insurance plan will **not** have to pay for pembrolizumab. However, you will need to pay for the costs of getting the pembrolizumab and chemotherapy agents (if assigned to Group 2) ready and giving them to you.
  – You/your insurance plan will **not** have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. Check with your doctor to find out what these might be.
• Taking part in this study may mean that you need to visit the clinic or hospital more often than if you were getting the usual treatment for your cancer.
• You will not be paid for taking part in this study.

**IF you would like to know more**

• About the EA5221/ACHIEVE study, talk with your doctor, or:
  – Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA5221, then select the link to the EA5221 Home Page.
    » If you are seeking information about the locations where the study is available, scroll down the page to Locations and Contacts and click the + sign.
  – Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
• About clinical trials:
  – General cancer information: visit the NCI website at [www.cancer.gov](http://www.cancer.gov)
• About ECOG-ACRIN:
  – Visit [www.ecog-acrin.org](http://www.ecog-acrin.org)
  – For a list of patient resources and links to patient advocacy groups, visit [https://ecog-acrin.org/patients/resources](https://ecog-acrin.org/patients/resources)