



**Do you have HPV throat cancer?**

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

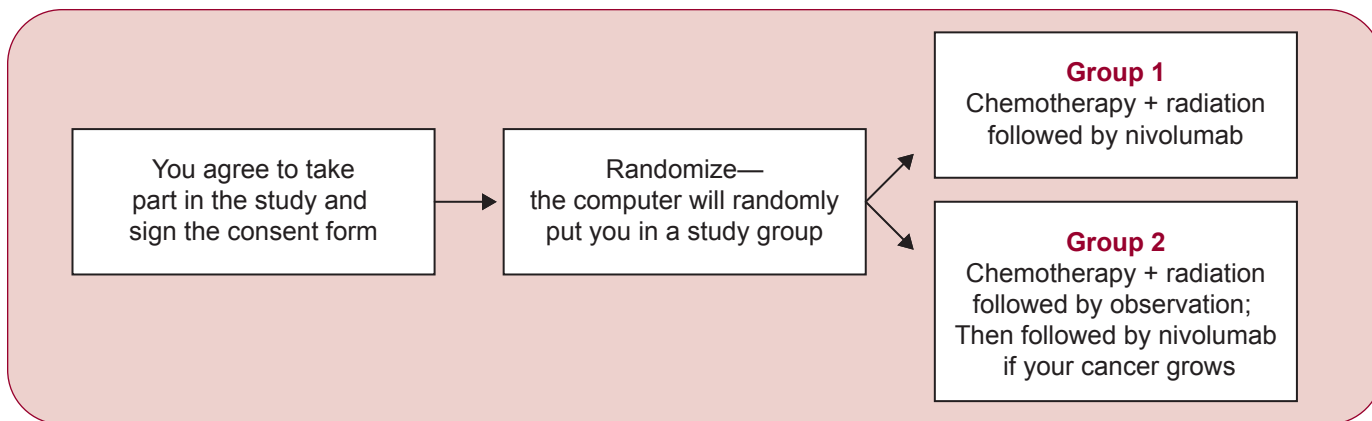
## Testing Immunotherapy versus Observation in Patients with HPV Throat Cancer

### **WHY** consider participating in this study?

- Research studies are an important way to test the effectiveness of new drugs for treating throat cancer.
- All study participants will receive the usual treatment for this cancer, which is radiation and chemotherapy.
- Some study participants will also receive an immunotherapy treatment, nivolumab, by vein (intravenously). Nivolumab has been shown to prevent cancer from returning in some patients.
- The purpose of the EA3161 study is to compare the usual treatment alone to the usual treatment plus nivolumab to find out which treatment approach is better.
- You can decide to stop taking part in the study at any time, even after you have enrolled.

### **WHAT** does this study involve?

- If you decide to participate in EA3161, you will be assigned by chance (randomized) to one of two study groups:
  - **Group 1**—chemotherapy (weekly for 7 weeks) and radiation (daily, excluding weekends, for up to 7 weeks), followed by nivolumab (every 4 weeks for up to 12 months)
  - **Group 2**—chemotherapy (weekly for 7 weeks) and radiation (daily, excluding weekends, for up to 7 weeks)
    - » If you are assigned to Group 2 and your cancer grows, you may be able to receive nivolumab.
- EA3161 study participation involves tests/procedures such as physical exams, blood work, and thyroid testing. Details regarding these tests can be found in the study consent form.
- After you finish your treatment, your doctor and study team will monitor you every 3–6 months for 3 years, then every year for up to 10 years.



## WHO will take part in this study?

- Approximately 636 people will be participating in EA3161.
- Participants must be at least 18 years old, and must not have had prior treatment (including radiation or surgery) for HPV throat cancer.

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

- You and/or your insurance plan will need to pay for some or all of the costs of treating your cancer in this study, just as you would if you were getting the usual care for your cancer. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **not** have to pay for nivolumab or the research test of PD-L1 on your tissue. However, you/your insurance provider will have to pay for the preparation and administration of nivolumab.
- For more information on insurance coverage and clinical trials, visit the National Cancer Institute (NCI) website at: [www.cancer.gov/clinicaltrials/learningabout/payingfor](http://www.cancer.gov/clinicaltrials/learningabout/payingfor) or call 1-800-4-CANCER (1-800-422-6237).

## IF you would like to know more

- About the EA3161 study, talk with your doctor, or:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA3161, then select the link to EA3161.
    - » If you are seeking information about medical facilities where the study is available, scroll down the page to Locations and Contacts
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- About nivolumab:
  - Visit [www.cancer.gov/drugdictionary](http://www.cancer.gov/drugdictionary)
- About clinical trials and 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)

