About DECAMP Study 2
Doctors want to determine the best way to monitor people who are at high risk for developing lung cancer. This monitoring is often called “lung cancer surveillance.” The study’s goal is to identify biomarkers that can be collected easily from patients to obtain information about their risk for developing lung cancer.

What are biomarkers?
With cancer, “biomarkers” is most often used to describe substances found in blood, other body fluids, or tissue that can be measured through a specialized test. The levels of these substances may help doctors learn if, or how quickly, a cancer is developing. Biomarkers that identify the early signs or presence of cancer could improve lung cancer surveillance, as well as the detection and treatment of early-stage cancer.

DECAMP Study 2 will include approximately 800 study participants who are current or former smokers and have one additional risk factor for lung cancer.

PURPOSE OF THE RESEARCH STUDY:

You are being asked to participate in this research study because you are at high risk for developing lung cancer. Approximately 50 study participants are expected to develop lung cancer during the study period. Doctors will compare the biomarkers of these study participants to the biomarkers of study participants who do not develop lung cancer. By comparing the biomarkers of the two groups, the study doctors hope to discover specific biomarkers that will help identify which patients are most likely to develop lung cancer.

Trial Conduct Information

National Trial Principal Investigators

Ehab Billatos, MD
Boston University School of Medicine, Boston, MA

Denise Aberle, MD
UCLA Medical Center, Los Angeles, CA

Program Coordinators

Elizabeth Moses, PhD
Boston University
emoses@bu.edu

Irene Mahon, DECAMP Project Manager
American College of Radiology
imahon@acr.org

For Local Trial Information, Contact:

Research Sponsor
Funding for the DECAMP trial is made available by the Department of Defense (DOD) Lung Cancer Research Program, Janssen Pharmaceuticals, Inc., Novartis Research and Development, and the National Cancer Institute.

More Information
Please visit www.decampresearch.org for more information about the study and healthy lung resources.

More comprehensive information on clinical trials is available on the National Cancer Institute (NCI) Web site http://cancertrials.nci.nih.gov.

Brochure Version: January 2020

DECAMP
BIOMARKER RESEARCH

Detection of Early Lung Cancer Among Military Personnel

DECAMP Study 2

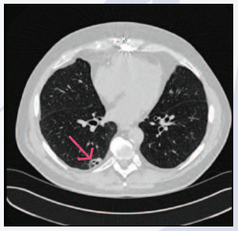
Screening of Patients at High Risk for Developing Lung Cancer

RESEARCH STUDY INFORMATION

Every year, about 1 million Americans participate in clinical trials to help researchers gather important information about tests and treatment methods. When recently surveyed, the majority of study participants reported receiving excellent care and viewed their participation as a positive experience.

About DECAMP

Lung cancer is the leading cause of death from cancer in the United States and in the world, with cigarette smoking as its major cause. The number of lung cancer related deaths in the U.S. has remained essentially unchanged over the last 3 decades, in part because of our inability to detect lung cancer at its earliest and potentially curable stage.



The image above is a CT scan. The arrow is pointing to a lung nodule.

Military personnel have higher rates of smoking than the general population as well as a greater potential for exposure to other cancer-causing substances. Therefore, military personnel and veterans have a significantly higher incidence of lung cancer. The Detection of Early Lung Cancer Among Military Personnel (DECAMP) research project is working to develop new ways to detect lung cancer early that, in the future, may help all people at high risk for this disease.

This brochure provides more information about ***DECAMP Study 2:*** Screening of Patients at High Risk for Developing Lung Cancer for patients considering participation.

FREQUENTLY ASKED QUESTIONS

Who can join this research study?

You may be eligible to participate if you:

- Are 50 to 79 years old
- Are a current smoker (smoke at least 10 cigarettes each day for at least 25 years) OR a former smoker who quit no more than 20 years ago and has at least 20 “pack years” of smoking
  - Pack years = number of packs smoked per day x number of years smoked
- Have emphysema or chronic bronchitis, which are two forms of chronic obstructive pulmonary disease (COPD), or have at least one first-degree relative (parent, brother or sister, child) who has been diagnosed with lung cancer
- Are willing to undergo fiber optic bronchoscopy (optional)
- Are able to tolerate the biospecimen collections required for the study

You cannot participate in this study if you have been previously diagnosed with lung cancer.

What am I being asked to do?

If you take part in this study, you will:

- Fill out a lung questionnaire
- Do the following once each year for 3 years:
  - Provide different types of biological samples (called “biospecimens”), including sputum, blood, urine, cells, and tissue. All biospecimens will be stored for future research.
  - Provide cells from your nose and mouth by brushings from your nose and scrapings from your mouth.
- Have an optional bronchoscopy the first and third year you are in the study. A bronchoscopy is a test to view the lungs using a flexible device (called a “bronchoscope”). If you chose to have a bronchoscopy, brushings of cells and biopsy samples will be collected during this procedure.
- Have a CT scan (an imaging study to evaluate the health of your lungs) when you enroll and in years 1, 2, and 4.
- Do the following once each year for 4 years:
  - Have a physical examination and diagnostic work-up
  - Do a pulmonary function test, which measures your ability to breathe when you blow into a special device
- If you are diagnosed with cancer during the course of the study, you will be asked to provide biological samples (biospecimens), including sputum, blood, urine, and cells from your nose and mouth, after your treatment is complete. Some of these samples will be saved for research in the future.

How long will I be in the study?

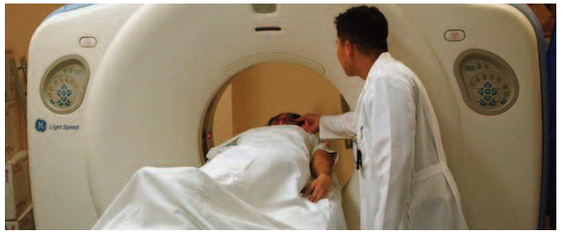
You will be in the study for about 8 years. If you are diagnosed with cancer while you are participating in the study you will be followed for outcomes for an additional 3 years. This study is expected to end after all patients have completed the follow-up visits and all information has been collected. Additional annual follow-up to document patient outcomes will continue until the last accrued participant completes his/her 4th year of follow-up.

What are the possible benefits of taking part in the study?

Taking part in this study will not make you better or improve your health. Your participation in this study may help doctors discover biomarkers to help identify patients who can most benefit from lung cancer surveillance. Patients in the future may benefit from this research. The results of the biospecimen tests will not be available during your treatment and will not change your treatment.

Are there costs for taking part in the study?

You will not be responsible for any costs associated with the biospecimen collection (sputum, blood, urine, cells, and tissue). You will be responsible for any medical care considered standard (these are costs that you would have whether or not you participated in this research study). Taking part in this study should not lead to any added costs for you or your insurance company. You may be responsible for any copayments and deductibles that are standard for your insurance coverage.



www.decampresearch.org