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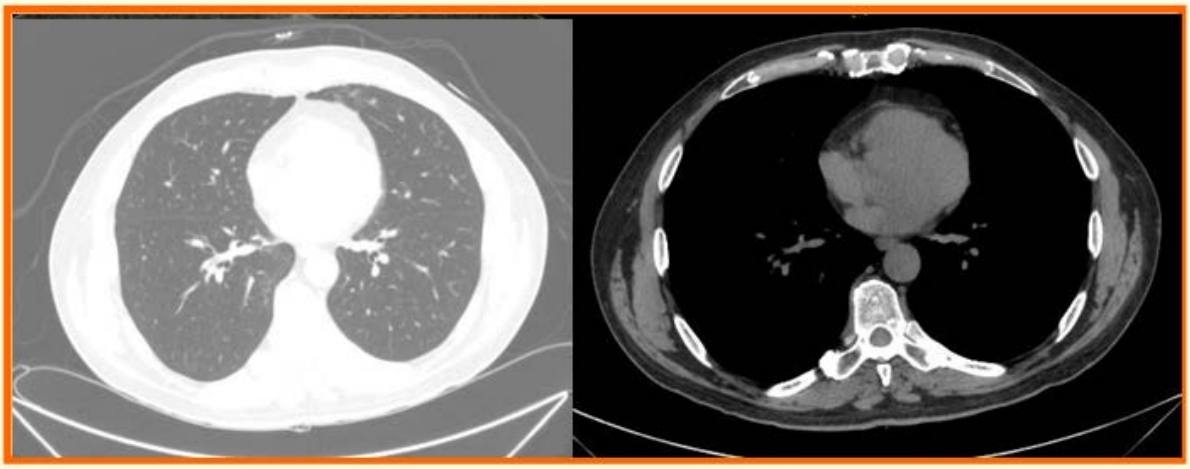
Site Imaging Manual

ACRIN 4703 DECAMP-1 Study



Detection of Early lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Version:	Final Version 4.1
Date:	30-Sep-2020

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References:

History of Revisions:

15-Nov-2012	1.0	Initial Draft
27-Dec-2012	2.0	Update TRIAD 4 URL. Additional TRIAD 4 Work Instructions
12-April-2013	2.1	Update TRIAD 4 Links
13June 2013	3.0	Update to comply with Protocol Amendment 2. Update TRIAD 4 instructions.
13 Aug 2014	4.0	Update to comply with Protocol Amendment 5. Changed Nodule size. Changed TRIAD 4.3Language.
30-Sep-2020	4.1	Update Current address of ACR Core Lab Office

Letter of Introduction

Dear Fellow Researchers,

This ACRIN 4703 Imaging Manual for Imaging and Image Submission contains the guidelines for image acquisition, processing, storage, shipping, and documenting of all imaging data collected in this study for the **ACRIN 4703 study, "*Detection of Early lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules*"**

To successfully meet the study objectives, it is critical that the participating sites follow the instructions and guidelines outlined in this manual.

Quality Control (QC) review of all image data will be performed by the ACR Imaging Core Laboratory. This review will be performed in a timely fashion as part of ACRIN standard operating procedures. If any protocol deviations or technical issues are identified during the QC review, an ACR Core Lab Imaging Technologist will contact your site to provide feedback expeditiously. This will allow your site to make any necessary adjustments early in the conduct of the study.

The ACRIN 4703 Research Team wishes to thank you in advance for your diligence in adhering to the procedures described in this manual to ensure the integrity of the image data collected for the study. Please do not hesitate to contact the ACRIN 4703 Research Team.

Sincerely,

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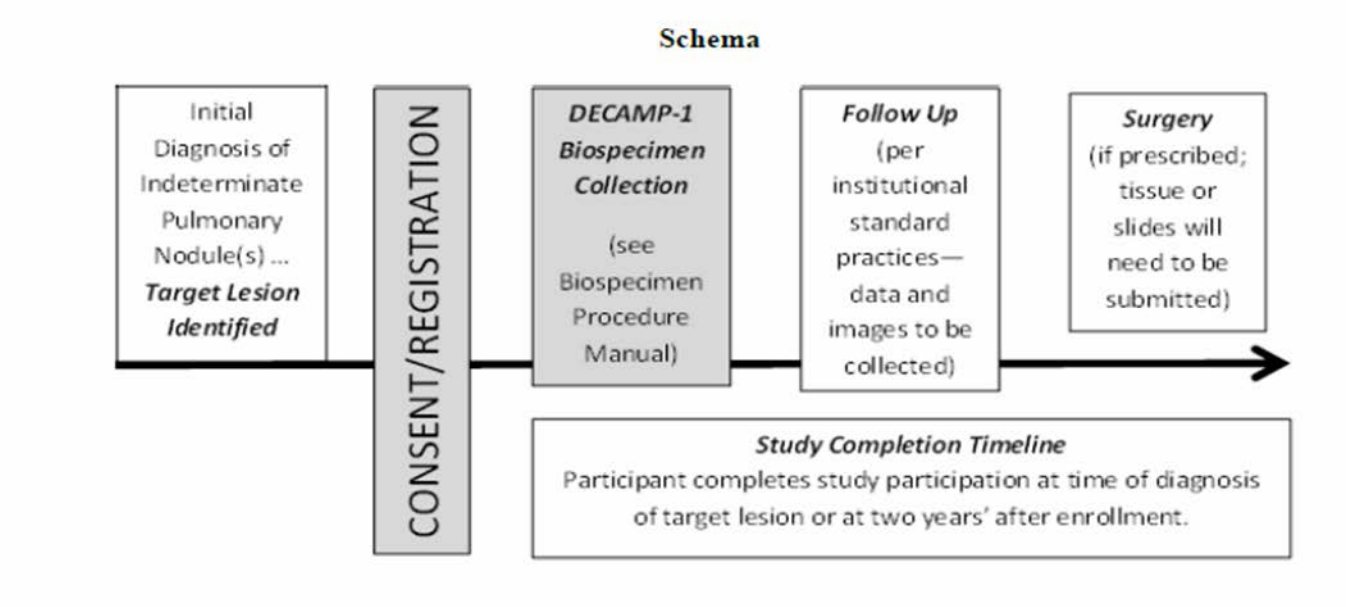
ACRIN 4703 Study Schema

Detection of Early Lung Cancer Among Military Personnel
Study 1 (DECAMP-1):
Surveillance of Indeterminate Pulmonary Nodules



STUDY OBJECTIVE

The goal of this Phase III project is to improve the efficiency of diagnosing indeterminate pulmonary nodules. Biomarkers for lung cancer diagnosis will be evaluated for their ability to distinguish between malignant vs. benign nodules. Minimally- and non-invasive bio specimens will be collected from military personnel and their families who are at high risk for lung cancer due to smoking history. Additional analyses will be performed on samples collected from subjects diagnosed with lung cancer subsequent to study enrollment, who will undergo additional bio specimen collection 12 to 24 weeks following cancer diagnosis (this range of 12 to 24 weeks is permitted to allow for specimen collection to occur after lung cancer treatment is completed, though if the subject is still undergoing treatment at 24 weeks, collection should be performed at this time point). Subjects with a lung cancer diagnosis will be followed for outcomes for three years.

ELIGIBILITY

Patients diagnosed with indeterminate pulmonary nodule(s) (target lesion size: 0.7 to 3.0 cm; if multiple nodules were diagnosed, choose the one with the longest diameter as the target lesion; if two or more nodules are measured at the same largest size, choose the one with the perpendicular longest diameter) of eligible size within 12 months prior to consent, ≥ 45 years old, and have a smoking status as a current or former smoker with ≥ 20 pack years (pack years = number of packs per day x number of years smoked).

SAMPLE SIZE

500 eligible participants are projected to participate in this study.

1.0 OVERVIEW OF IMAGING REQUIREMENTS

TRIAD Installation	TRIAD should be installed prior to study participant enrollment for secure, electronic submission of imaging to ACRIN.
Image Acquisition	• Baseline standard of care (SOC) chest CT • Yearly follow-up imaging per institutional standards. Imaging may include Chest xray (CXR), chest CT, PET-CT, as per institutional norms
Image Submission	ACRIN 4703 SOC imaging should be submitted in DICOM format to the ACR Imaging Core Lab via TRIAD. All imaging should be submitted **within 48 hours** after acquisition and should include an Image Transmittal Worksheet (ITW).
Data Queries	ACRIN will issue queries, as needed, based on QC review of imaging.

General Study Requirements:

- All CT exams must be acquired on a low dose ≥16 slice helical scanner
- May be acquired 2.5mm to 5.0mm but **must** be reconstructed separately to 1mm
- Same DFOV must be used for all follow-up studies
- Site must submit all SOC to ACRIN within 48 hours after acquisition

2.0 STUDY OBJECTIVES/SPECIFIC AIMS

2.1 Overview

The DECAMP consortium is a multidisciplinary and translational research program that includes clinical study sites (7 Veteran's Affairs Hospitals [VAH], 4 designated Military Treatment Facilities [MTF], and 3 academic hospitals), several molecular biomarker laboratories, and Biostatics, Bioinformatics, Pathology, and Biorepository core centers and laboratories. The DECAMP Coordinating Center facilitates rapid selection, design, and execution of clinical studies within this multi-institutional consortium.

In this Phase III project, a total of 500 people with a history of smoking who have indeterminate pulmonary nodules (0.7 to 3.0 cm) on chest CT will undergo fiberoptic bronchoscopy and other biospecimens collection and will be followed for 2 years. The diagnostic performance of four previously established lung cancer biomarkers will be validated in this cohort: 1) a gene-

expression biomarker measured in bronchial airway brushings; 2) a proteomic signatures measured in bronchial airway biopsies; 3) a proteomic signature measured in serum; and 4) a signature of serum cytokines. The added value of these emerging molecular markers will be evaluated with clinical and imaging markers routinely used in the diagnostic work up of these patients. The overarching study goal is to develop an integrated model (i.e., clinical, imaging, and molecular markers) that results in a robust diagnostic predictor for lung cancer.

2.2 Primary Aim

To determine the diagnostic accuracy of genomic and proteomic biomarkers in the airway, and blood to detect lung cancer in the study cohort.

2.3 Secondary Aim

To evaluate the added diagnostic value of the molecular biomarkers to routine clinical and radiographic features used in diagnostic workup of pulmonary nodules.

3.0 Participant Eligibility

3.1 Inclusion Criteria

- 45 years of age or older
- Radiologic diagnosis of indeterminate pulmonary nodule (0.7 to 3.0 cm); must be of appropriate size at enrollment, but nodule(s) may have been first identified within 12 months prior to enrollment
- CT scan completed within 3 months prior to enrollment
- Current or former cigarette smoker with ≥ 20 pack years (pack years = number of packs per day X number of years smoked)
- Willing to undergo fiberoptic bronchoscopy
- Able to tolerate all biospecimen collection as required by protocol
- Able to comply with standard of care follow up visits, including clinical exams, diagnostic work-ups, and imaging for approximately two years from enrollment
- Able to fill out Patient Lung History questionnaire
- Willing and able to provide a written informed consent

3.2 Exclusion Criteria

- History or previous diagnosis of lung cancer

5.2.1 Diagnosis of <u>pure</u> ground glass opacities for the target lesion (identified per Section 5.1.2 above) on chest CT (i.e., mixed features on the target lesion and pure ground glass opacity on non-target lesions are acceptable);

- Contraindications to nasal brushing or fiberoptic bronchoscopy, including: ulcerative nasal disease, hemodynamic instability, severe obstructive airway disease, unstable cardiac or pulmonary disease; inability to protect airway or altered level of consciousness;
- Allergies to any local anesthetic that may be used to obtain biosamples in the study.

4.0 CT Image Acquisition Requirements/Recommendations

ACRIN 4703, known as DECAMP-1, is a study to evaluate pulmonary nodules. Recognizing that the DECAMP-1 protocol is utilizing standard of care (SOC) imaging, the following Hi Resolution imaging parameters have been chosen as a guide to incorporate a variety Multi-Detector CT Scanners. Every attempt must be made to incorporate dose parameters **A**s **L**ow **A**s **R**easonably **A**ttainable.

***NOTE*: These parameters should be utilized for all follow-up CT imaging to allow for future 3D post processing if necessary**

Series	Recommendation
Scout/Topogram	• 100 kV • 10-40 mA • On Inspiration
Required **Hi-Resolution Axial Imaging**	• 100kV to 120 kV • mA: per standard of care • Utilize Dose Modulation • 2.5mm to 5.0mm Slice Thickness • 2.5mm to 5.0mm Slice Spacing • Soft Tissue Algorithm (Kernel) • Bone/Lung Algorithm (Kernel)
Optional **Post Processing**	• **Axial Plane:** o 1mm < Slice Thickness o 1mm <Slice Spacing o Soft Tissue Algorithm (Kernel) o Bone/Lung Algorithm (Kernel) **Optional**

Recommended Post Processing	• **Sagittal Plane:** o 1mm Slice Thickness o 1mm Slice Spacing o Soft Tissue Algorithm (Kernel) o Bone/Lung Algorithm (Kernel) **Optional**
Recommended Post Processing	• **Coronal Plane:** o 1mm Slice Thickness o 1mm Slice Spacing o Soft Tissue Algorithm (Kernel) o Bone/Lung Algorithm (Kernel) **Optional**

5.0 Image Data Submission

Each participating site is required to submit CT and all other follow-up image data to the ACR Imaging Core Laboratory within **48 hours** of the image acquisition.

5.1 Image Transmittal Worksheet (ITW)

All image submissions should include an Image Transmittal Worksheet (ITW). An Image Transmittal Worksheet (ITW) is used during the exam QC review to verify a complete transfer of images has been submitted to the ACR Imaging Core Lab. The ITW is completed in the iMedidata/Rave data management system and upon the completion of this form; an email will be automatically generated to the ACRIN Imaging Technologist to notify an image submission has taken place.

5.2 Image Submission via TRIAD

The preferred image transfer method is via TRIAD. TRIAD® is ACR's proprietary image exchange application that will be used as the sole method of data transfer to the ACR Clinical Research Center Core Laboratory for this trial. ACR will provide installation on one or several computers of choice within the institutional "firewall" and on the institutional network; internet access is required. The TRIAD application can then be configured as a DICOM destination on either scanner(s) and/or PACS system for direct network transfer of study related images into the TRIAD directory. When properly configured, the TRIAD software de-identifies, encrypts, and performs a lossless compression of the images before they are transferred to the ACRIN image archive in

Philadelphia.

5.3 Image submission via CD/DVD media

The other option for image submission includes submitting images in DICOM format via a CD/DVD

Please label with the following information:

- Site Name
- Study Name (ACRIN 4703)
- Date of Imaging (DD-MMM-YYY)
- Type of Imaging (e.g. Chest X-ray (CXR), CT Chest, PET-CT)

Ship all disk media, along with a copy of an Image Transmittal Worksheet to:

American College of Radiology
50 South 16th Street
Philadelphia, PA 19102
Attn: ACRIN 4703 Imaging Technologist

6.0 Image Quality Control (QC)

6.1 ACRIN Core Laboratory Quality Control Technical Review

The ACRIN 4703 protocol explicitly requires participating centers to meet technical specifications of the CT Scanners for data uniformity and image quality. Additionally, specific parameters for image acquisition are outlined in the protocol and provided in this manual. ACRIN will provide ongoing quality control through the ACRIN Imaging Core Laboratory. Specifically, the ACRIN Imaging Core Laboratory will conduct quality control evaluations on all submitted imaging data to help centers maintain study grade quality. The ACR Imaging Core Laboratory Imaging Technologist will provide feedback to sites, especially during early study imaging to ensure high-quality images. However, repeat of imaging will not be requested once the study is under way.

6.2 Image Data Queries

If it is found during the QC review that the submitted exam has missing data or does not follow the protocol guidelines, detailed in this manual, the iMedidata/Rave data management system will generate an auto-query. Sites are expected to resolve data queries expeditiously. Queries not resolved within **7** business days will be sent to the ACRIN 4703 study team for additional follow-up.