A phase III Randomized trial of lobectomy versus sublobar resection for small (≤2cm) peripheral non-small cell lung cancer

Study Chair
Nasser Altorki M.D.
Weil Medical College of Cornell University

Imaging Co-chair
Ernest Scalzetti M.D

Data Coordinator
Susan Sutherland

Protocol Co-coordinator
Colleen Walt
Participating Cooperative Groups

RTOG
SWOG
ACOSCOG
NCI- Canada (pending)
Study supported by NCI CTSU

Study Schema

Pre-Registration

Surgery: Confirm path diagnosis of NSCLC and N status by frozen exam of levels 4, 7, and 16 on the right side and 5, 6, 7 and 10 on the left side.

Randomization*

Limita RESECTIO
(segurectomy or wedge resection)

Lobectomy

Follow-up
Advantages of limited resection

- Preservation of pulmonary function.
- Expanded use of MAS with lower hospitalization and enhance quality of life.
- Increased likelihood of resections for second primaries.

Statistical Consideration

- Non-inferiority study
- Sample Size
  - Target Accrual 1297 pts (22/yr)
  - Randomized 908 pts (15/yr)
- Accrual period 5 years
- Follow-up 3 years
Primary Objective
CALGB 140503

Non inferiority of DFS after sublobar resection

Study Objectives
CALGB 140503

Secondary Objective
- Non inferiority of OS after sublobar resection
- To determine LR and systemic recurrence rates
- To determine differences in PFT’s (spirometry) at 6 months
### Objectives of Imaging sub-study

**CALGB 580602**

- To correlate preoperative CT and PET characteristics with outcome.
- To determine false –ve rate for PET if hilar and mediastinal nodal mets.
- To determine utility of annual follow-up CT after resection.

### On-Study Guidelines

- Inadequate pulmonary and cardiac function
- Psychiatric illness precluding informed consent
- Uncontrolled infection (including HIV)
- Uncontrolled diabetes mellitus
## Eligibility Criteria

- **Preoperative Eligibility**

- **Intraoperative eligibility**

  Only patients meeting both will be on the study

## Pre-registration Eligibility Criteria

- Peripheral lung nodule $\leq$ 2 cm on perioperative CT scan and located in outer 1/3 of lung and presumed to be NSCLC.

- Location suitable for lobar and sublobar resection.

- ECOG PS 0-2
### Pre-registration

#### Eligibility Criteria

- No prior malignancy for 5 years other than non-melanoma skin cancer, superficial bladder cancer or CIS of cervix
- No preoperative chemo or Radiation
- No evidence of metastatic disease
- Age $\geq 18$ years
- Randomization $\leq 14$ days after Registration

### Pre-registration Requirements

- Informed Consent
- Surgeon performing VATS lobectomy must be credentialed through CALGB
Credential for VATS lobectomy

- Previously credentialed from CALGB 39802 → no further action
- Surgeons not previously credentialed
  - Minimum 10 VATS lobectomies
  - 3 operative notes and pathology reports
  - Letter requesting credentialing detailing number of cases, mortality and major complications

Registration to Companion Imaging Study (CALGB 508602)

- Required
- Registration done at same time as 140503
### Pre-registration Procedures

- Must occur prior to operative procedure.
- Only CALGB member or affiliated institutions and CCOP.
- Confirm pre-registration eligibility.
- Complete pre-registration work sheet.
- Access web-based patient registration system OR phone or fax of CALGB registration.
- Obtain and record CALGB patient ID number.
- You will receive confirmation of registration and confirmation of randomization.

### Intraoperative Eligibility Criteria

- Confirmed NSCLC (unless preoperative diagnosis).
- Confirmed N0 by F.S.
  - Right side: levels 4, 7 and 10
  - Left side: levels 5, 6, 7 and 10
Intraoperative Randomization

- Must occur within 14 days of registration.
- Will occur only after dx of NSCLC and verification of N0 status.
- CRA will enter CALGB ID # and stratification factors (on-line) to obtain treatment assignment.
- CRA communicates assignment to surgeon.
- Note treatment in records.

Stratification Factors

- Tumor Size
  - < 1 cm, 1.1-1.5 and 1.6-2.0
- Histology
  - Squamous, Adeno, Other
- Smoking Status
  - Never, Former, Current
### Major Deviations

- Tumors larger than 2 cm or central tumors.
- F.S not done on at least 3 nodal station on the right and 4 on the left.
- Positive margins on F.S. after wedge not treated by a wider resection.

### Minor Deviations

- Operative Reports of segmentectomies not detailing individual vascular and bronchial divisions.
- No systematic sampling or dissection done.
PreStudy Testing

<table>
<thead>
<tr>
<th>Pre-Study Testing Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>To be completed within 42 DAYS before registration:</td>
</tr>
</tbody>
</table>

Chest CT scan

Tests & Observations

<table>
<thead>
<tr>
<th>Prior to Pre-registration</th>
<th>Post Treatment Follow up*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Examination</td>
<td>X</td>
</tr>
<tr>
<td>Performance Status</td>
<td>X</td>
</tr>
<tr>
<td>Tumor Measurements</td>
<td>X</td>
</tr>
</tbody>
</table>

Laboratory Studies

| Pulmonary Function Tests | B                         |

Staging

| Chest X-ray              | X                         | X                         |
| Chest CT scan**          | X                         | A                         |
| PET scan                 | PRN                       | PRN                       |

*At least every 3 months for 1 year, then every 6 months for 1 year, then yearly during years 3, 4 and 5 following surgery.

**See Sections 7.1 and 7.2 for CT scan and PET scan requirements.

Data Submission

➢ Submit to CALGB Statistical Center

➢ By Fax (919) 416-4990

➢ By Mail
**Imaging Sub-Study**

- Submit a CD of CT scan and PET (if done) of all patients (even non-randomized) to:
  
  CALGB Imaging Core Laboratory  
  Department of Radiology  
  Ohio State University Medical Center  
  1654 Upham Drive  
  Columbus, OH 43210-1228

---

**Submission Schedule**

<table>
<thead>
<tr>
<th>Form**</th>
<th>Submission Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit for all patients:</td>
<td></td>
</tr>
<tr>
<td>C-1564 140503 On-study Form</td>
<td>Submit within 1 month of pre-registration</td>
</tr>
<tr>
<td>C-1645 140503 Pre-operative Imaging Form**</td>
<td></td>
</tr>
<tr>
<td>C-274   CALGB Thoracic Lymph Node Sampling Report</td>
<td></td>
</tr>
<tr>
<td>C-1702 140503 FDG-PET Adjunctive Data Form** (if PET scan performed)</td>
<td></td>
</tr>
<tr>
<td>Report  Pre-operative X-ray and/or CT scan report Pre-operative PET scan report (if performed)</td>
<td></td>
</tr>
</tbody>
</table>

*Use C-260 CALGB Remarks Addenda if additional comments are necessary or additional writing space is needed.
** Submit original to CALGB Data Operations and a copy of form to the OSU Imaging Core Lab with CT and/or PET Images.
## Submission Schedule

### Submit only for patients who are intra-operatively randomized:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Submission Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-1644</td>
<td>140503 Surgical Resection Form</td>
<td></td>
</tr>
<tr>
<td>C-540</td>
<td>Thoracic Surgical Complications Form</td>
<td>Submit 30 days after surgery.</td>
</tr>
<tr>
<td>C-274</td>
<td>CALGB Thoracic Lymph Node Sampling Report</td>
<td></td>
</tr>
<tr>
<td>Report</td>
<td>Operative report</td>
<td></td>
</tr>
<tr>
<td>Report</td>
<td>Pathology report</td>
<td></td>
</tr>
</tbody>
</table>

### Submit for patients in whom surgical resection was performed:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Submission Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-1643</td>
<td>140503 Follow-up Form</td>
<td>Submit at months 3, 6, 9, 12, then yearly for 4 years or until death.</td>
</tr>
<tr>
<td>C-1646</td>
<td>140503 Post-operative Imaging Form**</td>
<td>Submit at months 6 and 12 and then yearly for 4 years or until death.</td>
</tr>
<tr>
<td>C-1702</td>
<td>140503 FDG-PET Adjunctive Data Form** (if PET scan performed)</td>
<td></td>
</tr>
<tr>
<td>Report</td>
<td>X-ray and/or CT scan report PET scan report (if performed)</td>
<td></td>
</tr>
</tbody>
</table>
Adverse Event Reporting (AER)

- Common Terminology Criteria for Adverse Events (CTCAE) version 3.0
- Use NCI Adverse Event Expedited Reporting System (Ad EERS)
- Report all SAE to CALGB central office, Study Chair and local IRB

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CALGB 140503 Adverse Event Reporting Requirements

<table>
<thead>
<tr>
<th>AdEERS Expedited Reporting Requirements for Adverse Events That Occur Within 30 Days(^*) of the Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>Unrelated</td>
</tr>
<tr>
<td>Not Required</td>
</tr>
<tr>
<td>Likely</td>
</tr>
<tr>
<td>Not Required</td>
</tr>
</tbody>
</table>

\(\)  Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the surgery require reporting as follows:
- AdEERS 10 calendar day report:
  - Grade 4 unexpected events
  - Grade 5 expected or unexpected events

Note: All deaths on study require both routine and expedited reporting regardless of causality. Attribution to surgery or other cause should be provided.
### CALGB 140503 PRE-REGISTRATION WORKSHEET

**Main Member Institution**

**Physician of Record**

**Affiliate/Treating Institution**

**Group Name**

If the patient has been on a previous CALGB study, specify CALGB Patient ID:

<table>
<thead>
<tr>
<th>Protocol Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Approval Date</td>
</tr>
<tr>
<td>Date Informed Consent Signed</td>
</tr>
<tr>
<td>HIPAA Authorization Date</td>
</tr>
<tr>
<td>Responsible Contact</td>
</tr>
<tr>
<td>Phone (_____) - - -</td>
</tr>
<tr>
<td>FAX (_____) - - -</td>
</tr>
</tbody>
</table>

### Patient Demographics/Pre-Treatment Characteristics

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Last</th>
<th>First</th>
<th>Middle</th>
<th>Social Security Number</th>
<th>Patient Hospital No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>American Indian or Alaskan Native</td>
<td>Asian</td>
<td>Black or African American</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>Unknown</td>
<td>White</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity (Mark one)</td>
<td>Hispanic or Latino</td>
<td>Non-Hispanic</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s Zip Code</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Country of Residence</td>
</tr>
</tbody>
</table>

### Registration Information

<table>
<thead>
<tr>
<th>Assigned CALGB Patient ID</th>
<th>Assigned Participating Group Patient ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Date</td>
<td>Registrar’s Signature</td>
</tr>
</tbody>
</table>

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### CALGB 140503 INTRA-OPE RATIVE REGISTRATION/RANDOMIZATION WORKSHEET

**Main Member Institution**

**Physician of Record**

**Affiliate/Treating Institution**

**Group Name**

If the patient has been on a previous CALGB study, specify CALGB Patient ID:

<table>
<thead>
<tr>
<th>Protocol Administration</th>
</tr>
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<tbody>
<tr>
<td>IRB Approval Date</td>
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<tr>
<td>Race</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Performance Status</td>
<td>Height</td>
<td>Weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical and Medicaid</td>
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<tr>
<td>Medicaid and Medicare</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Certification Of Eligibility

<table>
<thead>
<tr>
<th>Disease</th>
<th>NSCLC</th>
</tr>
</thead>
</table>

### Protocol Design

**Eligibility Criteria**

- Height:
  - < 1.5 cm
  - 1.5 - 2.0 cm
  - > 2.0 cm

- Diagnosis:
  - Squamous Cell Carcinoma
  - Adenocarcinoma
  - Other

- Smoking Status:
  - Never Smoker (< 100 cigarettes per lifetime) or Former (smoked > 100 cigarettes per day until < one year ago)
  - Current Smoker (one year ago or currently smoking)

- Assigned Treatment Arm:
  - Arms B, C, Excluded

### Companion Studies

- All patients will be registered in Study 200503 during registration to 140503.

### Registration Information

<table>
<thead>
<tr>
<th>Assigned CALGB Patient ID</th>
<th>Assigned Participating Group Patient ID</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Form R-140503 v1 08/28/2007 Page 1 of 1
### CALGB: THORACIC LYMPH NODE SAMPLING REPORT

**Surgical Approach** (Mark one with an X) (Complete a separate form for each procedure.)

- Thoracotomy
- Mediastinoscopy
- Thoracoscopy/Video-assisted (VATS), with conversion to thoracotomy
- Thoracoscopy/Video-assisted (VATS)

#### Lymph nodes type (right side)

<table>
<thead>
<tr>
<th>Lymph nodes type</th>
<th>Was biopsy performed?</th>
<th>Portion of node biopsied</th>
<th>Lymph node involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right upper parasternal (2L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Right lower parasternal (4R)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Subclavian (1)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Paraesophageal (6)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Pulmonary ligament (9)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Right hilar (10I)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Interlobar/ Hilus (11R)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Intrasubcardinal (12-14L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
</tbody>
</table>

(Continue to next page)

#### Lymph nodes type (left side)

<table>
<thead>
<tr>
<th>Lymph nodes type</th>
<th>Was biopsy performed?</th>
<th>Portion of node biopsied</th>
<th>Lymph node involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left upper parasternal (2L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Left lower parasternal (4L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Subclavian (5)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Subclavian (7)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Paraesophageal (9)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Pulmonary ligament (9)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Left hilar (10L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Interlobar/ Hilus (11L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
<tr>
<td>Intrasubcardinal (12-14L)</td>
<td>No</td>
<td>Yes</td>
<td>Whole</td>
</tr>
</tbody>
</table>

(Continue to next page)
### CALGB: 140503 ON-STUDY FORM

**Patient Data**

- **Patient initials**: [Blank]
- **Age**: [Blank]
- **Diagnosis**: [Blank]
- **Date of Pulmonary Function Test**: [Blank]
- **Forced Expiratory Volume (FEV1)**: [Blank]
- **Forced Expiratory Volume (Observed FEV1)**: [Blank]
- **Forced Vital Capacity (FVC)**: [Blank]
- **Forced Vital Capacity (Observed FVC)**: [Blank]

**Smoking Status**

- **Never smoked (smoked > 150 cigarettes over lifetime)**: [Blank]
- **Smoked in the past (smoked > 100 cigarettes and quit ≥ 1 year ago)**: [Blank]
- **Currently smoking (quit ≤ 1 year ago, or currently smoke)**: [Blank]

**Pack year = number of packs smoked/day × number of years smoked**

**Assigned Treatment arm (during intra-operative randomization)**

- **Wedge resection**
- **Lobectomy**
- **Patient not randomized, specify reason**

**Positive nodes (pre- or intra-operatively)**

- **Lung**
- **Gastrointestinal**
- **Other**, specify: [Blank]

**Completed by**: [Blank]

**Date arm originally assigned**: [Blank]

---

### CALGB: 140503 FOLLOW-UP FORM

**Patient Data**

- **Patient initials**: [Blank]
- **Age**: [Blank]
- **Diagnosis**: [Blank]
- **Date of Pulmonary Function Test**: [Blank]
- **Forced Expiratory Volume (FEV1)**: [Blank]
- **Forced Expiratory Volume (Observed FEV1)**: [Blank]
- **Forced Vital Capacity (FVC)**: [Blank]
- **Forced Vital Capacity (Observed FVC)**: [Blank]

**Smoking Status**

- **Never smoked (smoked > 150 cigarettes over lifetime)**: [Blank]
- **Smoked in the past (smoked > 100 cigarettes and quit ≥ 1 year ago)**: [Blank]
- **Currently smoking (quit ≤ 1 year ago, or currently smoke)**: [Blank]

**Pack year = number of packs smoked/day × number of years smoked**

**Assigned Treatment arm (during intra-operative randomization)**

- **Wedge resection**
- **Lobectomy**
- **Patient not randomized, specify reason**

**Positive nodes (pre- or intra-operatively)**

- **Lung**
- **Gastrointestinal**
- **Other**, specify: [Blank]

**Completed by**: [Blank]

**Date arm originally assigned**: [Blank]

---

**Patient Information**

- **Vital status (Mark one with an X)**: [Alive, Dead, Lost to follow-up]
- **Primary cause of death (Mark one with an X)**: [Complications of protocol surgery (within 30 days after surgery), Due to other causes, other causes of death, Other]
- **Due to this disease**: [Blank]

**Disease Status**

- **Date of most recent clinical assessment**: [Blank]
- **No evidence of disease**: [Blank]
- **Relapse/Recurrence**: [Blank]
- **Died with no evidence of disease**: [Blank]

**Progression/Relapse Data**

- **Time of relapse (Mark one with an X)**: [Locally, Distantly, Other]
- **Local**: [Blank]
- **Distant**: [Blank]
- **Other**: [Blank]

**Bites of Relapse**

- **Site of relapse (If relapse occurred during this reporting period, Mark all that apply with an X)**: [Bladder, Mediastinal nodes, Adrenal(s), Supraclavicular/scapula nodes, Bone, Primary lung, Bone marrow, Contralateral lung, Brain, Pleura, Other, specify: [Blank]]

**Continued on next page...**
## CALGB: PREOPERATIVE IMAGING FORM

### TUMOR FEATURES (cont.)

- Is a previous CT scan available for comparison? [ ] No [ ] Yes
- If yes, has the tumor changed? (blank one with an X)
  - [ ] New finding (i.e., not present on previous CT)
  - [ ] Tumor size increased; indicate previous maximum diameter (on lung window images) cm
  - [ ] Tumor size decreased; indicate previous maximum diameter (on lung window images) cm
- Date of previous scan: Y Y / Y Y

### TUMOR APPEARANCE

- Margin and shape based on lung window settings (blank all that apply with an X)
  - [ ] Well-defined
  - [ ] ill-defined
  - [ ] lobulated
  - [ ] speculated
  - [ ] round
- Tumor appearance on lung window settings (blank one with an X)
  - [ ] solid
  - [ ] Part-solid (mixed solid and ground-glass opacity)
- Tumor appearance on soft tissue (chest / abdomen) window settings (blank one with an X)
  - [ ] solid
  - [ ] Part-solid (mixed solid and ground-glass opacity)

If the scan includes contrast-enhanced images of the tumor, are any of the following present within the tumor? (blank all that apply with an X)
- [ ] High-attenuation fat (e.g., calcification)
- [ ] Water-attenuation fat (e.g., necrosis)
- [ ] Gas-attenuation fat

If the scan includes contrast-enhanced images of the tumor, are any of the following present within the tumor? (blank all that apply with an X)
- [ ] High-attenuation fat (e.g., calcification)
- [ ] Water-attenuation fat (e.g., necrosis)
- [ ] Gas-attenuation fat

(Continue on next page)

---

## CALGB: PREOPERATIVE IMAGING FORM

### LYMPH NODES

- Indicate stations of all enlarged lymph nodes (blank all that apply with an X)
  - Right upper paratracheal (DR)
  - Left upper paratracheal (DL)
  - Right superior mediastinal (SP)
  - Left superior mediastinal (SL)
  - Right lower paratracheal (DR)
  - Left lower paratracheal (DL)
  - Right hilar (H1, H2, H3, H4)
  - Left hilar (L1, L2, L3)

- Was a pre-operative PET scan performed? [ ] No [ ] Yes, specify date of PET scan

### PET SCAN RESULTS

- Site of lesion (Check all that apply with an X)
  - [ ] Primary lung
  - [ ] Nodal lesion, specify

- SUV Max
  - [ ]

- SUV Mean
  - [ ]

- What limits were performed to rule out possible distant metastases present on PET scan?

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## CALSER POST-OPERATIVE IMAGING FORM

### INSTRUCTIONS
Complete and submit this form as required by the site chief. Instructions in this section must be completed.

**Date of CT Scan:**

- **Slice of CT Scan:**
- **Date of CT Scan:**

**Patient Initials:**

- **Patient Name:**
- **Date of Birth:**
- **Sex:**
- **Race:**
- **Height:**
- **Weight:**
- **Hypertension:**
- **Diabetes:**
- **Liver Transplant:**
- **Prior Pulmonary Function Test:**
- **Current medical problems:**
- **Medication:**
- **Allergies:**
- **Sickle Cell Anemia:**
- **Chronic Liver Disease:**
- **Chronic Renal Failure:**
- **Chronic Obstructive Pulmonary Disease:**
- **Ascending Aortic Aneurysm:**
- **Other:**

**Hospital name or imaging center performing chest CT:**

- **Technique Factors:**
- **KVP:**
- **mA:**
- **Scan length (cranio-caudal extent):**

**Residual lung tumor:**

- **Yes:**
- **No:**

**Are any new calcified lung nodules or masses present?**

- **Yes:**
- **No:**

**Residual gross tumor:**

- **Yes:**
- **No:**

**Site of lesion (specify lung and lobe):**

<table>
<thead>
<tr>
<th>Lesion number</th>
<th>Site of lesion</th>
<th>Table position of section that shows lesion</th>
<th>Maximum diameter of tumor (cm)</th>
<th>Present on lung window settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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<tr>
<td>5</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Residual gross tumor:**

- **Yes:**
- **No:**

**PET Scan DATA:**

- **PET Scan performed during this period?**
  - **Yes:**
  - **No:**

**PET Scan Results:**

<table>
<thead>
<tr>
<th>Site of lesion (specify lung and lobe)</th>
<th>SUV Max</th>
<th>SUV Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**What tests were performed to rule out possible distant metastases present on PET scan?**

**Completed by:**

- **Date:**
- **Significant:**
- **Notes:**

**Send form to:**

- **Site Chief:**
CALGB: 140563 FDG-PET ADJUNCTIVE DATA SHEET

Instructions: Complete and submit this form as required by the protocol. If any section(s) on this form is required, it must be completed on the form to be accepted. For clinical accuracy, use black ink on this form. This form MUST be completed and returned with any other study-related documentation that pertains to this patient. This form should be completed by the investigator, or an authorized representative designated by the investigator. If you have any questions, please contact the study office at 1-301-223-0775.

Patient Initials: __________________________  Participating Group: __________________________
Patient Hospital No: __________________________  Participating group ID: __________________________
Institution: __________________________
Institutional ID: __________________________

Instructions: Submit this form to the OSU Imaging Core Lab via mail or fax (414-203-9276) and to the CALGB Statistical Center, Data Operations.

Duration of patient fasting pre-FDG injection: _______ hours

Patient weight at the PET Center prior to dosing: _______ kg  Patient height (on day of scan): _______ cm

Blood glucose measured prior to FDG injection at the site: _______ mg/dL

Pre-injection FDG syringe dose: _______ mCi  MIQ Time: _______ (24 hour clock)

Post-injection residual dose acquired: _______ mCi  MIQ Time: _______ (24 hour clock)

Effective FDG dose injected: _______ mCi  MIQ Time: _______ (24 hour clock)

(Effective FDG dose = Pre-injection syringe FDG dose - Post-injection residual dose)

Location of injection site: Right  Left

Emission scanning start time: _______  Emission scanning finish time: _______

Number of bed positions scanned: _______

Was the injection site covered within the field of view?  No  Yes

If no, was an additional scan obtained from the injection site?  No  Yes

(Continue to next page.)