Study Evaluation and Diagnosis Worksheet

**Instructions:** The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician at each SOC follow up visit for the patient. Any malignancy identified during the two-year follow-up time period will need to be reported on the Study Evaluation and Diagnosis Form.

1. Was the Study Evaluation and Diagnosis Form completed by the treating physician?
   - ○ No, complete Q1a and sign off worksheet
   - ○ Yes, continue to Q2

   **1a. If no, provide primary reason:**
   - ○ Patient refused follow up
   - ○ Patient lost to follow up
   - ○ Treating physician did not complete form
   - ○ Other, specify ___________________________

2. Date study evaluation and diagnosis completed: _____-____-_______ MMM-dd-yyyy

3. Is there malignancy in the lung?
   - ○ No, further follow up is required Q4 and Part IV are required
   - ○ Yes*, Q3a, Q3b, Q4, and Part IV are required. Part II is also required for primary lung malignancies
   - ○ Uncertain, but presumed malignant *Q3a, Q3b, Q4, and Part IV are required.
   - ○ Uncertain, Q4 and Part IV are required

   *These cases will be sent to the Adjudication Committee and should not be taken off trial until the outcome is determined

   **3a. If yes, provide date established:** _____-____-_______ MMM-dd-yyyy

   **3b. If yes, the malignancy is:**
   - ○ Primary Lung, complete Q4, then continue to Part II
   - ○ Metastatic to the Lung, complete Q3b1, then continue to Part IV
   - ○ Presumed Cancer- primary lung- continue to Part IV
   - ○ Presumed Cancer- metastatic to the lung complete Q3b1, then continue to Part IV
   - ○ Uncertain, continue to Part IV

   **3b1. If metastatic, provide the primary site of origin:** __________________________

4. Did the case have any other cancer diagnosis?
   - ○ No
   - ○ Yes, Q4a is required

   **4a. If yes, provide the primary site:** __________________________
Part II. Lung Malignancy complete this section only if Q3b=primary lung

5. Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form?
   ○ No, skip to Q6
   ○ Yes, continue to Q5a
   ○ Unknown, skip to Q6
   ○ Not applicable, skip to Q6

   5a. Has the patient developed progressive disease (e.g., progression at primary site, metastases, other recurrence) following treatment for lung cancer?
      ○ No, skip to Part IV
      ○ Yes, complete Q5a1 and 5a2, then skip to Part IV
      ○ Unknown, skip to Part IV

   5a1. If yes, date of first documentation of progressive lung cancer: _______ - _______ - _______ MMM-dd-yyyy

   5a2. List the site(s) of progression of lung cancer: ______________________________________________________

6. Lung Cancer Type
   ○ Small Cell Lung Cancer
   ○ Non-Small Cell Lung Cancer
   ○ Carcinoid
   ○ Unknown
   ○ Other, specify_____________________

7. Histologic Class
   ○ Adenocarcinoma
   ○ Adenosquamous Carcinoma
   ○ Epidermoid Carcinoma
   ○ Bronchioloalveolar Carcinoma
   ○ Carcinoid
   ○ Other, specify_____________________

8. Histologic Subtype
   ○ Acinar
   ○ Bronchioalveolar
   ○ Papillary
   ○ Solid carcinoma with mucus formation
   ○ Mixed
   ○ Large cell with rhabdoid phenotype
   ○ Other, specify_____________________

9. Cancer Stage
   ○ Occult
   ○ 0
   ○ IA
   ○ IB
   ○ IIA
   ○ IIB

After completion of Part II, skip to Part IV of this form
Part III. No Malignancy complete this section only if Q3= No, this is a benign case, follow up will cease

10. Provide the reasoning for the no malignancy diagnosis:
   ○ No Definitive Diagnosis During Two-Year Follow Up
   ○ Alternate Diagnosis, continue to Q11
   ○ Resolution of Abnormality, skip to Part IV
   ○ Stable mass, no additional FU, skip to Part IV
   ○ Stable mass, additional FU required, skip to Part IV
   ○ Other, specify ____________________________

11. If alternative diagnosis, what is the alternate diagnosis?
   ○ Sarcoïd
   ○ Altelectasis
   ○ Carcinoid
   ○ Infection
   ○ Other, specify ____________________________

11a. If the alternative diagnosis is infection, provide the type:
   ○ TB
   ○ Bacterial Pneumonia
   ○ Fungus
   ○ Viral Pneumonia
   ○ Other, specify ____________________________

After completion of Part III, continue to Part IV of this form

Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed required if Q1= yes

Note: For all diagnostic tests, sites will need to upload a de-identified copy of the report into Rave

<table>
<thead>
<tr>
<th>Diagnostic Test Type</th>
<th>Was test performed since last Study Evaluation and Diagnosis form was completed?</th>
<th>If performed, date of test MMM-dd-yyyy</th>
<th>Was test used to establish diagnosis described above?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Scan</td>
<td>○ No ○ Yes ○ Unknown</td>
<td>○ No ○ Yes</td>
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<tr>
<td>Bronchoscopy</td>
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<td>○ No ○ Yes</td>
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<tr>
<td>Chest X Ray</td>
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<td>○ No ○ Yes</td>
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<tr>
<td>CT Scan</td>
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<td>Lobectomy</td>
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<tr>
<td>Mediastinoscopy</td>
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<tr>
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<tr>
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<tr>
<td>TBNA</td>
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</tbody>
</table>

__________________________________________  ______________________
Signature of Treating Physician              Date Form Completed