

**The International Association for the Study of Lung Cancer (IASLC)  
Prospective Lung Cancer Staging Project**

**APPENDIX TO PROCOTOL  
FOR PURPOSE OF GRANT APPLICATION AND ETHICS REVIEW**

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## 18.1 Registration

<b>Registration</b>		Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project		
<hr/>		
Institution:	<input type="text"/>	
Please enter a code (up to 15 characters) to identify the patient (do not identify the patient by name): <input type="text"/>		
<hr/>		
<input type="button" value="Submit"/>	<input type="button" value="Cancel"/>	eCRF Version: 1.0

## 18.2 Register New Lab

<b>Register New Lab</b>		Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project		
<hr/>		
<b>IMPORTANT:</b> This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.		
<hr/>		
Institution:	<input type="text"/>	
Lab Name (up to 100 characters): <input type="text"/>		
<hr/>		
<input type="button" value="Submit"/>	<input type="button" value="Cancel"/>	eCRF Version: 1.0

## 18.3 Patient Characteristics

<b>Patient Characteristics</b>			Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project			
<b>Subject ID:</b> 10010001	<b>Code:</b> DLS	<b>Institution:</b> University of Michigan	
<b>IMPORTANT:</b> This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.			
<b>Patient birth date:</b>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
	Day    Month    Year (yyyy)		
<b>Sex:</b>	<input type="radio"/> Male	<input type="radio"/> Female	
<b>Race (select one):</b>	<input type="radio"/> Asian	<input type="radio"/> Black or African American	
	<input type="radio"/> White or Caucasian	<input type="radio"/> American Indian/Alaskan Native/Pacific Islander	
	<input type="radio"/> Other/Mixed/Uncertain		
<b>Smoking history (select one):</b>	<input type="radio"/> Never smoked	<input type="radio"/> Former smoker	
	<input type="radio"/> Current smoker	<input type="radio"/> No data	
<b>If a former smoker, number of years since quitting?</b>	<input type="text"/>		
<b>Number of years smoked:</b>	<input type="text"/>		
<b>Weight loss in previous six months (select one):</b>	<input type="radio"/> > 5%	<input type="radio"/> </= 5%	
<b>Zubrod Performance Status (select one):</b>	<input type="radio"/> Fully active	<input type="radio"/> Restricted	<input type="radio"/> No work, ambulatory
	<input type="radio"/> Limited self care	<input type="radio"/> Completely disabled	<input type="radio"/> Unknown
<b>Height:</b> <input type="text"/> cm	<b>Weight:</b> <input type="text"/> . <input type="text"/> kg		

### 18.3 Patient Characteristics (Continued)

**Cormorbidity:**

**Tobacco consumption** Yes This field is automatically filled based on the answer given for the Smoking History field.

**Diabetes mellitus**  Yes  No  No data

**Renal insufficiency**  Yes  No  No data

**Respiratory comorbidity**  Yes  No  No data

**Cardiovascular comorbidity**  Yes  No  No data

**Previously treated malignancy (other than squamous skin cancer)**  Yes  No  No data

**Alcoholism**  Yes  No  No data

**Date of trial entry if patient was enrolled on a clinical trial:**  -  -   
Day Month Year (yyyy)

**Check here if patient had multiple synchronous tumours**

**This box is to be checked only for those cases in which the synchronous and multiple tumours are considered to be separate "primary" tumours as defined below. If a patient has multiple synchronous tumours, please document treatment and staging data separately for each primary tumour. Please consistently designate one primary tumour as #1 and the other as #2. All treatment and staging forms will need to be completed twice, once for primary tumour #1 (identified by TUMOUR1 tab) and again for primary tumour #2 (identified by TUMOUR2 tab).**

The classification of additional tumour nodules in lung cancer depends upon their histological appearances.

a) In most situations in which additional tumour nodules are found in association with a lung primary these are metastatic nodules, with identical histological appearances to that of the primary tumour. If limited to the lobe of the primary tumour such tumours are classified as T3, when found in other ipsilateral lobes are designated as T4 and if found in the contralateral lung are designated M1a.

b) Multiple tumours may be considered to be synchronous primaries if they are of different histological cell types. Multiple tumours of similar histological appearance should only be considered to be synchronous primary tumours if in the opinion of the pathologist, based on features such as associated carcinoma in situ or differences in morphology, immunohistochemistry and/or molecular studies, they represent differing sub-types of the same histopathological cell type, and also have no evidence of mediastinal nodal metastases or of nodal metastases within a common nodal drainage.

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## 18.4 Pre-Treatment/Evaluative Laboratory Values

Logged in: Joan Smith (31023)

### Pre-Treatment/Evaluative Laboratory Values

International Association for the Study of Lung Cancer  
Data Elements for Prospective Lung Staging Project

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**Subject ID:** 10010001      **Code:** DLS      **Institution:** University of Michigan

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**Please indicate the type of units used for the laboratory values:**

**Sex:**  Male  Female

**Apply the Following Set of Normal Limits:**

**Laboratory Values:**

<b>LDH:</b>	<input type="text"/> IU/L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Hemoglobin:</b>	<input type="text"/> g/dL	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Calcium Level:</b>	<input type="text"/> mmol/L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Alkaline Phosphatase:</b>	<input type="text"/> IU/L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Sodium, NA:</b>	<input type="text"/> mmol/L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>White Cell Count:</b>	<input type="text"/> x 10 <sup>9</sup> /L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Neutrophil Count:</b>	<input type="text"/> x 10 <sup>9</sup> /L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Platelet Count:</b>	<input type="text"/> x 10 <sup>9</sup> /L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )
<b>Albumin:</b>	<input type="text"/> g/L	<b>(Lower:</b> <input type="text"/> <b>, Upper:</b> <input type="text"/> )

**Please indicate Limits of Normal**

If a pre-specified set of normal limits was specified above, check the following box to confirm this set is current:

**Pulmonary Function Tests:**

**Forced Vital Capacity (FVC):**  .  liter      **% Predicted FVC:**  .  %

**Forced Expiratory Volume in 1 Second (FEV1):**  .  liter      **% Predicted FEV1:**  .  %

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The appearance of the form will change depending how the “Please indicate the type of units used for the laboratory values” question is answered. When “Conventional Units” is selected, the form will use Conventional units for each of the laboratory values.

### 18.4 Pre-Treatment/Evaluative Laboratory Values (Continued)

**Logged in:** Joan Smith (31023)

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**Pre-Treatment/Evaluative Laboratory Values**  
International Association for the Study of lung Cancer  
Data Elements for Prospective Lung Staging Project

---

**Subject ID:** 10010001      **Code:** DLS      **Institution:** University of Michigan

---

**Please indicate the type of units used for the laboratory values:**

**Sex:**  Male    Female

**Apply the Following Set of Normal Limits:**

<b>Laboratory Values:</b>		<b>Please indicate Limits of Normal</b>
<b>LDH:</b>	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Hemoglobin:</b>	<input type="text"/> g/dl	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Calcium Level:</b>	<input type="text"/> mg/dl	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Alkaline Phosphatase:</b>	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Sodium, NA:</b>	<input type="text"/> mEq/L	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>White Cell Count:</b>	<input type="text"/> x 10 <sup>3</sup> /mm <sup>3</sup>	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Neutrophil Count:</b>	<input type="text"/> x 10 <sup>3</sup> /mm <sup>3</sup>	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Platelet Count:</b>	<input type="text"/> x 10 <sup>3</sup> /mm <sup>3</sup>	(Lower: <input type="text"/> , Upper: <input type="text"/> )
<b>Albumin:</b>	<input type="text"/> g/dl	(Lower: <input type="text"/> , Upper: <input type="text"/> )

If a pre-specified set of normal limits was specified above, check the following box to confirm this set is current:

**Pulmonary Function Tests:**

**Forced Vital Capacity (FVC):**  .  liter      % Predicted FVC:  .  %

**Forced Expiratory Volume in 1 Second (FEV1):**  .  liter      % Predicted FEV1:  .  %

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### 18.5 Disease Description at Diagnosis (Continued)

If histologic type is 'Small cell carcinoma (or combined SCLC),' 'Large cell neuroendocrine (or combined LCNEC),' 'Mixed other,' or 'Other,' please specify the histologic type(s):

If histologic type is 'Small cell carcinoma (or combined SCLC),' please complete the following:

Extent of Disease:  Limited disease  Extensive disease  No data on extent

Paraneoplastic syndrome:  Yes  No  No data

If yes, please complete the following:

SIADH:  Yes  No  No data

Ectopic ACTH:  Yes  No  No data

Myasthenic Syndrome (LEMS, ELS):  Yes  No  No data

If histologic type is 'Small cell lung cancer (or combined SCLC),' 'Large cell neuroendocrine (or combined LCNEC),' 'Carcinoid - typical,' 'Carcinoid - atypical,' 'Carcinoid - not otherwise specified,' or 'Carcinoid-like tumourlet (<0.5 cm),' please complete the following:

Chromogranin:  Positive  Negative  Equivocal/No data

Synaptophysin:  Positive  Negative  Equivocal/No data

CD56:  Positive  Negative  Equivocal/No data

Submit

Cancel

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## 18.6 Basis for Pre-Treatment/Evaluation Findings

<b>Logged in:</b> Joan Smith (31023)		
<b>Basis for Pre-Treatment/Evaluative Findings</b> International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project		
<b>Subject ID:</b> 10010001	<b>Code:</b> DLS	<b>Institution:</b> University of Michigan
<b>Tumour: #1</b>	<b>Location of Primary Tumour:</b> Lobe: RML	<b>Histologic Type:</b> Squamous
<b>IMPORTANT:</b> This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.		
<b>For each group of tests (C1-3 and subgroups thereof) listed below, please select:</b> - <b>"Yes"</b> if any test in the list was performed during pre-treatment diagnosis and staging. - <b>"No"</b> if no test in the list was performed. - <b>"No data"</b> if these data are not available.		
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C1</b>	Physical examination Standard radiology (chest x-rays) Endoscopy without biopsy
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C2a.1</b>	Bone scan
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C2a.2</b>	Brain CT/MRI
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C2a.3</b>	CT of chest +/- upper abdomen

### 18.6 Basis for Pre-Treatment/Evaluation Findings (Continued)

<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C2b</b>	PET or PET/CT
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C2c</b>	Bronchoscopy with or without ultrasonography (EBUS), with biopsy or cytology Oesophagoscopy with or without ultrasonography (EUS), with biopsy or cytology Percutaneous needle biopsy or cytology
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data	<b>C3</b>	Mediastinoscopy with biopsy or cytology Parasternal mediastinotomy with biopsy or cytology Extended cervical mediastinoscopy with biopsy or cytology Thoracoscopy with biopsy or cytology Video-assisted thoracoscopic surgery with biopsy or cytology Pericardioscopy with biopsy or cytology Exploratory and diagnostic thoracotomies with biopsy or cytology, but without removal of the primary tumour and without systematic nodal dissection


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## 18.7 Treatments

<b>Treatments</b>			Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project			
<b>Subject ID:</b> 10010001	<b>Code:</b> DLS	<b>Institution:</b> University of Michigan	
<b>IMPORTANT:</b> This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.			
<b>Was removal of the primary tumor attempted?:</b>			
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data			
<b>If resection of the primary tumor was attempted:</b>			
<b>Date of resection attempt:</b> <input type="text"/> - <input type="text"/> - <input type="text"/>			
<small>Day    Month    Year (yyyy)</small>			
<b>Extent of resection (select one):</b>			
<input type="radio"/> Thoractomy (no resection) <input type="radio"/> Segmentectomy <input type="radio"/> Wedge Resection			
<input type="radio"/> Endoscopic resection <input type="radio"/> Lobectomy <input type="radio"/> Bilobectomy			
<input type="radio"/> Resection of the airway without removal of lung parenchyma <input type="radio"/> Pneumonectomy <input type="radio"/> No data			
<input type="radio"/> Resection of the airway with parenchymal resection (sleeve/bronchioplastic resection)			
<b>Extent of parenchymal resection (if done, select one):</b>			
<input type="radio"/> Wedge resection			
<input type="radio"/> Segmentectomy			
<input type="radio"/> Lobectomy			
<input type="radio"/> Bilobectomy			
<input type="radio"/> Pneumonectomy			
<input type="radio"/> No data			
<b>Completeness of resection (select one):</b>			
<input type="radio"/> R0 (No residual tumor)			
<input type="radio"/> R1 (Microscopic residual tumor)			
<b>Specify location of microscopic residual:</b>			
<input type="radio"/> Bronchial margin - in situ (R1is)			
<input type="radio"/> Bronchial margin - other			
<input type="radio"/> Vascular (artery, vein, or both)			
<input type="radio"/> Peripheral (e.g. chest wall, mediastinum, or diaphragm)			
<input type="radio"/> No data			
<input type="radio"/> R2 (Macroscopic residual tumor)			
<b>Specify location of macroscopic residual:</b> <input type="text"/>			
<input type="radio"/> No data			


### 18.7 Treatments (Continued)


Please document the sequence of FIRST-LINE therapy only below, relative to resection (if attempted):


**Systemic therapy:**  


**Radiation administered to thorax:**  

**Was radiation administered to site(s) other than the thorax as part of first-line therapy?:**  
 Yes     No     No data

**Brain radiation therapy:**  

**Spine radiation therapy:**  


**Bone radiation therapy:**  


**Radiation therapy to other site(s):**  

**Specify other site(s):**

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Systemic therapy, no resection attempt  
No systemic therapy  
Systemic therapy after attempted resection  
Systemic therapy before attempted resection  
Systemic therapy before and after attempted resection  
Intraoperative systemic therapy  
Intraoperative systemic therapy with other therapy before or after surgery  
Sequence unknown, but both systemic therapy and surgery were given  
No data

  
Radiation therapy; no resection attempt  
No radiation therapy  
Radiation therapy after attempted resection  
Radiation before attempted resection  
Radiation before and after attempted resection  
Intraoperative radiation therapy  
Intraoperative radiation therapy with other RT before or after surgery  
Sequence unknown, but both radiation therapy and surgery were given  
No data

## 18.8 T-Descriptors, by Pre-Treatment/Evaluation Findings

Logged in: Joan Smith (31023)

### T-Descriptors, by Pre-Treatment/Evaluative Findings

International Association for the Study of Lung Cancer  
Data Elements for Prospective Lung Staging Project

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**Subject ID:** 10010001      **Code:** DLS      **Institution:** University of Michigan  
**Tumour: #1**      **Location of Primary Tumour:** Right Main Bronchus      **Histologic Type:** Squamous

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.

---

**Lung tumour T by pre-treatment/evaluative findings:**

**Size of primary tumour, by pre-treatment/evaluative findings:**  .  cm, longest dimension

**Is lymphangitis present:**  Yes     No

**If yes, specify all locations (select all that apply):**

- Adjacent to primary
- Elsewhere in lobe
- In other ipsilateral lobes
- Contralateral lung

**For each relevant section (as determined by T status), please check all that apply:**

**Section 1 (T1):**

- Tumour =< 3 cm, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion proximal to lobar bronchi (i.e. not in the main bronchus)
- Superficial spreading tumour of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus

Tx (Primary tumour cannot be assessed)  
Tx (Tumour proven by presence of malignant cell in sputum or bronchial washings)  
Tis (Carcinoma in situ)  
T1a  
T1b  
T1, NOS  
T2a  
T2b  
T2, NOS  
T3  
T4  
No data

## 18.8 T-Descriptors, by Pre-Treatment/Evaluation Findings (Continued)

**Section 2 (T2 - T4):** **Although these are T2-descriptors, please complete Section 2 for tumours classified as either T2 or T3 or T4.**

- Tumour more than 3 cm but less than or equal to 5 cm in greatest dimension
- Tumour more than 5 cm in greatest dimension but less than or equal to 7 cm
- Tumour involves the main bronchus, 2 cm or more distal to the carina
- Tumour with atelectasis/obstructive pneumonitis extending to hilar region but not involving entire lung
- Tumour invades the visceral pleura

**Section 3 (T3 - T4):** **Although these are T3-descriptors, please complete Section 3 for tumours classified as either T3 or T4.**

- Tumour greater than 7 cm in greatest dimension
- Tumour invades chest wall:
  - Specify depth of invasion (select one):
    - To parietal pleura
    - To bone and/or soft tissue
    - To endothoracic fascia
    - No data
- Apical chest wall invasion (formerly superior sulcus tumour) (select all that apply):
  - Involving subclavian vessels
  - Involving chest wall, including rib
  - Involving brachial plexus
  - Involving sympathetic chain
- Invasion of the diaphragm
- Invasion of mediastinal pleura
- Invasion of parietal pericardium
- Invasion of phrenic nerve
- Tumour in the main bronchus less than 2 cm distal to the carina, but without involvement of the carina
- Tumour with associated atelectasis or obstructive pneumonitis of the entire lung
- Separate tumour nodule(s) of same histologic type in the same lobe as the primary tumour

## 18.8 T-Descriptors, by Pre-Treatment/Evaluation Findings (Continued)

- Section 4a**  Invasion of mediastinum (mediastinal soft tissue)  
**(T4):**  Invasion of heart  
 Invasion of visceral pericardium  
 Invasion of great vessels, specify (select all that apply):  
 Superior vena cava  Inferior vena cava  Aorta  Main trunk pulmonary artery  
 Pulmonary artery (within the pericardium)  Pulmonary vein (within the pericardium)  
 Invasion of trachea  
 Invasion of oesophagus  
 Invasion of carcina  
 Invasion of recurrent laryngeal nerve  
 Apical chest wall invasion (formerly superior sulcus tumour) involving vertebral bone  
 Other invasion of the vertebrae  
 Additional tumour nodule(s) on the same side of lung as primary tumour but in different lobe

Submit

Cancel

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### 18.9 Pre-treatment/Evaluative N Category Based on Clinical and Imaging Assessment (Continued)

Size of largest node examined: <input type="text"/> . <input type="text"/> cm, longest dimension		
Location of the largest node examined:		
<input type="radio"/> Distant node (M1)	<input type="radio"/> N3 Ipsilateral	<input type="radio"/> N1
<input type="radio"/> Contralateral (not M1)	<input type="radio"/> N2	<input type="radio"/> No data
<input type="button" value="Submit"/>	<input type="button" value="Cancel"/>	eCRF Version: 1.0



### 18.10 Pre-treatment/Evaluative N Category Based on Cytology or Biopsy Results (Continued)

<b>Extracapsular involvement?:</b> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No data		
If yes, please complete the following:		
N3 extracapsular involvement:	<input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> No data
N2 extracapsular involvement:	<input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> No data
N1 extracapsular involvement:	<input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> No data
<b>Size of largest node explored:</b> <input type="text"/> . <input type="text"/> cm, longest dimension		
<b>Location of the largest node explored:</b>		
<input type="radio"/> Distant node (M1)	<input type="radio"/> N3 Ipsilateral	<input type="radio"/> N1
<input type="radio"/> Contralateral (not M1)	<input type="radio"/> N2	<input type="radio"/> No data
<b>If this site has agreed to provide additional information on the number of nodes explored, please enter the data below:</b>		
<b>Number of N3 nodes explored:</b> <input type="text"/>	<b>Number of positive N3 nodes:</b> <input type="text"/>	
<b>Number of N2 nodes explored:</b> <input type="text"/>	<b>Number of positive N2 nodes:</b> <input type="text"/>	
<b>Number of N1 nodes explored:</b> <input type="text"/>	<b>Number of positive N1 nodes:</b> <input type="text"/>	
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>		eCRF Version: 1.0





























