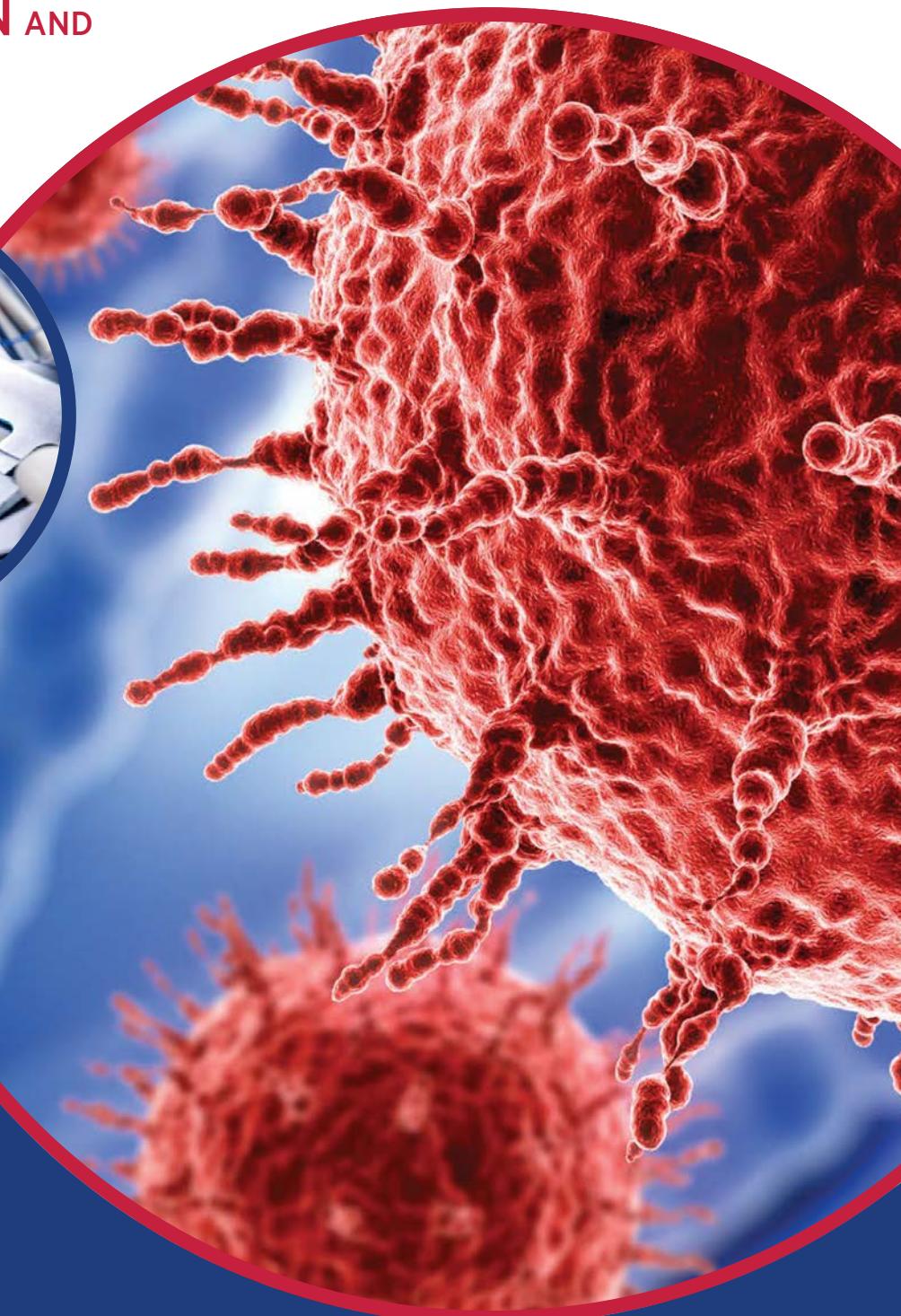


# INTERNATIONAL STAGING PROJECT

## DATA SUBMISSION AND QUERY TOOLKIT





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# PROJECT OVERVIEW

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The International Association for the Study of Lung Cancer (IASLC) Staging Project is a global effort to investigate and improve the current tumor, node, metastasis (TNM) staging system for lung cancer, mesothelioma, esophageal, and thymic cancers. Over the past two decades, the IASLC Staging Project has provided evidence-based recommendations for the TNM classification for lung cancer, which are published and adopted by the Union for International Cancer Control (UICC) and the American Joint Committee on Cancer (AJCC). The project is now entering the third cycle, with the goal of developing recommendations for the ninth edition of TNM. Staging lung cancer and other thoracic malignancies accurately is critical in deciding treatment regimens and ensures best standardized care for patients worldwide. New data elements such as genetic biomarkers, protein alterations and copy number alterations (CNAs) will be added to the staging project for the first time, and such additions and enhancements to the system may significantly improve the current staging system leading to more precise treatment decisions and improvement in patient survival.



# DATA SUBMISSION

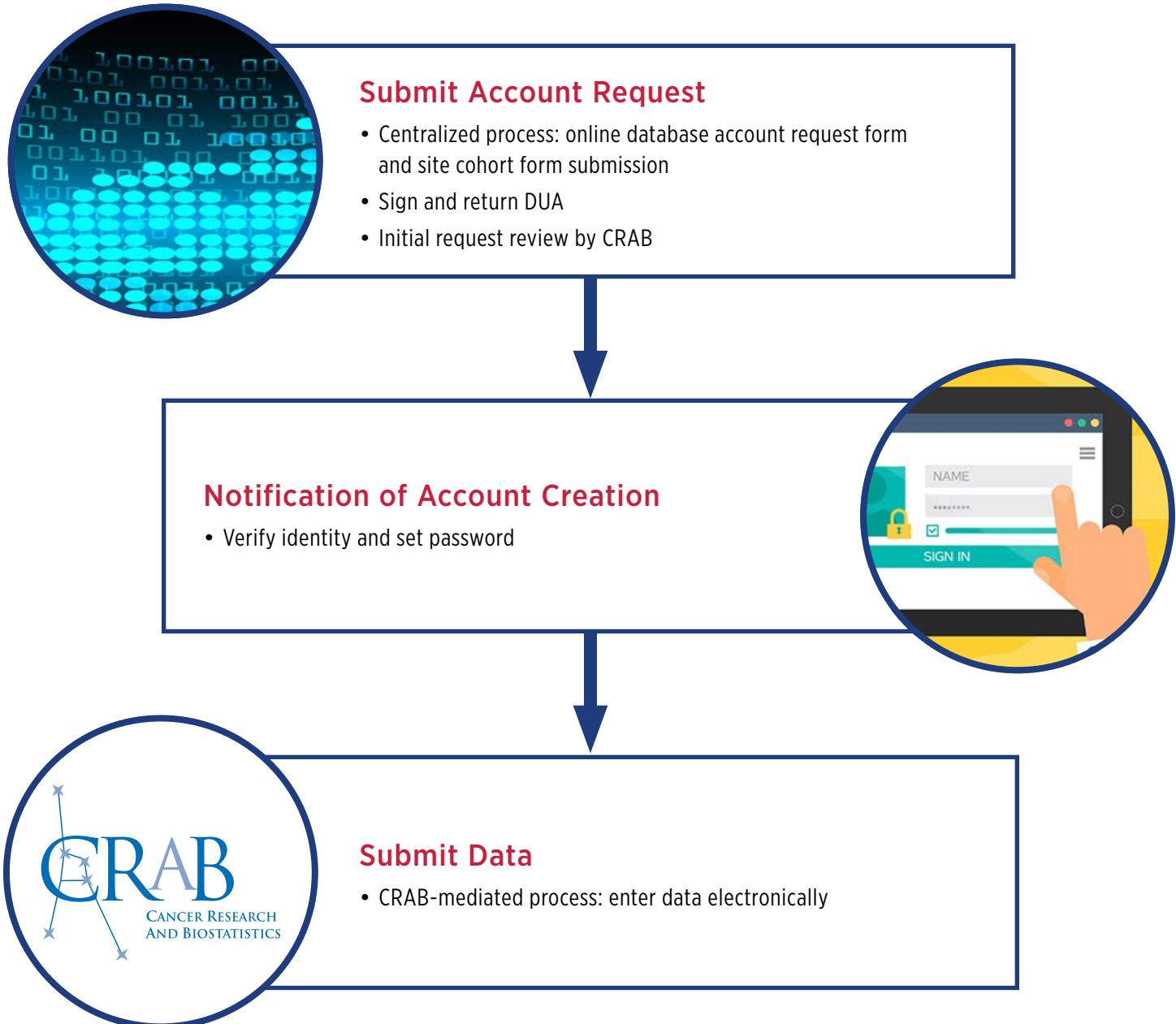
# DATA SUBMISSION PROCESS

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Institutions can participate in the project by registering lung cancer cases (diagnosed between January 2011 and the end of 2019) into the electronic database (EDC). Access to the database for data entry will be activated after application forms are complete. Sample forms can be found on page 7 of the toolkit. If you are ready to apply, the application forms can be accessed electronically [here](#). If there are issues accessing the electronic forms, please visit [www.iaslc.org/Research-Education/IASLC-Staging-Project](http://www.iaslc.org/Research-Education/IASLC-Staging-Project) to access PDF versions of the forms. Database participants will not be able to access the data submitted by other sites, but can download their own data from the EDC at any time. Please see the protocol, data elements, and FAQ for more information about the electronic database, its contents, and requirements. If you have questions about the database, please email [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org).

Please note that mesothelioma cases can also be entered into a different EDC.

# DATA SUBMISSION PROCESS OVERVIEW





INTERNATIONAL  
ASSOCIATION  
FOR THE STUDY  
OF LUNG CANCER  
Conquering Thoracic Cancers Worldwide



CANCER RESEARCH  
AND BIOSTATISTICS

## IASLC International Staging Project Database Account Request Form

Use this form to request Institution or User account. The first data user entry below is for the Principal Investigator and must be filled out for the form to be accepted. Please email the completed form to [staging@iaslc.org](mailto:staging@iaslc.org) and [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org).

**Please indicate the project in which you would like to participate. If you are participating in multiple staging projects, please submit a separate form for each disease site.**

### Submitter Information

Please complete this section even if the individual submitting the form is also requesting a user account

#### Name

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title      First Name      Last Name

### Institution Information

#### Institution Name

**Address**

Street Address

Street Address Line 2

City

State / Province

Postal / Zip Code

Country

**Fax Number**  

Country Code Area Code Phone Number

**Member of GCCB-II or GCCB-III Consortium?** Yes No**Principal Investigator - Data Entry System User #1****Name**  

Title

First Name

Last Name

**Data Entry System User #2**

**Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email**

example@example.com

**Data Entry System User #3****Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email**

example@example.com

**Data Entry System User #4****Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email**

example@example.com

**Data Entry System User #5**

**Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email**

example@example.com

**Data Entry System User #6****Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email**

example@example.com

SAMPLE



## IASLC International Staging Project Description of Site Cohort Form

Please indicate the project in which you would like to participate. If you are participating in multiple staging projects, please submit a separate form for each disease site.

**Site number (if known)**

**Name of Institution**

**Proposed method of data entry**

- Online data entry
- Data transfer

**Method of case selection**

- Population-based sample: Population-based sample selection involving enhancement of a population-based cancer registry with the data elements required for this study. All patients diagnosed within the study period may be included or a random sample of the same.
- Institution-based sample: Institution-based sample selection involving capture of information on all newly-diagnosed patients seen at the institution during the period of the study. May involve the use of an institution's tumor registry, enhanced with the data elements required for this study.
- Clinical series: Involving the capture of information on an inception cohort of all newly-diagnosed patients presenting to a defined clinical service during the period of the study.
- Other

**If other, please describe:**

**Estimated number of new cases per year:**

## **Additional Information**

In the box provided, please describe the additional relevant information according to the instructions below, depending on the method of case selection employed.

**If population-based, please describe the population coverage:**

**If institution-based, please describe the referral pattern:**

**If clinical series, please describe the clinical service, including all treatment modalities offered:**

## **Data Transfers Only**

Please complete the information below ONLY if this application is for data transfer

If this application is regarding a data set to be transferred, please complete the section below. If more than one data set is being transferred, please describe each data set separately, including any other important differences regarding patient selection.

**Total patients, please designate patient totals by data set**

**Years of diagnosis, please designate years of diagnosis by data set**

**Other information regarding patient selection, please designate the information by data set**

**Submit**

SAMPLE

**IASLC**  
**DATA USE AGREEMENT**

This Data Use Agreement (this “**Agreement**”) dated [day, month, year] (the “**Effective Date**”)

**BETWEEN**

\_\_\_\_\_, a \_\_\_\_\_, located at \_\_\_\_\_ (“**Institution**”);

INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER, a Colorado nonprofit corporation, (“**IASLC**”) located at 13100 East Colfax Avenue, Unit 10, Aurora, Colorado 80011 USA;

**AND**

CANCER RESEARCH AND BIOSTATISTICS, a Washington non-profit corporation (“**CRAB**”), located at 1505 Westlake Ave. N., Suite 750, Seattle, Washington 98109-3050 USA.

**RECITALS:**

- A. Institution is the owner or licensee of a dataset composed of clinical and molecular features (the “**Institution Dataset**”).
- B. IASLC is a global organization dedicated to the study of lung cancer that has compiled an extensive staging and clinical lung cancer dataset (the “**IASLC Dataset**”), which is maintained by CRAB.
- C. Institution desires to grant IASLC full access to the Institution Dataset for IASLC’s general research and publication purposes, which will include the inclusion of the Institution Dataset with the IASLC Dataset (the combination of which shall hereinafter be referred to as the “**Combined Dataset**”) as maintained by CRAB (collectively, the “**Institution-Approved Purpose**”).
- D. By this Agreement the parties seek to set out the terms under which they will cooperate in good faith to license the Institution Dataset and perform their respective obligations hereunder.

IN CONSIDERATION OF THE MUTUAL COOPERATION BETWEEN THE PARTIES, IT IS AGREED BETWEEN THE PARTIES AS FOLLOWS:

1. Definitions.

- a. “**Confidential Information**” means, subject to Section 6(b), all written, electronic or oral information, disclosed by IASLC or the Institution (the “**Discloser**”) to the other or its designee (the “**Recipient**”), identified as confidential or proprietary, as well as information that, based on its nature and the circumstances surrounding its disclosure, a reasonable person would consider to be confidential or proprietary. The parties agree that the IASLC Dataset shall be deemed Confidential Information of IASLC.
- b. “**Dataset(s)**” means either individually or collectively as the context may require the Institution Dataset, IASLC Dataset or the Combined Dataset.
- c. “**GDPR**” means EU General Data Protection Regulation 2016/679.
- d. “**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations at 45 C.F.R. Parts 160, 162 and 164, as amended by the Health Information Technology for Economic and Clinical Health Act, which is at Section 13400, *et. seq.* of ARRA, 42 U.S.C. §§ 17921, *et. seq.*, and guidance promulgated thereunder.

2. Combined Dataset Creation and Management.

- a. *Combined Dataset.* Within a reasonable time after the Effective Date, Institution shall deliver to CRAB, at IASLC’s direction, the Institution Dataset in a format mutually agreeable to the parties. Upon receipt of the Institution Dataset, CRAB, on IASLC’s behalf, shall create the Combined Dataset by incorporating the Institution Dataset into the IASLC Dataset as set forth herein or otherwise agreed to by the parties in writing.
- b. *CRAB Dataset Management and Maintenance.* Institution acknowledges that IASLC has engaged CRAB to maintain, manage and perform certain research tasks with respect to the Combined Dataset. All fees and expenses associated with CRAB’s management and maintenance of the Combined Dataset shall be born exclusively by IASLC pursuant to then effective agreements between IASLC and CRAB.
- c. *Additional Third-Party Datasets.* No rights are granted to Institution to any third-party data whether currently held or later acquired by IASLC. To the extent Institution desires to acquire any additional rights or licenses to any third-party dataset, Institution agrees it will enter into separate agreements with such third parties, exclusive of IASLC and CRAB.

- d. *Required Forms.* Institution shall complete and submit all required forms, as determined by IASLC and CRAB, online. Institution shall also timely update such required forms as necessary to insure their continued accuracy.
- e. *SPFC Viewing Rights.* The members of the subcommittee of the IASLC Staging and Prognostic Factors Committee (“SPFC”) that provides a data quality review for CRAB and the SPFC Advisory Committee members are permitted to view the Combined Dataset for adherence to quality standards.

3. Licenses and Ownership.

- a. *Assignment of Rights to the Combined Dataset.* Institution hereby assigns, transfers and conveys to IASLC all its right, title and interest, including all intellectual property and other proprietary rights, in and to the Combined Dataset.
- b. *License to Institution Dataset.* Institution hereby grants to IASLC a perpetual (subject to each the termination rights in Section 8(b)), non-exclusive, royalty-free, fully-paid, sublicensable, transferable license to use the Institution Dataset for the Institution-Approved Purpose.
- c. *Ownership.* The parties agree that IASLC shall be the sole owner of all right, title and interest, including all intellectual property rights, in the IASLC Dataset and Combined Dataset and that Institution shall be the sole owner of all right, title and interest, including all intellectual property rights, in the Institution Dataset. Except for the limited licenses granted in this Section, each party shall retain all rights to and title in its respective Dataset and any other intellectual, proprietary or property rights owned by, or otherwise controlled by that party. CRAB shall not have an ownership interest in any Dataset.
- d. *Institution right to IASLC Dataset and Combined Dataset.* Unless otherwise provided pursuant to Section 5, Institution is granted no right, title, interest or license of any kind in or to the IASLC Dataset or the Combined Dataset.

4. Mutual Obligations.

- a. *Security.* Without limiting any party’s obligations under this Agreement or under applicable law, each party shall implement administrative, physical and technical safeguards to protect the Datasets that are no less rigorous than accepted industry practices, and shall ensure that all such safeguards, including the manner in which the data comprising the Datasets is collected, accessed, used, stored, processed, disposed of and disclosed, comply with applicable data protection and privacy laws, as well as the terms and conditions of this Agreement.
- b. *Compliance with Law.* The parties agree to comply with all applicable law, including laws, rules and regulations, including U.S. federal and state law (e.g., HIPAA) in the performance of their obligations under this Agreement. In the event of a conflict between the requirements of any applicable law, rule or regulation and

the requirements stated in this Agreement, the applicable law, rule or regulation under a conflict-of-law analysis, including the preemption analysis required under HIPAA, shall apply.

5. **Use of Combined Dataset by Institution.** Institution may not access or use the Combined Dataset (including for any research or publication purposes) unless it receives the prior written approval of IASLC, which IASLC may refuse in its sole discretion. Institution may petition for IASLC's consent by sending IASLC a written research proposal containing a detailed description of the proposed research, which proposal will not be unreasonably denied by IASLC. In any case, Institution may not directly access individual cases within the Combined Dataset. IASLC shall consider only non-commercial research purposes.
6. **Confidential Information.**
  - a. In addition to the parties other obligations under this Agreement and with respect to any Confidential Information received by the Recipient from the Discloser, the Recipient shall: (i) protect and maintain confidentiality of the Confidential Information using the same care that it would use for its own confidential information, but in any event no less than reasonable care; (ii) use the Confidential Information solely for the purposes of fulfilling its obligations under the Agreement and only for the benefit of the Discloser; (iii) not disclose any Confidential Information of Discloser to third parties or to Recipient's employees, except where employees of Recipient have a need to know about the Confidential Information and are subject to obligations of confidentiality at least as restrictive as those in this Agreement; (iv) cease use of such Confidential Information immediately upon termination or expiration of the Agreement and either return or permanently destroy all Confidential Information upon request of the Discloser; and (v) not attempt to reverse engineer, decompile or create derivative works from or using the Confidential Information.
  - b. The confidentiality obligations of this Section 6 shall terminate with respect to any Confidential Information when the Recipient can prove that such information was (i) in the public domain at the time of Discloser's communication to the Recipient, or it subsequently entered the public domain through no fault of the Recipient, (ii) in the Recipient's possession free of any obligation of confidence at the time of the Discloser's communication to the Recipient, (iii) subsequently rightfully communicated to the Recipient free of any obligation of confidence, or (iv) was or is independently developed by the Recipient without reference or recourse to the Discloser's Confidential Information.
  - c. Notwithstanding the foregoing, each party may disclose Confidential Information to the limited extent required in order to comply with the order of a court or other governmental body, or as otherwise necessary to comply with Applicable Laws, provided that the party making the disclosure pursuant to the order shall first have given written notice to the other in order to seek protective relief, if legally

permissible, and provided such assistance as may be reasonably requested to limit or prevent such disclosure.

7. Representations and Warranties; Disclaimer.

- a. *Mutual Representations and Warranties.* Each party hereby represents and warrants that such party is duly organized, validly existing and in good standing under the laws of the state of its incorporation or organization and has all requisite power and authority to enter into this Agreement.
- b. *Institution Representations and Warranties.* Institution hereby represents and warrants that:
  - i. Institution has all rights, permissions and authority necessary to grant the licenses and ownership rights in the Institution Dataset to IASLC under this Agreement for the uses contemplated hereunder and that the Institution Dataset does not infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of any third party;
  - ii. Institution gathered all identifiable private information of subject in compliance with applicable law and with respect and regards for human subjects;
  - iii. Institution agrees unequivocally to prohibit the release of individually identifiable private data to CRAB for research purposes and to provide only a limited data set described in the applicable project documents;
  - iv. neither Institution's license or assignment of any right in the Institution Dataset nor the use of such Dataset for the purposes contemplated by this Agreement will violate any law, rule or regulation or conflict with, result in any breach of, or constitute a default (or an event which would, with the passage of time or the giving of notice or both, constitute a default) under, or give rise to a right to terminate, amend, modify, abandon or accelerate, any contract which is applicable to, binding upon or enforceable against Institution; and
  - v. to the extent a Dataset may be derived from Protected Health Information (as such term is defined by HIPAA), each Dataset is compromised solely of either (A) de-identified data, which excludes all of the necessary identifiers as required by the applicable HIPAA regulations; (B) anonymized data, which cannot be used to identify or authenticate an individual and is not subject to regulation by any law, rule or regulation, including, but not limited to, the HIPAA regulations; or (C) a limited dataset as specified under 45 C.F.R. § 164.514(e). Institution acknowledges that neither CRAB nor IASLC have any obligation to ensure that Institution provides data in compliance with this subsection (v).
- c. *CRAB Representations and Warranties.* CRAB hereby represents and warrants that:

- i. where CRAB identifies that personal identifiers have been inadvertently included with the data received , CRAB will delete or destroy this identified data, and immediately notify Institution to replace with de-identified or anonymized data;
  - ii. if ever visiting Institution, CRAB employees may access or utilize individually private information, but these activities become subject to the oversight of Institution's institutional review board, and at no time will CRAB employees record any private information;
  - iii. CRAB will not provide any information to IASLC or include any information in the IASLC Dataset or the Combined Dataset unless it is de-identified (as such term is defined by HIPAA) and, to the extent that GDPR applies, has been rendered anonymous in such a manner that data subjects (as such phrase is defined by GDPR) are not or are no longer identifiable; and
  - iv. CRAB, as an institution, is not considered to be "engaged" in human subjects research for the Institution-Approved Purpose.
- d. *Disclaimer.* EXCEPT AS OTHERWISE PROVIDED HEREIN AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY HEREBY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, OF ANY KIND, INCLUDING ANY REPRESENTATIONS AND WARRANTIES, CONDITIONS OR OTHER TERMS WITH RESPECT TO A PARTY'S DATASET, INCLUDING ANY REPRESENTATION OR WARRANTY OF NONINFRINGEMENT, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

8. Term; Termination.

- a. *Term.* This Agreement shall be binding on IASLC and the Institution from the Effective Date until terminated in accordance with this Section. This Agreement shall be binding on CRAB from the Effective Date until the termination of all then applicable agreements between CRAB and IASLC in accordance with their terms.
- b. *Termination.* This Agreement may be terminated by either IASLC or the Institution, but not CRAB, (i) immediately if the other party breaches a material term of this Agreement and cure of such breach is not possible, or (ii) if the other party breaches a material term of this Agreement that is subject to cure and fails to cure such breach within thirty (30) days of receiving notice of such breach from the non-breaching party. This Agreement may be terminated by the Institution, but not IASLC or CRAB, (i) immediately if CRAB breaches a material term of this Agreement and cure of such breach is not possible, or (ii) if CRAB breaches a material term of this Agreement that is subject to cure and fails to cure such breach within thirty (30) days of receiving notice of such breach from the non-breaching party. CRAB shall not have any termination rights under this Agreement; however, to the extent that CRAB ceases to provide services with respect to the IASLC

Dataset or the Combined Dataset pursuant to one or more then applicable agreements between IASLC and CRAB, CRAB shall have no liability for the acts or omissions of its successor.

- c. *Knowledge of Non-compliance.* Any non-compliance by Institution with this Agreement or with HIPAA, or any equivalent laws or regulations, automatically will be considered a breach or violation of a material term of this Agreement if Institution knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

- d. *Effect of Termination.*

- i. Upon termination of this Agreement by IASLC, Institution shall confirm that all data, analysis or reports from the Combined Dataset (if it has received information from the Combined Dataset in accordance with Section 5) and all Confidential Information received from IASLC has been destroyed or returned to IASLC, and Institution shall provide written confirmation of such destruction to IASLC.
- ii. All of the terms of the Agreement which by their nature extend beyond the expiration or termination of the Agreement, including indemnification obligations, confidentiality obligations, shall survive expiration or termination of the Agreement and remain in full force and effect.

## 9. Indemnification.

- a. Each of IASLC and the Institution (“**Indemnitor**”) shall indemnify, defend and hold harmless the other and its Affiliates, and their respective licensors, officers, directors, employees and contractors (each, an “**Indemnitee**” and collectively “**Indemnitees**”), from and against any and all third-party claims (including, but not limited to, labour claims), liabilities, demands, causes of action, judgments, settlements and expenses (including, but not limited to, reasonable attorneys’ fees and court costs) arising out of or in connection with any breach of any covenant, representation or warranty made by Indemnitor or, with respect to IASLC only, CRAB hereunder (each a “**Claim**”).
- b. If any Claim is initiated against any Indemnitee, the Indemnitee shall give prompt written notice of such Claim to the Indemnitor. Indemnitee may elect to assume the defense of a Claim and Indemnitor shall reimburse Indemnitee for all reasonable expenses (including reasonable attorneys’ fees which may include, without limitation, an allocation for in-house counsel) as such expenses are incurred, relating to the defense of such Claim. If Indemnitee elects not to assume the defense of a Claim, then Indemnitor, at Indemnitor’s own expense, shall assume the defense of such Claim. If Indemnitor assumes the defense of such Claim, (i) Indemnitor shall keep the Indemnitees informed of all material developments and events relating to such Claim, (ii) the Indemnitees shall have the right to participate, at its own expense, in the defense of such Claim (but such participation shall not be deemed to give the Indemnitees the right to control such defense), (iii) the

Indemnitees shall cooperate as reasonably requested by Indemnitor in the defense of such Claim, and (iv) Indemnitor shall not settle such Claim without the prior written consent of the Indemnitees, which consent shall not be unreasonably withheld.

- c. Any indemnification obligations between IASLC and CRAB shall be governed by the then applicable separate agreement or agreements between IASLC and CRAB. CRAB shall not have any direct indemnification obligations to the Institution pursuant to this Agreement.

10. Miscellaneous.

- a. *Equitable Relief.* Each party agrees that any other party's breach of any provision of this Agreement will cause immediate and irreparable harm to the other party for which money damages are not an adequate remedy at law. Therefore, the parties agree that, in the event either party breaches or threatens to breach this Agreement, the other party shall be entitled to an injunction to restrain said breach or threatened breach, without posting any bond or other security.
- b. *Binding Effect.* This Agreement shall be legally binding as between the parties until such time as it has been expressly superseded by a more detailed agreement should one be duly signed.
- c. *Applicable Law.* The validity and interpretation of this Agreement shall be governed by the laws of the State of Colorado. The parties agree that any conflict of law provisions, where applicable, are hereby excluded by this express agreement to an applicable law and jurisdiction.
- d. *Assignment.* Neither IASLC nor the Institution shall transfer, delegate, or assign this Agreement to any other person or legal entity, whether by written agreement, operation of law or otherwise, without the prior written consent of the other party. To the extent that CRAB ceases to provide services with respect to the IASLC Dataset and the Combined Dataset pursuant to any then applicable agreement or agreements between IASLC and CRAB, CRAB's rights and obligations under this Agreement on and after the date when CRAB ceases to provide such services shall be automatically assigned to its successor; however, such successor shall not have any liability for the acts or omissions of any of its predecessors or successors. Any assignment or transfer by a party hereto that is not in compliance with the terms and conditions set forth in this Section shall be void and of no effect. Any permitted assignment or transfer of or under this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assigns of the assigning or transferring party hereto.
- e. *Entire Agreement.* Subject to this Section 10(e), this Agreement embodies the entire understanding of the parties with respect to the subject matter hereof and shall supersede all previous communications, representations, or understandings, either oral or written, between the parties relating to the subject matter hereof. This

Agreement and the subject matter hereof may not be modified except by a written agreement signed on behalf of IASLC, the Institution and, if the amendment directly impacts CRAB's representations, rights or obligations under this Agreement, CRAB, by their respective duly authorized representatives. Only with respect to IASLC and CRAB, to the extent of any conflict or inconsistency between the provisions in the body of this Agreement and any other then applicable agreement or agreements between CRAB and IASLC, the terms of such other agreement or agreements between CRAB and IASLC will prevail. The terms of any agreement or agreements between CRAB and IASLC will not impact the rights and obligations of the Institution under this Agreement.

- f. *Independent Contractor Status.* In connection with this Agreement, each party is an independent contractor and as such will not have any authority to bind or commit the other. Furthermore, neither this Agreement, nor any terms and conditions contained herein, shall be construed as creating a partnership, joint venture or agency relationship or as granting a franchise.
- g. *Severability; No Waiver.* To the extent that any term, condition or provision of this Agreement is held to be invalid, illegal or otherwise unenforceable under applicable law, rule, or regulation then such term, condition or provision shall be deemed excluded from this Agreement and the other terms, conditions and provisions hereof shall remain in full force and effect as if such unenforceable term, condition or provision had not been included herein. The failure of a party to prosecute its rights with respect to a default or breach hereunder shall not constitute a waiver of the right to enforce its rights with respect to any other or later breach. No waiver of any right or remedy available to a party under this Agreement, at law, or in equity shall be effective unless signed in writing by the waiving party. Unless otherwise specifically limited under this Agreement, all rights and remedies reserved to either party shall be cumulative and shall not be in limitation of any other right or remedy which such party may have at law or in equity.

[Signature page follows]

IN WITNESS WHEREOF, as of the Effective Date, an authorised representative of each party has duly executed this Data Use Agreement.

INSTITUTION

INTERNATIONAL ASSOCIATION FOR  
THE STUDY OF LUNG CANCER

Signed: \_\_\_\_\_

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

CANCER RESEARCH AND  
BIOSTATISTICS

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

# DATA SUBMISSION FAQS

---

## **What is the timeline for receiving access to my account?**

- Once the Data Use Agreement has been signed and the Account Request Form submitted, the account is usually activated within 1-2 business days.

## **Who at my institution/organization needs to sign the DUA?**

- Someone at the Institution with authorized authority to sign a document of this nature.

## **Can users share an account?**

- Each user needs to be listed on an Account Request Form. Users may not share an account.

## **Do I need to submit application materials and a DUA for each disease site?**

- Yes, each disease site requires the completion of the application materials and DUA.

## **What are the data elements for each disease site?**

- Please review the data elements found in the appendix

## **I have looked at the data dictionary for the IASLC database, and I will not be able to enter all the data fields. Can I still participate?**

- If you have concerns about meeting the data elements, please contact [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org) and we will help you determine whether to participate.

## **Can I get my data back?**

- Yes, the data that you submit can be accessed.

## **Can I access the entire data set?**

- No, if you are interested in analyzing the data set please refer to the data query section of the toolkit.

## **Is there funding available for data submission?**

- Yes, there is limited funding for qualified situations. Information regarding the funding process can be found [here](#).

## **What happens if a user needs to be removed or edited?**

- Please complete the account change form found [here](#).



# DATA ELEMENTS

# IASLC Lung Cancer Staging Project

## Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

Report Generated: 2/26/2020 12:36:35 PM

| COLUMN NAME   | CODE VALUE | CODE DEFINITION   | CODE ORDER |
|---------------|------------|---|------------|
| C_AFT_CYTO    | POS        | Positive  | 1          |
| C_AFT_CYTO    | NEG        | Negative  | 2          |
| C_AFT_CYTO    | ND         | Not done  | 3          |
| C_AFT_CYTO    | UNK        | Unknown   | 4          |
| C_AFT_DISTMET | SINGLES    | Single lesion   | 1          |
| C_AFT_DISTMET | MULTLES    | Multiple lesions  | 2          |
| C_AFT_DISTMET | PRES       | Present, number of lesions not specified                    | 3          |
| C_AFT_DISTMET | ABS        | Absent  | 4          |
| C_AFT_MCAT    | M0         | M0  | 1          |
| C_AFT_MCAT    | M1a        | M1a   | 2          |
| C_AFT_MCAT    | M1b        | M1b   | 3          |
| C_AFT_MCAT    | M1c        | M1c   | 4          |
| C_AFT_MPERI   | PRES       | Present   | 1          |
| C_AFT_MPERI   | ABS        | Absent  | 2          |
| C_AFT_MPERI   | UNK        | Unknown   | 3          |
| C_AFT_MPLEU   | NONE       | None  | 1          |
| C_AFT_MPLEU   | IPSIL      | Ipsilateral   | 2          |
| C_AFT_MPLEU   | CONTRA     | Contralateral   | 3          |
| C_AFT_MPLEU   | BILAT      | Bilateral   | 4          |
| C_AFT_MPLEU   | PRES       | Present, side not specified                                 | 5          |
| C_AFT_MPLEU   | UNK        | Unknown   | 6          |
| C_CAUSDTH     | DTHLOCO    | Death due to lung cancer - locoregional relapse             | 1          |
| C_CAUSDTH     | DTHDIS     | Death due to lung cancer - distant relapse                  | 2          |
| C_CAUSDTH     | DTHLDIS    | Death due to lung cancer - locoregional and distant relapse | 3          |
| C_CAUSDTH     | DTHNOS     | Death due to lung cancer - not otherwise specified          | 4          |
| C_CAUSDTH     | DTH2PRIM   | Death due to second primary cancer                          | 5          |
| C_CAUSDTH     | DTHNOCAN   | Death, non-cancer cause                                     | 6          |
| C_CAUSDTH     | DTHUNK     | Cause of death unknown                                      | 7          |
| C_CNA_CNA     | ARAMP      | AR amplification  | 1          |
| C_CNA_CNA     | BRAFAMP    | BRAF amplification  | 2          |
| C_CNA_CNA     | CCND1      | CCND1 11q13 AMP   | 3          |
| C_CNA_CNA     | CCND2AMP   | CCND2 amplification   | 4          |
| C_CNA_CNA     | CCNE1      | CCNE1 11q12 AMP   | 5          |
| C_CNA_CNA     | CDK4       | CDK4 12q14 AMP  | 6          |
| C_CNA_CNA     | CDK6AMP    | CDK6 amplification  | 7          |
| C_CNA_CNA     | CDKN2A     | CDKN2A 9p21 DEL   | 8          |
| C_CNA_CNA     | CDKN2B     | CDKN2B 9p21 DEL   | 9          |
| C_CNA_CNA     | CEBPA      | CEBPA 19q13.1 AMP   | 10         |
| C_CNA_CNA     | EGFR       | EGFR 7p12 AMP   | 11         |
| C_CNA_CNA     | ERBB2      | ERBB2 17q12 AMP   | 12         |
| C_CNA_CNA     | ETV1       | ETV1 7p21.3 AMP   | 13         |
| C_CNA_CNA     | FGF19      | FGF19 11q13.1 AMP   | 14         |
| C_CNA_CNA     | FGF3       | FGF3 11q13 AMP  | 15         |

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(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION                                       | CODE ORDER |
|---------------|------------|---|------------|
| C_CNA_CNA     | FGF4       | FGF4 11q13.3 AMP                                      | 16         |
| C_CNA_CNA     | FGFR1      | FGFR1 8p11.23-p11.22 AMP                              | 17         |
| C_CNA_CNA     | FGFR1A     | FGFR1 Amplification                                   | 18         |
| C_CNA_CNA     | FGFR2      | FGFR2 Amplification                                   | 19         |
| C_CNA_CNA     | FGFR3      | FGFR3 Amplification                                   | 20         |
| C_CNA_CNA     | FGFR4      | FGFR4 Amplification                                   | 21         |
| C_CNA_CNA     | FOXA1      | FOXA1 14q21.1 AMP                                     | 22         |
| C_CNA_CNA     | KITAMP     | KIT amplification                                     | 23         |
| C_CNA_CNA     | KRAS       | KRAS 12p12.1 AMP                                      | 24         |
| C_CNA_CNA     | MCL1       | MCL1 11q21 AMP  | 25         |
| C_CNA_CNA     | MDM2       | MDM2 12q14.3-q15 AMP                                  | 26         |
| C_CNA_CNA     | MET        | MET 7q31 AMP  | 27         |
| C_CNA_CNA     | MYC        | MYC 8q24.21 AMP                                       | 28         |
| C_CNA_CNA     | NFKBIA     | NFKBIA 14q13 AMP                                      | 29         |
| C_CNA_CNA     | NKC2-1     | NKX2-114q13 AMP                                       | 30         |
| C_CNA_CNA     | PDGFRAAM   | PDGFRA amplification                                  | 31         |
| C_CNA_CNA     | PIK3CA     | PIK3CA 3q26.3 AMP                                     | 32         |
| C_CNA_CNA     | PTEN       | PTEN 10q23.3 DEL                                      | 33         |
| C_CNA_CNA     | RAF1AMP    | RAF1 amplification                                    | 34         |
| C_CNA_CNA     | RECQL4     | RECQL4 8q24.3 AMP                                     | 35         |
| C_CNA_CNA     | RICTOR     | RICTOR AMP  | 36         |
| C_CNA_CNARES  | NORM       | Normal  | 1          |
| C_CNA_CNARES  | ABNORM     | Abnormal  | 2          |
| C_CNA_CNARES  | INCON      | Inconclusive  | 3          |
| C_CNA_PLATCNA | FISHMET    | FISH: MET Amplifications                              | 2          |
| C_CNA_PLATCNA | NGSTHER2   | NGS: ThermoFisher Ion Ampliseq v2                     | 4          |
| C_CNA_PLATCNA | NGSODX     | NGS: Oncomine Dx Target Test                          | 5          |
| C_CNA_PLATCNA | NGSOLUNG   | NGS: Oncomine Lung cfDNA Assay                        | 6          |
| C_CNA_PLATCNA | NGSOFOC    | NGS: Oncomine Focus                                   | 7          |
| C_CNA_PLATCNA | NGSSOLID   | NGS: Oncomine Solid Tumor Fusion                      | 8          |
| C_CNA_PLATCNA | NGSS1PAN   | NGS: OncoGenBasic S1 Panel (BRAF, KRAS, NRAS, EGFR)   | 9          |
| C_CNA_PLATCNA | NGSS2PAN   | NGS: OncoGenBasic S2 Panel (AKT1, PIK3CA)             | 10         |
| C_CNA_PLATCNA | NGS360G    | NGS: Guardant360                                      | 11         |
| C_CNA_PLATCNA | NGSMSK     | NGS: MSK-IMPACT                                       | 12         |
| C_CNA_PLATCNA | NGSCDX     | NGS: FoundationOne CDX                                | 13         |
| C_CNA_PLATCNA | NGS425C    | NGS: Geneseeq Pan-Genomic (425 cancer genes)          | 14         |
| C_CNA_PLATCNA | NGS139L    | NGS: Geneseeq Pulmocan (139 lung cancer genes)        | 15         |
| C_CNA_PLATCNA | NGS14N     | NGS: Geneseeq Tetradecan (14 NCCN lung cancer genes)  | 16         |
| C_CNA_PLATCNA | NGSMIPRO   | NGS: Caris MI Profile                                 | 17         |
| C_CNA_PLATCNA | NGSMITUM   | NGS: Caris MI Tumor Seek                              | 18         |
| C_CNA_PLATCNA | NGSLFUS    | NGS: NeoGenomics Lung NGS Fusion Profile              | 19         |
| C_CNA_PLATCNA | NGSLPRO    | NGS: NeoGenomics NeoTYPE Lung Tumor Profile           | 20         |
| C_CNA_PLATCNA | NGSTHPAN   | NGS: ThermoFisher Oncomine Pan-Cancer Cell-Free Assay | 21         |
| C_CNA_PLATCNA | NGSTHER1   | NGS: ThermoFisher Oncomine Comprehensive Assay v1     | 22         |
| C_CNA_PLATCNA | NGSTHER3   | NGS: ThermoFisher Oncomine Comprehensive Assay v3     | 23         |

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| COLUMN NAME   | CODE VALUE | CODE DEFINITION   | CODE ORDER |
|---------------|------------|---|------------|
| C_CNA_PLATCNA | NGSILL     | NGS: Illumina TruSight(tm) Oncology 500                       | 24         |
| C_CNA_PLATCNA | CISHMET    | CISH: MET Amplifications                                      | 27         |
| C_CNA_PLATCNA | ACGH       | aCGH (Array comparative genomic hybridisation)                | 28         |
| C_CNA_PLATCNA | SNP500K    | SNP array: Affymetrix 500K array                              | 29         |
| C_CNA_PLATCNA | SNP5ARR    | SNP array: Affymetrix 5.0 SNP array                           | 30         |
| C_CNA_PLATCNA | SNP6ARR    | SNP array: Affymetrix 6.0 SNP array                           | 31         |
| C_CNA_PLATCNA | SNPONCO    | SNP array: OncoScan CNV Plus Assay                            | 32         |
| C_CNA_PLATCNA | NANODNA    | NanoString nCounter: Vantage 3D DNA:Fusion:Protein Lung Assay | 33         |
| C_CNA_PLATCNA | NANOLUNG   | NanoString nCounter: Vantage 3D Lung Fusion Panel             | 34         |
| C_CNA_TYPE    | BIOPSY     | Biopsy  | 1          |
| C_CNA_TYPE    | CYTO       | Cytology  | 2          |
| C_CNA_TYPE    | PLASMA     | Plasma  | 3          |
| C_GEN_DNAVAR  | AKT1       | AKT1 c.49G>A (E17K)   | 1          |
| C_GEN_DNAVAR  | ALKFUS     | ALK Fusions (partner unknown)                                 | 2          |
| C_GEN_DNAVAR  | ALKEML     | ALK-EML4 fusion   | 3          |
| C_GEN_DNAVAR  | ALKTFR     | ALK-TFR fusion  | 4          |
| C_GEN_DNAVAR  | ALKKIF     | ALK-KIF5B fusion  | 5          |
| C_GEN_DNAVAR  | ALKKLC     | ALK-KLC1 fusion   | 6          |
| C_GEN_DNAVAR  | ALKPTPN    | ALK-PTPN3 fusion  | 7          |
| C_GEN_DNAVAR  | ALKHIP     | ALK-HIP1 fusion   | 8          |
| C_GEN_DNAVAR  | ALKTPR     | ALK-TPR fusion  | 9          |
| C_GEN_DNAVAR  | ALKBIRC    | ALK-BIRC6 fusion  | 10         |
| C_GEN_DNAVAR  | ALKDCTN    | ALK-DCTN1 fusion  | 11         |
| C_GEN_DNAVAR  | ALKSQST    | ALK-SQSTM1 fusion   | 12         |
| C_GEN_DNAVAR  | ALKPRK     | ALK-PRKAR1A fusion  | 13         |
| C_GEN_DNAVAR  | ALKPPM     | ALK-PPM1B fusion  | 14         |
| C_GEN_DNAVAR  | ALKEIF     | ALK-EIF2AK3 fusion  | 15         |
| C_GEN_DNAVAR  | ALKBCL     | ALK-BCL11A fusion   | 16         |
| C_GEN_DNAVAR  | ALKCEBP    | ALK-CEBPZ fusion  | 17         |
| C_GEN_DNAVAR  | ALKPICA    | ALK-PICALM fusion   | 18         |
| C_GEN_DNAVAR  | ALKGCC     | ALK-GCC2 fusion   | 19         |
| C_GEN_DNAVAR  | ALKLMO     | ALK-LMO7 fusion   | 20         |
| C_GEN_DNAVAR  | ALKPHAC    | ALK-PHACTR1 fusion  | 21         |
| C_GEN_DNAVAR  | ALKCMTR    | ALK-CMTR1 fusion  | 22         |
| C_GEN_DNAVAR  | ALKOTH     | ALK-other fusion  | 23         |
| C_GEN_DNAVAR  | I151Tins   | I151Tins  | 24         |
| C_GEN_DNAVAR  | L1152R     | L1152R  | 25         |
| C_GEN_DNAVAR  | C1156Y     | C1156Y  | 26         |
| C_GEN_DNAVAR  | I1171TNS   | I1171T/N/S  | 27         |
| C_GEN_DNAVAR  | F1174LC    | F1174L/C  | 28         |
| C_GEN_DNAVAR  | V1180L     | V1180L  | 29         |
| C_GEN_DNAVAR  | L1196M     | L1196M  | 30         |
| C_GEN_DNAVAR  | L1198F     | L1198F  | 31         |
| C_GEN_DNAVAR  | F1202Rdel  | F1202R/del  | 32         |
| C_GEN_DNAVAR  | S1206F     | S1206F  | 33         |

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| COLUMN NAME  | CODE VALUE | CODE DEFINITION                         | CODE ORDER |
|--------------|------------|---|------------|
| C_GEN_DNAVAR | D1203N     | D1203N                                  | 34         |
| C_GEN_DNAVAR | S1206YC    | S1206Y/C                                | 35         |
| C_GEN_DNAVAR | G1269A     | G1269A                                  | 36         |
| C_GEN_DNAVAR | G1548E     | G1548E                                  | 37         |
| C_GEN_DNAVAR | BRAFG466V  | BRAF c.1397G>T (G466V)                  | 38         |
| C_GEN_DNAVAR | BRAFG469L  | BRAF c.1405_1406delGinsTT (G469L)       | 39         |
| C_GEN_DNAVAR | BRAFG469A  | BRAF c.1406G>C (G469A)                  | 40         |
| C_GEN_DNAVAR | BRAFY472C  | BRAF c.1415A>G (Y472C)                  | 41         |
| C_GEN_DNAVAR | BRAFL597V  | BRAF c.1789C>G (L597V)                  | 42         |
| C_GEN_DNAVAR | BRAFV600E  | BRAF c.1799T>A (V600E)                  | 43         |
| C_GEN_DNAVAR | DDR2S768R  | DDR2 c2304T>A (S768R)                   | 44         |
| C_GEN_DNAVAR | EDFRSU     | EGFR Status Unknown                     | 45         |
| C_GEN_DNAVAR | EGFRNMD    | EGFR No Mutation Detected (obsolete)    | 46         |
| C_GEN_DNAVAR | EGFRKDD    | EGFR Kinase Domain Duplication          | 47         |
| C_GEN_DNAVAR | EGFRG719A  | EGFR c.2156G>C (G719A)                  | 48         |
| C_GEN_DNAVAR | EGFRG719C  | EGFR c.2155G>T (G719C)                  | 49         |
| C_GEN_DNAVAR | EGFRG719S  | EGFR c.2156G>A (G719S)                  | 50         |
| C_GEN_DNAVAR | EGFREX19D  | EGFR Exon 19 Deletion                   | 51         |
| C_GEN_DNAVAR | EGFREX19I  | EGFR Exon 19 Insertion                  | 52         |
| C_GEN_DNAVAR | EGFREX20I  | EGFR Exon 20 Insertion                  | 53         |
| C_GEN_DNAVAR | EGFRA763   | EGFR c.2290_2291ins (A763_Y764insFQEAA) | 54         |
| C_GEN_DNAVAR | EGFRT790M  | EGFR c.2369C>T (T790M)                  | 55         |
| C_GEN_DNAVAR | EGFRL858R  | EGFR c.2573T>G (L858R)                  | 56         |
| C_GEN_DNAVAR | EGFRL861Q  | EGFR c.2582T>A (L861Q)                  | 57         |
| C_GEN_DNAVAR | EGFRS768I  | EGFR c.2303G>T (S768I)                  | 58         |
| C_GEN_DNAVAR | EGFRC797S  | EGFR c.2390G>C (C797S)                  | 59         |
| C_GEN_DNAVAR | EGFRS720F  | EGFR c.2159C>T (S720F)                  | 60         |
| C_GEN_DNAVAR | EGFRD761Y  | EGFR c.2281G>T (D761Y)                  | 61         |
| C_GEN_DNAVAR | EGFRV765A  | EGFR c.2294T>C (V765A)                  | 62         |
| C_GEN_DNAVAR | EGFRT783A  | EGFR c.2347A>G (T783A)                  | 63         |
| C_GEN_DNAVAR | EGFRV769L  | EGFR c.2305G>T (V769L)                  | 64         |
| C_GEN_DNAVAR | EGFRN771T  | EGFR c.2312A>C (N771T)                  | 65         |
| C_GEN_DNAVAR | EGFRL861R  | EGFR c.2582 T>G (L861R)                 | 66         |
| C_GEN_DNAVAR | EGFRNPGI   | EGFR D770_N771(insNPG)                  | 67         |
| C_GEN_DNAVAR | EGFRSVQI   | EGFR D770_N771(insSVQ)                  | 68         |
| C_GEN_DNAVAR | EGFRGI     | EGFR D770_N771(insG)                    | 69         |
| C_GEN_DNAVAR | HER2EX20I  | HER2 Exon 20 Insertion                  | 70         |
| C_GEN_DNAVAR | FGFR1FUS   | FGFR1 Fusions                           | 71         |
| C_GEN_DNAVAR | FGFR2FUS   | FGFR2 Mutation                          | 72         |
| C_GEN_DNAVAR | FGFR3FUS   | FGFR3 Fusions                           | 73         |
| C_GEN_DNAVAR | FGFR3MUT   | FGFR3 mutation at 248/249 pos.          | 74         |
| C_GEN_DNAVAR | FGFR3RE    | FGFR3 Rearrangement                     | 75         |
| C_GEN_DNAVAR | FGFR4MUT   | FGFR4 Mutation                          | 76         |
| C_GEN_DNAVAR | KRASC34GT  | KRAS c.34G>T (G12C)                     | 77         |
| C_GEN_DNAVAR | KRASG12R   | KRAS c.34G>C (G12R)                     | 78         |

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| COLUMN NAME  | CODE VALUE   | CODE DEFINITION                | CODE ORDER |
|--------------|--------------|--------------------------------|------------|
| C_GEN_DNAVAR | KRASG12S     | KRAS c.34G>A (G12S)            | 79         |
| C_GEN_DNAVAR | KRASG12A     | KRAS c.35G>C (G12A)            | 80         |
| C_GEN_DNAVAR | KRASG12D     | KRAS c.35G>A (G12D)            | 81         |
| C_GEN_DNAVAR | KRASG12V     | KRAS c.35G>T (G12V)            | 82         |
| C_GEN_DNAVAR | KRASG13C     | KRAS c.37G>T (G13C)            | 83         |
| C_GEN_DNAVAR | KRASG13R     | KRAS c.37G>C (G13R)            | 84         |
| C_GEN_DNAVAR | KRASG13S     | KRAS c.37G>A (G13S)            | 85         |
| C_GEN_DNAVAR | KRASG13A     | KRAS c.38G>C (G13A)            | 86         |
| C_GEN_DNAVAR | KRASG13D     | KRAS c.38G>A (G13D)            | 87         |
| C_GEN_DNAVAR | KRASQ61K     | KRAS c.181C>A (Q61K)           | 88         |
| C_GEN_DNAVAR | KRASQ61L     | KRAS c.182A>T (Q61L)           | 89         |
| C_GEN_DNAVAR | KRASQ61R     | KRAS c.182A>G (Q61R)           | 90         |
| C_GEN_DNAVAR | KRASQ61HC    | KRAS c.183A>C (Q61H)           | 91         |
| C_GEN_DNAVAR | KRASQ61T     | KRAS c.183A>T (Q61H)           | 92         |
| C_GEN_DNAVAR | MEK1Q56P     | MEK1 c.167A>C (Q56P)           | 93         |
| C_GEN_DNAVAR | MEK1K57N     | MEK1 c.171G>T (K57N)           | 94         |
| C_GEN_DNAVAR | MEK1D67N     | MEK1 C.199G>A (D67N)           | 95         |
| C_GEN_DNAVAR | METEX14M     | MET Exon 14 Skipping Mutations | 96         |
| C_GEN_DNAVAR | NRASG12C     | NRAS c.34G>T (G12C)            | 97         |
| C_GEN_DNAVAR | NRASG12R     | NRAS c.34G>C (G12R)            | 98         |
| C_GEN_DNAVAR | NRASG12S     | NRAS c.34G>A (G12S)            | 99         |
| C_GEN_DNAVAR | NRASG12A     | NRAS c.35G>C (G12A)            | 100        |
| C_GEN_DNAVAR | NRASG12D     | NRAS c.35G>A (G12D)            | 101        |
| C_GEN_DNAVAR | NRASQ61K     | NRAS c.181C>A (Q61K)           | 102        |
| C_GEN_DNAVAR | NRASQ61L     | NRAS c.182A>T (Q61L)           | 103        |
| C_GEN_DNAVAR | NRASQ61R     | NRAS c.182A>G (Q61R)           | 104        |
| C_GEN_DNAVAR | NRASQ61HC    | NRAS c.183A>C (Q61H)           | 105        |
| C_GEN_DNAVAR | NRASQ61HT    | NRAS c.183A>T (Q61H)           | 106        |
| C_GEN_DNAVAR | NTR51FUS     | NTRK1 (TRKA) Fusions           | 107        |
| C_GEN_DNAVAR | PIK3CAE542K  | PIK3CA c.1624G>A (E542K)       | 108        |
| C_GEN_DNAVAR | PIK3CAE545K  | PIK3CA c.1633G>A (E545K)       | 109        |
| C_GEN_DNAVAR | PIK3CAE545Q  | PIK3CA c.1633G>C (E545Q)       | 110        |
| C_GEN_DNAVAR | PIK3CAH1047L | PIK3CA c.3140A>T (H1047L)      | 111        |
| C_GEN_DNAVAR | PIK3CAH1047R | PIK3CA c.3140A>G (H1047R)      | 112        |
| C_GEN_DNAVAR | PTENR233     | PTEN c.697C>T (R233*)          | 113        |
| C_GEN_DNAVAR | RETFUS       | RET Fusions (partner unknown)  | 114        |
| C_GEN_DNAVAR | RETKIF       | RET-KIF5B fusion               | 115        |
| C_GEN_DNAVAR | RETCCDC      | RET-CCDC6 fusion               | 116        |
| C_GEN_DNAVAR | RETTRIM      | RET-TRIM33 fusion              | 117        |
| C_GEN_DNAVAR | RETOOTH      | RET-other fusion               | 118        |
| C_GEN_DNAVAR | S1986YF      | S1986Y/F                       | 119        |
| C_GEN_DNAVAR | G2032R       | G2032R                         | 120        |
| C_GEN_DNAVAR | D2033N       | D2033N                         | 121        |
| C_GEN_DNAVAR | D2155S       | D2155S                         | 122        |
| C_GEN_DNAVAR | ROS1FUS      | ROS1 Fusions (partner unknown) | 123        |

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| COLUMN NAME   | CODE VALUE | CODE DEFINITION         | CODE ORDER |
|---------------|------------|-------------------------|------------|
| C_GEN_DNAVAR  | ROSCD      | ROS1-CD74 fusion        | 124        |
| C_GEN_DNAVAR  | ROSSDC     | ROS1-SDC4 fusion        | 125        |
| C_GEN_DNAVAR  | ROSSL      | ROS1-SLC34A2 fusion     | 126        |
| C_GEN_DNAVAR  | ROSEZR     | ROS1-EZR fusion         | 127        |
| C_GEN_DNAVAR  | ROSTPM     | ROS1-TPM3 fusion        | 128        |
| C_GEN_DNAVAR  | ROSOTH     | ROS1-other fusion       | 129        |
| C_GEN_DNAVAR  | NOABN      | No abnormality detected | 130        |
| C_GEN_GENEAB  | PRES       | Present                 | 1          |
| C_GEN_GENEAB  | ABSENT     | Absent                  | 2          |
| C_GEN_GENEAB  | INCON      | Inconclusive            | 3          |
| C_GEN_GENPLAT | ABL1       | ABL1                    | 1          |
| C_GEN_GENPLAT | AKT1       | AKT1                    | 2          |
| C_GEN_GENPLAT | ALK        | ALK                     | 3          |
| C_GEN_GENPLAT | AMER1      | AMER1                   | 4          |
| C_GEN_GENPLAT | APC        | APC                     | 5          |
| C_GEN_GENPLAT | AR         | AR                      | 6          |
| C_GEN_GENPLAT | ARAF       | ARAF                    | 7          |
| C_GEN_GENPLAT | ARID1A     | ARID1A                  | 8          |
| C_GEN_GENPLAT | ARID1B     | ARID1B                  | 9          |
| C_GEN_GENPLAT | ARID2      | ARID2                   | 10         |
| C_GEN_GENPLAT | ASXL1      | ASXL1                   | 11         |
| C_GEN_GENPLAT | ATM        | ATM                     | 12         |
| C_GEN_GENPLAT | ATR        | ATR                     | 13         |
| C_GEN_GENPLAT | ATRX       | ATRX                    | 14         |
| C_GEN_GENPLAT | AXL        | AXL                     | 15         |
| C_GEN_GENPLAT | BAP1       | BAP1                    | 16         |
| C_GEN_GENPLAT | BCOR       | BCOR                    | 17         |
| C_GEN_GENPLAT | BCORL1     | BCORL1                  | 18         |
| C_GEN_GENPLAT | BLM        | BLM                     | 19         |
| C_GEN_GENPLAT | BRAF       | BRAF                    | 20         |
| C_GEN_GENPLAT | BRCA1      | BRCA1                   | 21         |
| C_GEN_GENPLAT | BRCA2      | BRCA2                   | 22         |
| C_GEN_GENPLAT | BRIP1      | BRIP1                   | 23         |
| C_GEN_GENPLAT | CARD11     | CARD11                  | 24         |
| C_GEN_GENPLAT | CBL        | CBL                     | 25         |
| C_GEN_GENPLAT | CDC73      | CDC73                   | 26         |
| C_GEN_GENPLAT | CD74NRG1   | CD74-NRG1               | 27         |
| C_GEN_GENPLAT | CDH1       | CDH1                    | 28         |
| C_GEN_GENPLAT | CDKN2A     | CDKN2A                  | 29         |
| C_GEN_GENPLAT | CIITA      | CIITA                   | 30         |
| C_GEN_GENPLAT | CREBBP     | CREBBP                  | 31         |
| C_GEN_GENPLAT | CSF1R      | CSF1R                   | 32         |
| C_GEN_GENPLAT | CTNNB1     | CTNNB1                  | 33         |
| C_GEN_GENPLAT | CUX1       | CUX1                    | 34         |
| C_GEN_GENPLAT | DDR2       | DDR2                    | 35         |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION | CODE ORDER |
|---------------|------------|-----------------|------------|
| C_GEN_GENPLAT | DICER1     | DICER1          | 36         |
| C_GEN_GENPLAT | DIS3       | DIS3            | 37         |
| C_GEN_GENPLAT | DMD        | DMD             | 38         |
| C_GEN_GENPLAT | DNMT3A     | DNMT3A          | 39         |
| C_GEN_GENPLAT | EGFR       | EGFR            | 40         |
| C_GEN_GENPLAT | EML4       | EML4            | 41         |
| C_GEN_GENPLAT | EP300      | EP300           | 42         |
| C_GEN_GENPLAT | EPHA3      | EPHA3           | 43         |
| C_GEN_GENPLAT | EPHA5      | EPHA5           | 44         |
| C_GEN_GENPLAT | EPHA7      | EPHA7           | 45         |
| C_GEN_GENPLAT | EPHB1      | EPHB1           | 46         |
| C_GEN_GENPLAT | ERBB2      | ERBB2 (HER2)    | 47         |
| C_GEN_GENPLAT | ERBB3      | ERBB3 (HER3)    | 48         |
| C_GEN_GENPLAT | ERBB4      | ERBB4           | 49         |
| C_GEN_GENPLAT | ERCC2      | ERCC2           | 50         |
| C_GEN_GENPLAT | ERCC3      | ERCC3           | 51         |
| C_GEN_GENPLAT | ERCC4      | ERCC4           | 52         |
| C_GEN_GENPLAT | ERCC5      | ERCC5           | 53         |
| C_GEN_GENPLAT | ESR1       | ESR1            | 54         |
| C_GEN_GENPLAT | ETV1       | ETV1            | 55         |
| C_GEN_GENPLAT | FANCA      | FANCA           | 56         |
| C_GEN_GENPLAT | FAT1       | FAT1            | 57         |
| C_GEN_GENPLAT | FBXW7      | FBXW7           | 58         |
| C_GEN_GENPLAT | FGFR1      | FGFR1           | 59         |
| C_GEN_GENPLAT | FGFR2      | FGFR2           | 60         |
| C_GEN_GENPLAT | FGFR3      | FGFR3           | 61         |
| C_GEN_GENPLAT | FGFR4      | FGFR4           | 62         |
| C_GEN_GENPLAT | FLT1       | FLT1            | 63         |
| C_GEN_GENPLAT | FLT3       | FLT3            | 64         |
| C_GEN_GENPLAT | FLT4       | FLT4            | 65         |
| C_GEN_GENPLAT | GATA3      | GATA3           | 66         |
| C_GEN_GENPLAT | GLI1       | GLI1            | 67         |
| C_GEN_GENPLAT | GLI2       | GLI2            | 68         |
| C_GEN_GENPLAT | GLI3       | GLI3            | 69         |
| C_GEN_GENPLAT | GNAS       | GNAS            | 70         |
| C_GEN_GENPLAT | GRIN2A     | GRIN2A          | 71         |
| C_GEN_GENPLAT | HGF        | HGF             | 72         |
| C_GEN_GENPLAT | HIST1H3F   | HIST1H3F        | 73         |
| C_GEN_GENPLAT | IGF1R      | IGF1R           | 74         |
| C_GEN_GENPLAT | IKZF1      | IKZF1           | 75         |
| C_GEN_GENPLAT | INPP4B     | INPP4B          | 76         |
| C_GEN_GENPLAT | JAK2       | JAK2            | 77         |
| C_GEN_GENPLAT | JAK3       | JAK3            | 78         |
| C_GEN_GENPLAT | KDM5C      | KDM5C           | 79         |
| C_GEN_GENPLAT | KDM6A      | KDM6A           | 80         |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION | CODE ORDER |
|---------------|------------|-----------------|------------|
| C_GEN_GENPLAT | KDR        | KDR             | 81         |
| C_GEN_GENPLAT | KEAP1      | KEAP1           | 82         |
| C_GEN_GENPLAT | KIT        | KIT             | 83         |
| C_GEN_GENPLAT | KMT2A      | KMT2A           | 84         |
| C_GEN_GENPLAT | KMT2C      | KMT2C           | 85         |
| C_GEN_GENPLAT | KMT2D      | KMT2D           | 86         |
| C_GEN_GENPLAT | KRAS       | KRAS            | 87         |
| C_GEN_GENPLAT | MAP2K1     | MAP2K1          | 88         |
| C_GEN_GENPLAT | MAP3K1     | MAP3K1          | 89         |
| C_GEN_GENPLAT | MED12      | MED12           | 90         |
| C_GEN_GENPLAT | MEN1       | MEN1            | 91         |
| C_GEN_GENPLAT | MET        | MET             | 92         |
| C_GEN_GENPLAT | MGA        | MGA             | 93         |
| C_GEN_GENPLAT | MPL        | MPL             | 94         |
| C_GEN_GENPLAT | MSH2       | MSH2            | 95         |
| C_GEN_GENPLAT | MSH6       | MSH6            | 96         |
| C_GEN_GENPLAT | MTOR       | MTOR            | 97         |
| C_GEN_GENPLAT | NBN        | NBN             | 98         |
| C_GEN_GENPLAT | NF1        | NF1             | 99         |
| C_GEN_GENPLAT | NF2        | NF2             | 100        |
| C_GEN_GENPLAT | NFE2L2     | NFE2L2          | 101        |
| C_GEN_GENPLAT | NOTCH1     | NOTCH1          | 102        |
| C_GEN_GENPLAT | NOTCH2     | NOTCH2          | 103        |
| C_GEN_GENPLAT | NOTCH3     | NOTCH3          | 104        |
| C_GEN_GENPLAT | NOTCH4     | NOTCH4          | 105        |
| C_GEN_GENPLAT | NRAS       | NRAS            | 106        |
| C_GEN_GENPLAT | NTRK1      | NTRK1           | 107        |
| C_GEN_GENPLAT | NTRK2      | NTRK2           | 108        |
| C_GEN_GENPLAT | NTRK3      | NTRK3           | 109        |
| C_GEN_GENPLAT | PAK5       | PAK5            | 110        |
| C_GEN_GENPLAT | PALB2      | PALB2           | 111        |
| C_GEN_GENPLAT | PARK2      | PARK2           | 112        |
| C_GEN_GENPLAT | PBRM1      | PBRM1           | 113        |
| C_GEN_GENPLAT | PDGFRA     | PDGFRA          | 114        |
| C_GEN_GENPLAT | PDGFRB     | PDGFRB          | 115        |
| C_GEN_GENPLAT | PIK3C2B    | PIK3C2B         | 116        |
| C_GEN_GENPLAT | PIK3C2G    | PIK3C2G         | 117        |
| C_GEN_GENPLAT | PIK3CA     | PIK3CA          | 118        |
| C_GEN_GENPLAT | PIK3CG     | PIK3CG          | 119        |
| C_GEN_GENPLAT | PMS1       | PMS1            | 120        |
| C_GEN_GENPLAT | PMS2       | PMS2            | 121        |
| C_GEN_GENPLAT | POLE       | POLE            | 122        |
| C_GEN_GENPLAT | PRKDC      | PRKDC           | 123        |
| C_GEN_GENPLAT | PTCH1      | PTCH1           | 124        |
| C_GEN_GENPLAT | PTEN       | PTEN            | 125        |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION                                     | CODE ORDER |
|---------------|------------|---|------------|
| C_GEN_GENPLAT | PTPN11     | PTPN11  | 126        |
| C_GEN_GENPLAT | PTPRD      | PTPRD   | 127        |
| C_GEN_GENPLAT | PTPRT      | PTPRT   | 128        |
| C_GEN_GENPLAT | RB1        | RB1   | 129        |
| C_GEN_GENPLAT | RBM10      | RBM10   | 130        |
| C_GEN_GENPLAT | RECQL4     | RECQL4  | 131        |
| C_GEN_GENPLAT | RET        | RET   | 132        |
| C_GEN_GENPLAT | RFWD2      | RFWD2   | 133        |
| C_GEN_GENPLAT | ROS1       | ROS1  | 134        |
| C_GEN_GENPLAT | SETBP1     | SETBP1  | 135        |
| C_GEN_GENPLAT | SETD2      | SETD2   | 136        |
| C_GEN_GENPLAT | SF3B1      | SF3B1   | 137        |
| C_GEN_GENPLAT | SMAD4      | SMAD4   | 138        |
| C_GEN_GENPLAT | SMARCA4    | SMARCA4   | 139        |
| C_GEN_GENPLAT | SMO        | SMO   | 140        |
| C_GEN_GENPLAT | SPEN       | SPEN  | 141        |
| C_GEN_GENPLAT | STAG2      | STAG2   | 142        |
| C_GEN_GENPLAT | STK11      | STK11   | 143        |
| C_GEN_GENPLAT | TBX3       | TBX3  | 144        |
| C_GEN_GENPLAT | TCF3       | TCF3  | 145        |
| C_GEN_GENPLAT | TERT       | TERT  | 146        |
| C_GEN_GENPLAT | TET1       | TET1  | 147        |
| C_GEN_GENPLAT | TET2       | TET2  | 148        |
| C_GEN_GENPLAT | TLR4       | TLR4  | 149        |
| C_GEN_GENPLAT | TP53       | TP53  | 150        |
| C_GEN_GENPLAT | TSC1       | TSC1  | 151        |
| C_GEN_GENPLAT | TSC2       | TSC2  | 152        |
| C_GEN_GENPLAT | WT1        | WT1   | 153        |
| C_GEN_GENPLAT | ZFHX3      | ZFHX3   | 154        |
| C_GEN_PLATBIO | SANGEGFR   | Sanger: EGFR Point Mutations                        | 2          |
| C_GEN_PLATBIO | SANGBRAF   | Sanger: BRAF Point Mutations                        | 3          |
| C_GEN_PLATBIO | SANGHER2   | Sanger: HER2 (ERBB2) Point Mutations                | 4          |
| C_GEN_PLATBIO | SANGKRAS   | Sanger: KRAS Point Mutations                        | 5          |
| C_GEN_PLATBIO | NGSCOBAS   | COBAS EGFR Mutation Test v2                         | 6          |
| C_GEN_PLATBIO | NGSTHER2   | NGS: ThermoFisher Ion Ampliseq v2                   | 9          |
| C_GEN_PLATBIO | NGSODX     | NGS: Oncomine Dx Target Test                        | 10         |
| C_GEN_PLATBIO | NGSOLUNG   | NGS: Oncomine Lung cfDNA Assay                      | 11         |
| C_GEN_PLATBIO | NGSOFOC    | NGS: Oncomine Focus                                 | 12         |
| C_GEN_PLATBIO | NGSSOLID   | NGS: Oncomine Solid Tumor Fusion                    | 13         |
| C_GEN_PLATBIO | NGSS1PAN   | NGS: OncoGenBasic S1 Panel (BRAF, KRAS, NRAS, EGFR) | 14         |
| C_GEN_PLATBIO | NGSS2PAN   | NGS: OncoGenBasic S2 Panel (AKT1, PIK3CA)           | 15         |
| C_GEN_PLATBIO | NGS360G    | NGS: Guardant360                                    | 16         |
| C_GEN_PLATBIO | MSK        | NGS: MSK-IMPACT                                     | 17         |
| C_GEN_PLATBIO | NGSFONE    | NGS: FoundationOne                                  | 18         |
| C_GEN_PLATBIO | NGSONE     | NGS: FoundationOne CDX                              | 19         |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION   | CODE ORDER |
|---------------|------------|---|------------|
| C_GEN_PLATBIO | NGS425C    | NGS: Geneseeq Pan-Genomic (425 cancer genes)                  | 20         |
| C_GEN_PLATBIO | NGS139L    | NGS: Geneseeq Pulmocan (139 lung cancer genes)                | 21         |
| C_GEN_PLATBIO | NGS14N     | NGS: Geneseeq Tetradecan (14 NCCN lung cancer genes)          | 22         |
| C_GEN_PLATBIO | NGSMIPRO   | NGS: Caris MI Profile   | 23         |
| C_GEN_PLATBIO | NGSMITUM   | NGS: Caris MI Tumor Seek                                      | 24         |
| C_GEN_PLATBIO | NGSLFUS    | NGS: NeoGenomics Lung NGS Fusion Profile                      | 25         |
| C_GEN_PLATBIO | NGSLPRO    | NGS: NeoGenomics NeoTYPE Lung Tumor Profile                   | 26         |
| C_GEN_PLATBIO | NGSTHPAN   | NGS: ThermoFisher Oncomine Pan-Cancer Cell-Free Assay         | 27         |
| C_GEN_PLATBIO | NGSTHER1   | NGS: ThermoFisher Oncomine Comprehensive Assay v1             | 28         |
| C_GEN_PLATBIO | NGSTHER3   | NGS: ThermoFisher Oncomine Comprehensive Assay v3             | 29         |
| C_GEN_PLATBIO | NGSMUTL    | NGS: ThermoFisher Oncomine Tumor Mutation Load Assay          | 30         |
| C_GEN_PLATBIO | NGSILL     | NGS: Illumina TruSight(tm) Oncology 500                       | 31         |
| C_GEN_PLATBIO | DDPCR      | ddPCR: Biodesix Lung Reflex genestrat                         | 32         |
| C_GEN_PLATBIO | QPCREGFR   | qPCR/RT-qPCR/ddPCR: EGFR Point Mutations                      | 35         |
| C_GEN_PLATBIO | QPCRBAF    | qPCR/RT-qPCR/ddPCR: BRAF Point Mutations                      | 36         |
| C_GEN_PLATBIO | QPCRHER2   | qPCR/RT-qPCR/ddPCR: HER2 (ERBB2) Point Mutations              | 37         |
| C_GEN_PLATBIO | QPCRKRAS   | qPCR/RT-qPCR/ddPCR: KRAS Point Mutations                      | 38         |
| C_GEN_PLATBIO | RTQPEGFR   | RT-PCR Biocartis Idylla: EGFR Point Mutations                 | 39         |
| C_GEN_PLATBIO | RTQPBRAF   | RT-PCR Biocartis Idylla: BRAF Point Mutations                 | 40         |
| C_GEN_PLATBIO | RTQPHER2   | RT-PCR Biocartis Idylla: KRAS Point Mutations                 | 41         |
| C_GEN_PLATBIO | RTQPNRAS   | RT-PCR Biocartis Idylla: NRAS-BRAF Point Mutations            | 42         |
| C_GEN_PLATBIO | FISHALK    | FISH: ALK Fusion  | 44         |
| C_GEN_PLATBIO | FISHROS1   | FISH: ROS1 Fusion   | 45         |
| C_GEN_PLATBIO | FISHMET    | FISH: MET Amplifications                                      | 46         |
| C_GEN_PLATBIO | FISHRET    | FISH: RET Fusion  | 47         |
| C_GEN_PLATBIO | CISHALK    | CISH: ALK Fusion  | 48         |
| C_GEN_PLATBIO | CISHROS1   | CISH: ROS1 Fusion   | 49         |
| C_GEN_PLATBIO | CISHMET    | CISH: MET Amplifications                                      | 50         |
| C_GEN_PLATBIO | CISHRET    | CISH: RET Fusion  | 51         |
| C_GEN_PLATBIO | ACGHARR    | aCGH (array comparative genomic hybridisation)                | 53         |
| C_GEN_PLATBIO | SNP500K    | SNP array: Affymetrix 500K array                              | 54         |
| C_GEN_PLATBIO | SNP5ARR    | SNP array: Affymetrix 5.0 SNP array                           | 55         |
| C_GEN_PLATBIO | SNPARR     | SNP array: Affymetrix 6.0 SNP array                           | 56         |
| C_GEN_PLATBIO | SNPCNV     | SNP array: OncoScan CNV Plus Assay                            | 57         |
| C_GEN_PLATBIO | SNPONCO    | SNP array: Sequenom OncoCarta v1.0                            | 58         |
| C_GEN_PLATBIO | SNPLUNG    | SNP array: Sequenom LungCarta                                 | 59         |
| C_GEN_PLATBIO | NANODNA    | NanoString nCounter: Vantage 3D DNA:Fusion:Protein Lung Assay | 60         |
| C_GEN_PLATBIO | NANOLUNG   | NanoString nCounter: Vantage 3D Lung Fusion Panel             | 61         |
| C_GEN_TYPE    | BIOPSY     | Biopsy  | 1          |
| C_GEN_TYPE    | CYTO       | Cytology  | 2          |
| C_GEN_TYPE    | PLASMA     | Plasma  | 3          |
| C_GEN_YN      | Y          | Yes   | 1          |
| C_GEN_YN      | N          | No  | 2          |
| C_GENO        | HOMO       | Homozygous  | 1          |
| C_GENO        | HETERO     | Heterozygous  | 2          |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME     | CODE VALUE | CODE DEFINITION            | CODE ORDER |
|-----------------|------------|----------------------------|------------|
| C_LAB_CELLS     | CELLS      | 109 X cells/L              | 1          |
| C_LAB_GDLMMOL   | GDL        | g/dL                       | 1          |
| C_LAB_GDLMMOL   | MMOL       | mmol/L                     | 2          |
| C_LAB_GL        | GL         | g/L                        | 1          |
| C_LAB_GL        | GDL        | g/dL                       | 2          |
| C_LAB_IULUKAT   | UKAT       | ukat/L                     | 1          |
| C_LAB_IULUKAT   | IUL        | IU/L                       | 2          |
| C_LAB_MGDLMMOL  | MMOL       | mmol/L                     | 1          |
| C_LAB_MGDLMMOL  | MGDL       | mg/dl                      | 2          |
| C_LAB_MMOL      | MMOL       | mmol/L                     | 1          |
| C_LAB_SUVAPP    | HILAR      | Hilar/interlobar nodes     | 1          |
| C_LAB_SUVAPP    | MEDNODE    | Mediastinal nodes          | 2          |
| C_LAB_SUVAPP    | SUPNODE    | Supraclavicular nodes      | 3          |
| C_LAB_UKAT      | UKAT       | ukat/L                     | 1          |
| C_MONTH         | JAN        | Jan                        | 1          |
| C_MONTH         | FEB        | Feb                        | 2          |
| C_MONTH         | MAR        | Mar                        | 3          |
| C_MONTH         | APR        | Apr                        | 4          |
| C_MONTH         | MAY        | May                        | 5          |
| C_MONTH         | JUN        | Jun                        | 6          |
| C_MONTH         | JUL        | Jul                        | 7          |
| C_MONTH         | AUG        | Aug                        | 8          |
| C_MONTH         | SEP        | Sep                        | 9          |
| C_MONTH         | OCT        | Oct                        | 10         |
| C_MONTH         | NOV        | Nov                        | 11         |
| C_MONTH         | DEC        | Dec                        | 12         |
| C_PC_SMOKHIST   | NEVER      | Never smoked               | 1          |
| C_PC_SMOKHIST   | FORMER     | Former smoker              | 2          |
| C_PC_SMOKHIST   | CURRENT    | Current smoker             | 3          |
| C_PC_SMOKHIST   | ND         | No Data                    | 4          |
| C_PC_WT6LOSS    | L5PER      | < 5% of body weight        | 1          |
| C_PC_WT6LOSS    | G5PER      | >= 5% - 10% of body weight | 2          |
| C_PC_WT6LOSS    | G10PER     | >= 10% of body weight      | 3          |
| C_PC_WT6LOSS    | ND         | No Data                    | 4          |
| C_PC_ZUBROD     | 0          | 0 - Fully active           | 1          |
| C_PC_ZUBROD     | 1          | 1- Restricted              | 2          |
| C_PC_ZUBROD     | 2          | 2 - No work, ambulatory    | 3          |
| C_PC_ZUBROD     | 3          | 3 - Limited self-care      | 4          |
| C_PC_ZUBROD     | 4          | 4 - Completely disabled    | 5          |
| C_PC_ZUBROD     | ND         | No Data                    | 6          |
| C_POST_LYMPHINV | LY0        | Ly0: No invasion           | 1          |
| C_POST_LYMPHINV | LY1        | Ly1: Invasion              | 2          |
| C_POST_LYMPHINV | UNK        | Unknown                    | 3          |
| C_POST_NCAT     | N0         | N0                         | 1          |
| C_POST_NCAT     | N1         | N1                         | 2          |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME     | CODE VALUE | CODE DEFINITION  | CODE ORDER |
|-----------------|------------|--|------------|
| C_POST_NCAT     | N2         | N2   | 3          |
| C_POST_NCAT     | N3         | N3   | 4          |
| C_POST_NCAT     | NX         | NX   | 5          |
| C_POST_NCATLR   | PLUS       | +  | 1          |
| C_POST_NCATLR   | NEG        | -  | 2          |
| C_POST_NCATLR   | ND         | ND   | 3          |
| C_POST_PLEUCYTO | POS        | Positive   | 1          |
| C_POST_PLEUCYTO | NEG        | Negative   | 2          |
| C_POST_PLEUCYTO | ND         | Not done   | 3          |
| C_POST_PLEUCYTO | NONE       | No Data  | 4          |
| C_POST_STATFISS | ADJINV     | Adjacent lobe invaded  | 1          |
| C_POST_STATFISS | ADJNOINV   | Adjacent lobe not invaded  | 2          |
| C_POST_STATFISS | UNK        | Unknown  | 3          |
| C_POST_STATFISS | NA         | Not Applicable   | 4          |
| C_POST_TCAT     | TX         | TX   | 1          |
| C_POST_TCAT     | T0         | T0   | 2          |
| C_POST_TCAT     | TIS        | Tis  | 3          |
| C_POST_TCAT     | T1MI       | T1mi   | 4          |
| C_POST_TCAT     | T1A        | T1a  | 5          |
| C_POST_TCAT     | T1B        | T1b  | 6          |
| C_POST_TCAT     | T1C        | T1c  | 7          |
| C_POST_TCAT     | T2A        | T2a  | 8          |
| C_POST_TCAT     | T2B        | T2b  | 9          |
| C_POST_TCAT     | T3         | T3   | 10         |
| C_POST_TCAT     | T4         | T4   | 11         |
| C_POST_TSTAS    | PRESENT    | Present  | 1          |
| C_POST_TSTAS    | ABSENT     | Absent   | 2          |
| C_POST_TSTAS    | NOTEVAL    | Not evaluated  | 3          |
| C_POST_VASCINV  | V0         | V0: None   | 1          |
| C_POST_VASCINV  | V1         | V1: Microscopic  | 2          |
| C_POST_VASCINV  | V2         | V2: Macroscopic  | 3          |
| C_POST_VASCINV  | UNK        | Unknown  | 4          |
| C_PRE_CYTO      | POS        | Positive   | 1          |
| C_PRE_CYTO      | NEG        | Negative   | 2          |
| C_PRE_CYTO      | ND         | Not done   | 3          |
| C_PRE_CYTO      | UNK        | Unknown  | 4          |
| C_PRE_DISTMET   | SINGLES    | Single lesion  | 1          |
| C_PRE_DISTMET   | MULTLES    | Multiple lesions   | 2          |
| C_PRE_DISTMET   | PRES       | Present, number of lesions not specified   | 3          |
| C_PRE_DISTMET   | ABS        | Absent   | 4          |
| C_PRE_MCAT      | M0         | M0   | 1          |
| C_PRE_MCAT      | M1A        | M1a  | 2          |
| C_PRE_MCAT      | M1B        | M1b  | 3          |
| C_PRE_MCAT      | M1C        | M1c  | 4          |
| C_PRE_MNOASP    | ASPBEN     | Aspiration not needed; evidence of benignity (e.g. improvement without anti-cancer treatments) | 1          |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION  | CODE ORDER |
|---------------|------------|--|------------|
| C_PRE_MNOASP  | ASPOTH     | Aspiration not needed; evidence of other metastatic disease (M1b, M1c)                             | 2          |
| C_PRE_MNOASP  | ASPEIOL    | Unable to be aspirated; alternative etiology clinically likely (e.g. parapneumonic, heart failure) | 3          |
| C_PRE_MNOASP  | ASPMALIG   | Unable to be aspirated; clinically likely malignant  | 4          |
| C_PRE_MNOASP  | OTH        | Other reason   | 5          |
| C_PRE_MPERI   | PRES       | Present  | 1          |
| C_PRE_MPERI   | ABS        | Absent   | 2          |
| C_PRE_MPERI   | UNK        | Unknown  | 3          |
| C_PRE_MPLEU   | NONE       | None   | 1          |
| C_PRE_MPLEU   | IPSIL      | Ipsilateral  | 2          |
| C_PRE_MPLEU   | CONTRA     | Contralateral  | 3          |
| C_PRE_MPLEU   | BILAT      | Bilateral  | 4          |
| C_PRE_MPLEU   | PRES       | Present, side not specified  | 5          |
| C_PRE_MPLEU   | UNK        | Unknown  | 6          |
| C_PRE_NCAT    | NO         | NO   | 1          |
| C_PRE_NCAT    | N1         | N1   | 2          |
| C_PRE_NCAT    | N2         | N2   | 3          |
| C_PRE_NCAT    | N3         | N3   | 4          |
| C_PRE_NCAT    | NX         | NX   | 5          |
| C_PRE_NCATORL | PLUS       | +  | 1          |
| C_PRE_NCATORL | NEG        | -  | 2          |
| C_PRE_NCATORL | ND         | ND   | 3          |
| C_PRE_NMEAS   | XRAY       | X-ray  | 1          |
| C_PRE_NMEAS   | CT         | CT   | 2          |
| C_PRE_NMEAS   | ULTRA      | Ultrasound   | 3          |
| C_PRE_NMEAS   | BIO        | Biopsy   | 4          |
| C_PRE_TCAT    | TX         | TX   | 1          |
| C_PRE_TCAT    | T0         | T0   | 2          |
| C_PRE_TCAT    | TIS        | Tis  | 3          |
| C_PRE_TCAT    | T1MI       | T1mi   | 4          |
| C_PRE_TCAT    | T1A        | T1a  | 5          |
| C_PRE_TCAT    | T1B        | T1b  | 6          |
| C_PRE_TCAT    | T1C        | T1c  | 7          |
| C_PRE_TCAT    | T2A        | T2a  | 8          |
| C_PRE_TCAT    | T2B        | T2b  | 9          |
| C_PRE_TCAT    | T3         | T3   | 10         |
| C_PRE_TCAT    | T4         | T4   | 11         |
| C_PRO_ANTI    | DAKO288    | DAKO 28-8  | 1          |
| C_PRO_ANTI    | DAKO22C3   | DAKO 22-C3   | 2          |
| C_PRO_ANTI    | DAKO7310   | DAKO 73-10   | 3          |
| C_PRO_ANTI    | VNTSP142   | Ventana SP142  | 4          |
| C_PRO_ANTI    | VNTSP263   | Ventana SP263  | 5          |
| C_PRO_ANTI    | CSE1L3N    | Cell Signaling E1L3N   | 6          |
| C_PRO_ANTI    | DAKOALK1   | Dako ALK1  | 7          |
| C_PRO_ANTI    | VNTD5F3    | Ventana D5F3 CDx   | 8          |
| C_PRO_ANTI    | CSD5F3     | Cell Signaling D5F3  | 9          |

# IASLC Lung Cancer Staging Project codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME     | CODE VALUE | CODE DEFINITION  | CODE ORDER |
|-----------------|------------|--|------------|
| C_PRO_ANTI      | NALN5A4    | Novocastra/Abcam/Leica/Novus 5A4   | 10         |
| C_PRO_ANTI      | CSD4D6     | Cell Signaling D4D6  | 11         |
| C_PRO_ANTI      | CS43B2     | Cell Signaling 43B2 (L858R Mutant Specific)  | 12         |
| C_PRO_ANTI      | CSD6B6     | Cell Signaling D6B6 (E746-A750del Specific)  | 13         |
| C_PRO_ANTI      | ATHER5A4   | Thermo Fisher/Abcam 5A4  | 14         |
| C_PRO_ANTI      | VNTSP384   | Ventana SP384  | 15         |
| C_PRO_ANTI      | VNTSP44    | Ventana SP44   | 16         |
| C_PRO_ANTI      | OTH        | Other  | 17         |
| C_PRO_EXP       | POS        | Positive   | 1          |
| C_PRO_EXP       | NEG        | Negative   | 2          |
| C_PRO_EXP       | INCON      | Inconclusive   | 3          |
| C_PRO_PLATPA    | IHC        | IHC  | 1          |
| C_PRO_PLATPA    | MASSSPEC   | Mass spectrometry  | 2          |
| C_PRO_PLATPA    | ELISA      | ELISA  | 3          |
| C_PRO_PLATPA    | LUMINEX    | Luminex  | 4          |
| C_PRO_PLATPA    | NANO       | NanoString nCounter: Vantage 3D DNA:Fusion:Protein Lung Assay                      | 5          |
| C_PRO_PROT      | PDL1       | PD-L1  | 1          |
| C_PRO_PROT      | ALK        | ALK  | 2          |
| C_PRO_PROT      | ROS        | ROS1   | 3          |
| C_PRO_PROT      | EGFR       | EGFR   | 4          |
| C_PRO_PROT      | MET        | MET  | 5          |
| C_PRO_TYPE      | BIOPSY     | Biopsy   | 1          |
| C_PRO_TYPE      | CYTO       | Cytology   | 2          |
| C_PRO_TYPE      | PLASMA     | Plasma   | 3          |
| C_PTUM_DIFFGRD  | GX         | Gx: Cannot be assessed   | 1          |
| C_PTUM_DIFFGRD  | G1         | G1: Well differentiated  | 2          |
| C_PTUM_DIFFGRD  | G2         | G2: Moderately differentiated  | 3          |
| C_PTUM_DIFFGRD  | G3         | G3: Poorly differentiated  | 4          |
| C_PTUM_DIFFGRD  | G4         | G4: Undifferentiated   | 5          |
| C_PTUM_DIFFGRD  | UNK        | Unknown  | 6          |
| C_PTUM_HISTTYPE | ADINSITU   | Adenocarcinoma, noninvasive: Adenocarcinoma in situ                                | 1          |
| C_PTUM_HISTTYPE | ADMININV   | Adenocarcinoma: Minimally invasive adenocarcinoma                                  | 2          |
| C_PTUM_HISTTYPE | ADLEPID    | Adenocarcinoma, Invasive: Lepidic adenocarcinoma                                   | 3          |
| C_PTUM_HISTTYPE | ADACINAR   | Adenocarcinoma, Invasive: Acinar adenocarcinoma                                    | 4          |
| C_PTUM_HISTTYPE | ADPAPILL   | Adenocarcinoma, Invasive: Papillary adenocarcinoma                                 | 5          |
| C_PTUM_HISTTYPE | ADENMICR   | Adenocarcinoma, Invasive: Micropapillary adenocarcinoma                            | 6          |
| C_PTUM_HISTTYPE | SOLIDADE   | Adenocarcinoma, Invasive: Solid adenocarcinoma                                     | 7          |
| C_PTUM_HISTTYPE | ADENMUCI   | Adenocarcinoma, Invasive: Invasive mucinous adenocarcinoma                         | 8          |
| C_PTUM_HISTTYPE | ADENNOS    | Adenocarcinoma, NOS  | 9          |
| C_PTUM_HISTTYPE | SQUASITU   | Squamous cell carcinoma: Squamous cell carcinoma in situ                           | 10         |
| C_PTUM_HISTTYPE | SQUAINVA   | Squamous cell carcinoma: Invasive squamous cell carcinoma                          | 11         |
| C_PTUM_HISTTYPE | DIPNECH    | Neuroendocrine tumor: Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia | 12         |
| C_PTUM_HISTTYPE | NEURSCLC   | Neuroendocrine tumor: Small cell carcinoma   | 13         |
| C_PTUM_HISTTYPE | NEURLCC    | Neuroendocrine tumor: Large cell neuroendocrine carcinoma                          | 14         |
| C_PTUM_HISTTYPE | CARCTYP    | Carcinoid tumor: typical carcinoid   | 15         |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME     | CODE VALUE | CODE DEFINITION   | CODE ORDER |
|-----------------|------------|---|------------|
| C_PTUM_HISTTYPE | CARCATYP   | Carcinoid tumor: atypical carcinoid                       | 16         |
| C_PTUM_HISTTYPE | LARGCELL   | Large cell carcinoma                                      | 17         |
| C_PTUM_HISTTYPE | ADENSQUA   | Adenosquamous carcinoma                                   | 18         |
| C_PTUM_HISTTYPE | SARPLEO    | Sarcomatoid carcinomas: Pleomorphic carcinoma             | 19         |
| C_PTUM_HISTTYPE | SARGIANT   | Sarcomatoid carcinomas: Giant cell carcinoma              | 20         |
| C_PTUM_HISTTYPE | SARCARC    | Sarcomatoid carcinoma: Carcinosarcoma                     | 21         |
| C_PTUM_HISTTYPE | SALVMUCO   | Salivary gland type tumors: Mucoepidermoid carcinoma      | 22         |
| C_PTUM_HISTTYPE | SALVADEN   | Salivary gland type tumors: Adenoid cystic carcinoma      | 23         |
| C_PTUM_HISTTYPE | NONSCLC    | Non Small Cell Lung Cancer - Not otherwise specified      | 24         |
| C_PTUM_HISTTYPE | COMBCARC   | Combined small cell carcinoma and nonsmall cell carcinoma | 25         |
| C_PTUM_HISTTYPE | OTH        | Other (None of the above)                                 | 26         |
| C_PTUM_METDET   | SYMPT      | Symptoms  | 1          |
| C_PTUM_METDET   | SCREEN     | Screening   | 2          |
| C_PTUM_METDET   | INCID      | Incidental  | 3          |
| C_PTUM_METDET   | UNK        | Unknown   | 4          |
| C_PTUM_PLEUEFF  | CYTPOS     | Present - cytology positive                               | 1          |
| C_PTUM_PLEUEFF  | CYTNEG     | Present - cytology negative                               | 2          |
| C_PTUM_PLEUEFF  | CYTUNK     | Present - cytology unknown                                | 3          |
| C_PTUM_PLEUEFF  | ABSENT     | Absent  | 4          |
| C_PTUM_PLEUEFF  | UNK        | Unknown   | 5          |
| C_SEX           | M          | Male  | 1          |
| C_SEX           | F          | Female  | 2          |
| C_SYS_LINETX    | FIRST      | First line  | 1          |
| C_SYS_LINETX    | SECOND     | Second line   | 2          |
| C_SYS_LINETX    | THIRD      | Third line or more  | 3          |
| C_SYS_LINETX    | NEO        | Neoadjuvant   | 4          |
| C_SYS_LINETX    | ADJ        | Adjuvant  | 5          |
| C_SYS_THERAPY   | AFAT       | Afatinib  | 1          |
| C_SYS_THERAPY   | ALECT      | Alectinib   | 2          |
| C_SYS_THERAPY   | ATEZOL     | Atezolizumab  | 3          |
| C_SYS_THERAPY   | AVEL       | Avelumab  | 4          |
| C_SYS_THERAPY   | BEVAC      | Bevacizumab   | 5          |
| C_SYS_THERAPY   | BRIGAT     | Brigatinib  | 6          |
| C_SYS_THERAPY   | CABOZ      | Cabozantinib  | 7          |
| C_SYS_THERAPY   | CARBO      | Carboplatin   | 8          |
| C_SYS_THERAPY   | CERIT      | Ceritinib   | 9          |
| C_SYS_THERAPY   | CETUX      | Cetuximab   | 10         |
| C_SYS_THERAPY   | CISPLAT    | Cisplatin   | 11         |
| C_SYS_THERAPY   | CRIZOT     | Crizotinib  | 12         |
| C_SYS_THERAPY   | DABRA      | Dabrafenib  | 13         |
| C_SYS_THERAPY   | DACOM      | Dacomitinib   | 14         |
| C_SYS_THERAPY   | DOCET      | Docetaxel   | 15         |
| C_SYS_THERAPY   | DURVA      | Durvalumab  | 16         |
| C_SYS_THERAPY   | ENTREC     | Entrectinib   | 17         |
| C_SYS_THERAPY   | ERLOT      | Erlotinib   | 18         |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION  | CODE ORDER |
|---------------|------------|--|------------|
| C_SYS_THERAPY | ETOP       | Etoposide  | 19         |
| C_SYS_THERAPY | GEFIT      | Gefitinib  | 20         |
| C_SYS_THERAPY | GEMCIT     | Gemcitabine  | 21         |
| C_SYS_THERAPY | HYCAM      | Hycamtin   | 22         |
| C_SYS_THERAPY | INTED      | Intedanib  | 23         |
| C_SYS_THERAPY | LORLA      | Lorlatinib   | 24         |
| C_SYS_THERAPY | LOXO101    | LOXO 101   | 25         |
| C_SYS_THERAPY | LOXO292    | LOXO 292   | 26         |
| C_SYS_THERAPY | NECIT      | Necitumumab  | 27         |
| C_SYS_THERAPY | NEDAP      | Nedaplatin   | 28         |
| C_SYS_THERAPY | NINTED     | Nintedanib   | 29         |
| C_SYS_THERAPY | NIVOL      | Nivolumab  | 30         |
| C_SYS_THERAPY | OCTRE      | Octreotide   | 31         |
| C_SYS_THERAPY | OSIMER     | Osimertinib  | 32         |
| C_SYS_THERAPY | PACLIT     | Paclitaxel   | 33         |
| C_SYS_THERAPY | PEMBRO     | Pembrolizumab  | 34         |
| C_SYS_THERAPY | PEMET      | Pemetrexed   | 35         |
| C_SYS_THERAPY | PONAT      | Ponatinib  | 36         |
| C_SYS_THERAPY | RADDEF     | Radiation: Definitive  | 37         |
| C_SYS_THERAPY | RADPALL    | Radiation: Palliative  | 38         |
| C_SYS_THERAPY | RADSTER    | Radiation: Stereotactic  | 39         |
| C_SYS_THERAPY | RAMIC      | Ramicirumab  | 40         |
| C_SYS_THERAPY | TRAMET     | Trametinib   | 41         |
| C_SYS_THERAPY | VEMUR      | Vemurafenib  | 42         |
| C_SYS_THERAPY | VINBLA     | Vinblastine  | 43         |
| C_SYS_THERAPY | VINOR      | Vinorelbine  | 44         |
| C_SYS_THERAPY | OTH        | Other  | 45         |
| C_TX_IMMTHER  | NOIMM      | No Immunotherapy   | 1          |
| C_TX_IMMTHER  | NORESECT   | Immunotherapy, no resection attempt  | 2          |
| C_TX_IMMTHER  | BEFORE     | Immunotherapy before resection, no immunotherapy after resection (or no data on immunotherapy after resection)             | 3          |
| C_TX_IMMTHER  | AFTER      | Immunotherapy after attempted resection  | 4          |
| C_TX_IMMTHER  | BEFORAFT   | Immunotherapy before and after attempted resection   | 5          |
| C_TX_IMMTHER  | UNK        | Attempted resection, sequence of immunotherapy unknown (or no data on immunotherapy after resection)                       | 6          |
| C_TX_RADTHOR  | NORAD      | No radiation therapy   | 1          |
| C_TX_RADTHOR  | NORESECT   | Radiation therapy, no resection attempt: standard or stereotactic  | 2          |
| C_TX_RADTHOR  | BEFORE     | Radiation therapy before resection, no radiation therapy after resection (or no data on radiation therapy after resection) | 3          |
| C_TX_RADTHOR  | AFTER      | Radiation therapy after attempted resection  | 4          |
| C_TX_RADTHOR  | BEFORAFT   | Radiation therapy before and after attempted resection   | 5          |
| C_TX_RADTHOR  | UNK        | Attempted resection, sequence of radiation therapy unknown (or no data on radiation therapy after resection)               | 6          |
| C_TX_RESECTCO | R0         | R0   | 1          |
| C_TX_RESECTCO | R1         | R1   | 2          |
| C_TX_RESECTCO | R2         | R2   | 3          |
| C_TX_RESECTCO | UNK        | Unknown  | 4          |
| C_TX_RESECTEX | THORAC     | Thoracotomy, no resection  | 1          |
| C_TX_RESECTEX | WITHLUNG   | Resection of the airway without removal of lung parenchyma   | 2          |

# IASLC Lung Cancer Staging Project Codelists for Coded Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| COLUMN NAME   | CODE VALUE | CODE DEFINITION   | CODE ORDER |
|---------------|------------|---|------------|
| C_TX_RESECTEX | WOLUNG     | Resection of the airway with removal of lung parenchyma   | 3          |
| C_TX_RESECTEX | ENDOSCOP   | Endoscopic resection  | 4          |
| C_TX_RESECTEX | SEGMENT    | Segmentectomy   | 5          |
| C_TX_RESECTEX | WEDGE      | Wedge resection   | 6          |
| C_TX_RESECTEX | LOBECT     | Lobectomy   | 7          |
| C_TX_RESECTEX | BILOBECT   | Bilobectomy   | 8          |
| C_TX_RESECTEX | PNEUMON    | Pneumonectomy   | 9          |
| C_TX_RESECTEX | OTH        | Other   | 10         |
| C_TX_RESECTST | NEG        | Negative free margins   | 1          |
| C_TX_RESECTST | MICRO      | Microscopic residual disease  | 2          |
| C_TX_RESECTST | MACRO      | Macroscopic residual disease  | 3          |
| C_TX_SYSTHER  | NOSYST     | No Systemic therapy   | 1          |
| C_TX_SYSTHER  | NORESECT   | Systemic therapy, no resection attempt  | 2          |
| C_TX_SYSTHER  | BEFORE     | Systemic therapy before resection, no systemic therapy after resection (or no data on systemic therapy after resection) | 3          |
| C_TX_SYSTHER  | AFTER      | Systemic therapy after attempted resection  | 4          |
| C_TX_SYSTHER  | BEFORAFT   | Systemic therapy before and after attempted resection   | 5          |
| C_TX_SYSTHER  | UNK        | Attempted resection, sequence of systemic therapy unknown (or no data on systemic therapy after resection)              | 6          |
| C_VST         | A          | Alive   | 1          |
| C_VST         | D          | Dead  | 2          |
| C_YN          | Y          | Yes   | 1          |
| C_YN          | N          | No  | 2          |
| C_YNNND       | Y          | Yes   | 1          |
| C_YNNND       | N          | No  | 2          |
| C_YNNND       | ND         | No Data   | 3          |
| C_YNNO        | Y          | Yes   | 1          |
| C_YNNO        | N          | No  | 2          |
| C_YNNO        | NO         | No Data   | 3          |
| C_YNU         | Y          | Yes   | 1          |
| C_YNU         | N          | No  | 2          |
| C_YNU         | UNK        | Unknown   | 3          |



# IASLC Lung Cancer Staging Project

## Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

Report Generated: 2/26/2020 12:20:50 PM

NOT TESTED - FOR INTERNAL USE ONLY

| Form ID | Form Name (Table Name) | Column Name   | Column Description                                       | Control Type  | Code List     | Date Type     | Validation Type | Status   |
|---------|------------------------|---------------|--|---------------|---------------|---------------|-----------------|----------|
| 1       | (FM_REGISTRATION)      | AFRICAN       | African  | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | AFRICANDES    | North American or African Descent                        | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | ASIAN         | East, Central, and Southeast Asian                       | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | ASIANNOS      | Asian, NOS   | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | BIRTHDY       | Birth Date - Day   | Text box      |               | NUMBER (2)    |                 | ACTIVE   |
|         |                        | BIRTHMO       | Birth Date - Month                                       | Dropdown      | C_MONTH       | VARCHAR (3)   |                 | ACTIVE   |
|         |                        | BIRTHYR       | Birth Date - Year  | Text box      |               | NUMBER (4)    |                 | ACTIVE   |
|         |                        | CAUCASIAN     | Caucasian (including Middle East and North African)      | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | CODE          | Subject Code   | Dropdown      |               | VARCHAR (15)  |                 | ACTIVE   |
|         |                        | INSTITUTIONID | Institution  | Dropdown      |               | NUMBER        |                 | ACTIVE   |
|         |                        | INVESTID      | Principal Investigator                                   | Dropdown      |               | NUMBER        |                 | ACTIVE   |
|         |                        | NATIVE        | Native North or South American                           | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | OTHRACE       | Other  | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | OTHRACESP     | If Other, Specify (Race)                                 | Text box      |               | VARCHAR (50)  |                 | ACTIVE   |
|         |                        | PACIFIC       | Pacific Islander (Oceania)                               | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
|         |                        | SEX           | Sex  | Radio buttons | C_SEX         | VARCHAR (8)   |                 | ACTIVE   |
|         |                        | SOUTHASIAN    | South Asian (India, Pakistan, Nepal, Bhutan, Bangladesh) | Checkbox      |               | VARCHAR (1)   |                 | ACTIVE   |
| 2       | (FM_TREATMENT)         | AMNDCTMT      | Amendment Comments                                       | TextBox       |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |                        | AMNDERR       | Error Correction   | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDESUB      | Entire form submitted in error                           | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDMISS      | Entry of missing or previously unavailable information   | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTH       | Reason(s) for Amending Form: Other                       | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTH_P     | Reason(s) for Amending Form: Other, Specify              | TextBox       |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |                        | TXCARCBRONC   | Carcinoma in situ at the bronchial resection margin      | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | TXIMMTHER     | Immunotherapy  | DropDownList  | C_TX_IMMTHER  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXRADBONE     | Bone   | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | TXRADBRAIN    | Brain  | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | TXRADOTH      | Other  | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | TXRADSPINE    | Spine  | CheckBox      |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | TXRADTHOR     | Radiation administered to thorax                         | DropDownList  | C_TX_RADTHOR  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXREMOVETUM   | Was removal of the primary tumour attempted?             | DropDownList  | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXRESECTCOMP  | Completeness of resection                                | DropDownList  | C_TX_RESECTCO | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXRESECTDY    | Date of resection attempt - Day                          | TextBox       |               | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |                        | TXRESECTTEXT  | Extent of resection                                      | DropDownList  | C_TX_RESECTEX | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXRESECTMO    | Date of resection attempt - Month                        | DropDownList  | C_MONTH       | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |                        | TXRESECTSTAT  | Status of resection margin                               | DropDownList  | C_TX_RESECTST | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | TXRESECTYR    | Date of resection attempt - Year                         | TextBox       |               | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |                        | TXSYSTHER     | Systemic therapy   | DropDownList  | C_TX_SYSTHER  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name)   | Column Name  | Column Description  | Control Type     | Code List     | Date Type     | Validation Type | Status   |
|---------|--|--------------|---|------------------|---------------|---------------|-----------------|----------|
| 3       | M-Descriptors, by Pre-Treatment/Evaluative Findings (FM_PREMDESCRIPTORS) | AMNDCMT      | Amendment Comments  | TextBox          |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDERR      | Error Correction  | CheckBox         |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB     | Entire form submitted in error                                | CheckBox         |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNMDMISS    | Entry of missing or previously unavailable information        | CheckBox         |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOOTH     | Reason(s) for Amending Form: Other                            | CheckBox         |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTHP     | Reason(s) for Amending Form: Other, Specify                   | TextBox          |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |  | PREMABLYMNO  | Number of lesions - Abdominal lymph nodes                     | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMABLYMPR  | Presence/Number of Lesions - Abdominal lymph nodes            | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMABLYMSZ  | Size of largest lesion - Abdominal lymph nodes                | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMADRNO    | Number of lesions - Adrenals                                  | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMADRPR    | Presence/Number of Lesions - Adrenals                         | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMADRSZ    | Size of largest lesion - Adrenals                             | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMBONENO   | Number of lesions - Bone                                      | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMBONEPR   | Presence/Number of Lesions - Bone                             | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMBONESZ   | Size of largest lesion - Bone                                 | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMBRAINNO  | Number of lesions - Brain                                     | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMBRAINPR  | Presence/Number of Lesions - Brain                            | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMBRAINSZ  | Size of largest lesion - Brain                                | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMCAT      | M Category by pre-treatment/evaluative findings:              | DropDownList     | C_PRE_MCAT    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMCYTO     | Was cytologic or histologic evidence obtained for M1 Disease? | DropDownList     | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMDISLYMNO | Number of lesions - Other distant lymph nodes                 | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMDISLYMPR | Presence/Number of Lesions - Other distant lymph nodes        | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMDISLYMSZ | Size of largest lesion - Other distant lymph nodes            | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMDISMET   | Are there any distant (extrathoracic) metastases?             | DropDownList     | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMLIVERNO  | Number of lesions - Liver                                     | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMLIVERPR  | Presence/Number of Lesions - Liver                            | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMLIVERSZ  | Size of largest lesion - Liver                                | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMLUNGMET  | Contralateral lung metastasis:                                | CheckBox         |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PREMMARRNO   | Number of lesions - Bone Marrow                               | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMMARRPR   | Presence/Number of Lesions - Bone Marrow                      | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMNOASP    | If pleural effusion was detected but not aspirated            | RadioButton-List | C_PRE_MNOASP  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMOTHNO    | Number of lesions - Other                                     | TextBox          |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMOTHPR    | Presence/Number of Lesions - Other                            | DropDownList     | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMOTHSZ    | Size of largest lesion - Other                                | TextBox          |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)   | COLUMN NAME  | COLUMN DESCRIPTION   | CONTROL TYPE | CODE LIST     | DATE TYPE     | VALIDATION TYPE | STATUS   |
|---------|--|--------------|--|--------------|---------------|---------------|-----------------|----------|
| 3       | M-Descriptors, by Pre-Treatment/Evaluative Findings (FM_PREMDESCRIPTORS) | PREMPERCYT   | Pericardial effusion - Cytology  | DropDownList | C_PRE_CYTO    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPEREFF   | Pericardial effusion:  | DropDownList | C_PRE_MPERI   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPERITNO  | Number of lesions - Peritoneum   | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PREMPERITPR  | Presence/Number of Lesions - Peritoneum  | DropDownList | C_PRE_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPERITSZ  | Size of largest lesion - Peritoneum  | TextBox      |               | VARCHAR (6)   | NUMBER (5,2)    | ACTIVE   |
|         |  | PREMPERNOD   | Pericardial nodules:   | DropDownList | C_PRE_MPERI   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPELCYT   | Pleural effusion - Cytology  | DropDownList | C_PRE_CYTO    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPELEFF   | Pleural effusion:  | DropDownList | C_PRE_MPLEU   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMPLENOD   | Pleural nodules:   | DropDownList | C_PRE_MPLEU   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PREMSKINNO   | Number of lesions - Skin   | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
| 4       | Lung Cancers with Multiple Lesions (FM_LUNGMULTILESIONS)                 | AMNDCMT      | Amendment Comments   | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDRERR     | Error Correction   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB     | Entire form submitted in error   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDMISS     | Entry of missing or previously unavailable information   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTH      | Reason(s) for Amending Form: Other   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTHSP    | Reason(s) for Amending Form: Other, Specify  | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |  | CONTRAINV    | Involvement of contralateral lung (M1a)  | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | INTRAMETOPP  | Separate Tumour Nodules with similar histopathologic features in opposite lung (interpulmonary metastases) | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | INTRAMETSAME | Separate Tumour Nodules with similar histopathologic features in same lung (intrapulmonary metastases)     | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | IPSILLOBE    | Lesions are located in more than one ipsilateral lobe  | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | LESLOBE      | All lesions are located in one lobe  | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | MULTADEN     | Multifocal adenocarcinoma with GGO/ lepidic features   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | MULTFOC      | Multiple foci  | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | MULTLES      | Are there multiple lung lesions?   | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | NUMLES       | If checked, number of lesions  | TextBox      |               | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |  | PNEUMAD      | Diffuse pneumonic-type lung adenocarcinoma   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
| 5       | Patient Characteristics (FM_PATIENTCTCS)                                 | PRITUM       | Synchronous primary tumour(s)  | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | SINGFOC      | Single focus   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | ALCOHOL      | Alcoholism   | DropDownList | C_YNND        | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | AMNDCMT      | Amendment Comments   | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDRERR     | Error Correction   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB     | Entire form submitted in error   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDMISS     | Entry of missing or previously unavailable information   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTH      | Reason(s) for Amending Form: Other   | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTHSP    | Reason(s) for Amending Form: Other, Specify  | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME) | COLUMN NAME | COLUMN DESCRIPTION  | CONTROL TYPE | CODE LIST     | DATE TYPE    | VALIDATION TYPE | STATUS   |
|---------|------------------------|-------------|---|--------------|---------------|--------------|-----------------|----------|
| 5       | (FM_PATIENTCTCS)       | CARDCOMOR   | Cardiovascular comorbidity  | DropDownList | C_YNND        | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | DIABMELL    | Diabetes mellitus   | DropDownList | C_YNND        | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | HT          | Height  | TextBox      |               | VARCHAR(3)   | VARCHAR(3)      | ACTIVE   |
|         |                        | PRETXMAL    | Previously treated malignancy   | DropDownList | C_YNND        | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | RENALINSUF  | Renal insufficiency   | DropDownList | C_YNND        | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | RESPCOMOR   | Respiratory comorbidity   | DropDownList | C_YNND        | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | SMOKDAY     | Average number  | TextBox      |               | VARCHAR(4)   | NUMBER(3,1)     | ACTIVE   |
|         |                        | SMOKHIST    | Smoking history   | DropDownList | C_PC_SMOKHIST | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | SMOKQUIT    | If a former smoker, number of years since quitting?                               | TextBox      |               | VARCHAR(2)   | VARCHAR(2)      | ACTIVE   |
|         |                        | SMOKYRS     | Number of years smoked  | TextBox      |               | VARCHAR(2)   | VARCHAR(2)      | ACTIVE   |
|         |                        | TABACCO     | Tobacco consumption   | TextBox      |               | VARCHAR(7)   | VARCHAR(7)      | ACTIVE   |
|         |                        | WT          | Weight  | TextBox      |               | VARCHAR(3)   | VARCHAR(3)      | ACTIVE   |
| 6       | (FM_PREXTNMTESTS)      | WTLOSS      | Weight loss in previous six months  | DropDownList | C_PC_WTLOSS   | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | ZUBROD      | Zubrod Performance Status   | DropDownList | C_PC_ZUBROD   | VARCHAR(8)   | VARCHAR(8)      | ACTIVE   |
|         |                        | AMNDCMT     | Amendment Comments  | TextBox      |               | VARCHAR(300) | VARCHAR(300)    | INACTIVE |
|         |                        | AMNDERR     | Error Correction  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | INACTIVE |
|         |                        | AMNDESUB    | Entire form submitted in error  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | INACTIVE |
|         |                        | AMNDMISS    | Entry of missing or previously unavailable information                            | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | INACTIVE |
|         |                        | AMNDOTH     | Reason(s) for Amending Form: Other  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | INACTIVE |
|         |                        | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify                                       | TextBox      |               | VARCHAR(200) | VARCHAR(200)    | INACTIVE |
|         |                        | BONESCANM   | Bone Scan - M   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | CTABM       | CT of chest/upper abdomen - M   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | CTABN       | CT of chest/upper abdomen - N   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | CTABT       | CT of chest/upper abdomen - T   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | CTBRNM      | CT of the brain - M   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | DIAGTHORM   | Diagnostic thoracotomy - M  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | DIAGTHORN   | Diagnostic thoracotomy - N  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | DIAGTHORT   | Diagnostic thoracotomy - T  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EBUSM       | Bronchoscopy with or without ultrasonography (EBUS), with biopsy or cytology - M  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EBUSN       | Bronchoscopy with or without ultrasonography (EBUS), with biopsy or cytology - N  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EBUST       | Bronchoscopy with or without ultrasonography (EBUS), with biopsy or cytology - T  | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EUSM        | Oesophagoscopy with or without ultrasonography (EUS), with biopsy or cytology - M | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EUSN        | Oesophagoscopy with or without ultrasonography (EUS), with biopsy or cytology - N | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | EUST        | Oesophagoscopy with or without ultrasonography (EUS), with biopsy or cytology - T | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | LAPARM      | Laparoscopy - M   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |
|         |                        | LAPARN      | Laparoscopy - N   | CheckBox     |               | VARCHAR(1)   | VARCHAR(1)      | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)                        | COLUMN NAME | COLUMN DESCRIPTION  | CONTROL TYPE | CODE LIST | DATE TYPE     | VALIDATION TYPE | STATUS |
|---------|---|-------------|---|--------------|-----------|---------------|-----------------|--------|
| 6       | Pre-Treatment TNM Tests<br>(FM_PREXTN-MTESTS) | LAPART      | Laparoscopy - T   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDBIOM     | Mediastinoscopy with biopsy or cytology - M                   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDBION     | Mediastinoscopy with biopsy or cytology - N                   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDBIOT     | Mediastinoscopy with biopsy or cytology - T                   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDCERVM    | Mediastinoscopy with or extended cervical mediastinoscopy - M | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDCERVN    | Mediastinoscopy with or extended cervical mediastinoscopy - N | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MEDCERTV    | Mediastinoscopy with or extended cervical mediastinoscopy - T | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MRIABM      | MRI of chest/upper abdomen - M                                | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MRIABN      | MRI of chest/upper abdomen - N                                | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MRIABT      | MRI of chest/upper abdomen - T                                | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | MRIBRNM     | MRI of the brain - M  | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | OTHERSPM    | Other - M   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | OTHERSPN    | Other - N   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | OTHERSPT    | Other - T   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | OTHRESP     | If Other, specify   | TextBox      |           | VARCHAR (100) | VARCHAR (100)   | ACTIVE |
|         |   | PERCUTM     | Percutaneous needle biopsy or cytology - M                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PERCUTN     | Percutaneous needle biopsy or cytology - N                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PERCUTT     | Percutaneous needle biopsy or cytology - T                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PETM        | PET or PET/CT - M   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PETN        | PET or PET/CT - N   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PETT        | PET or PET/CT - T   | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PHYEXAMM    | Physical examination - M                                      | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PHYEXAMN    | Physical examination - N                                      | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PHYEXAMT    | Physical examination - T                                      | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PRETNMNM    | Data not available - M  | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PRETNMNN    | Data not available - N  | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | PRETNMNT    | Data not available - T  | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | RADIOM      | Standard radiology (e.g. chest x-rays) - M                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | RADION      | Standard radiology (e.g. chest x-rays) - N                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | RADIOT      | Standard radiology (e.g. chest x-rays) - T                    | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | TEMLAN      | Transcervical extended mediastinal lymphadenectomy - N        | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | THORBIOM    | Thoracoscopic biopsy or cytology - M                          | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | THORBION    | Thoracoscopic biopsy or cytology - N                          | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | THORBIOT    | Thoracoscopic biopsy or cytology - T                          | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | TRANSCERVM  | Transcervical lymphadenectomy - M                             | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | TRANSCERVN  | Transcervical lymphadenectomy - N                             | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | TRANSCERTV  | Transcervical lymphadenectomy - T                             | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |
|         |   | VIDASSISTN  | Video-assisted mediastinal lymphadenectomy - N                | CheckBox     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE |

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| FORM ID | FORM NAME (TABLE NAME)                                  | COLUMN NAME  | COLUMN DESCRIPTION                                     | CONTROL TYPE | CODE LIST       | DATE TYPE     | VALIDATION TYPE | STATUS   |
|---------|---|--------------|--|--------------|-----------------|---------------|-----------------|----------|
| 6       | Pre-Treatment TNM Tests<br>(FM_PRETXN-MTESTS)           | VIDMEDIAN    | Videomediastinoscopy - N                               | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
| 7       | Primary Tumour Description<br>(FM_TUMORDESCRIPTION)     | AMNDCTMT     | Amendment Comments                                     | TextBox      |                 | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR      | Error Correction                                       | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB     | Entire form submitted in error                         | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS     | Entry of missing or previously unavailable information | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTH      | Reason(s) for Amending Form: Other                     | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP     | Reason(s) for Amending Form: Other, Specify            | TextBox      |                 | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | CARNIA       | Carina   | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | INTERMBRONC  | Intermediate Bronchus                                  | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | LLOWERLOBE   | Left Lower Lobe  | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | LLOWLBRONC   | Left Lower Lobar Bronchus                              | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | LMAINBRONC   | Left Main Bronchus                                     | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | LUPPERLOBE   | Left Upper Lobe  | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | LUPPLBRONC   | Left Upper Lobar Bronchus                              | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | MAINBRONC    | Main Bronchus, Side Not Specified                      | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | PTUMDETECT   | Method of detection                                    | DropDownList | C_PTUM_METDET   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | PTUMDIAGCYT  | Diagnosed by - Cytology                                | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | PTUMDIAHIST  | Diagnosed by - Histology                               | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | PTUMDIFFGRD  | Differentiation grade                                  | DropDownList | C_PTUM_DIFF-GRD | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | PTUMHIST_DY  | Date of histology or cytology obtained - Day           | TextBox      |                 | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | PTUMHIST_MO  | Date of histology or cytology obtained - Month         | DropDownList | C_MONTH         | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | PTUMHIST_YR  | Date of histology or cytology obtained - Year          | TextBox      |                 | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | PTUMHISTTYPE | Histologic Type, WHO 2015 edition                      | DropDownList | C_PTUM_HISTTYPE | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
| 8       | Systemic Treatments and Radiotherapy<br>(FM_STREATMENT) | PTUMPARANEO  | Paraneoplastic syndrome                                | DropDownList | C_YNNO          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | PTUMPLEUEFF  | Pleural Effusion                                       | DropDownList | C_PTUM_PLEUEFF  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | RLOWERLOBE   | Right Lower Lobe                                       | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RLOWLBRONC   | Right Lower Lobar Bronchus                             | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RMAINBRONC   | Right Main Bronchus                                    | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RMIDLBRONC   | Right Middle Lobar Bronchus                            | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RMIDLOBE     | Right Middle Lobe                                      | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RUPPERLOBE   | Right Upper Lobe                                       | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | RUPPLBRONC   | Right Upper Lobar Bronchus                             | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | TRACHEA      | Trachea  | CheckBox     |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | VISITNO      | Tumour visit   | Label        |                 | NUMBER        | NUMBER          | ACTIVE   |

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(continued)

| Form ID | Form Name (Table Name)                                    | Column Name | Column Description                                     | Control Type                 | Code List | Date Type     | Validation Type | Status   |
|---------|---|-------------|--|------------------------------|-----------|---------------|-----------------|----------|
| 8       | Systemic Treatments and Radiotherapy (FM_STREATMENT)      | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOOTH    | Reason(s) for Amending Record: Other                   | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Record: Other, Specify          | TextBox                      |           | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | SYSENDDY    | End Date of Systemic Treatment - Day                   | TextBox                      |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | SYSENDMO    | End Date of Systemic Treatment - Month                 | DropDownList C_MONTH         |           | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | SYSENDYR    | End Date of Systemic Treatment - Year                  | TextBox                      |           | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | SYSLINETX   | Line of Treatment                                      | DropDownList C_SYS_LINETX    |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | SYSONGO     | Ongoing  | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | SYSOTHOTHER | Other therapy, specify                                 | TextBox                      |           | VARCHAR (70)  | VARCHAR (70)    | ACTIVE   |
|         |   | SYSSTARTDY  | Start Date of Systemic Treatment - Day                 | TextBox                      |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | SYSSTARTMO  | Start Date of Systemic Treatment - Month               | DropDownList C_MONTH         |           | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | SYSSTARTYR  | Start Date of Systemic Treatment - Year                | TextBox                      |           | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | SYSTHERAPY  | Therapy  | DropDownList C_SYS_THERAPY   |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
| 9       | Copy Number Alteration (CNA) Biomarkers (FM_BIOMARKERCNA) | AMNDCMT     | Amendment Comments                                     | TextBox                      |           | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR     | Error Correction                                       | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB    | Entire form submitted in error                         | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOOTH    | Reason(s) for Amending Record: Other                   | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Record: Other, Specify          | TextBox                      |           | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | AVGGCR      | Average Gene: Centromere Ratio                         | TextBox                      |           | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | CENTCN      | Centromere Copy Number                                 | TextBox                      |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | CNA         | Copy Number Alteration                                 | DropDownList C_CNA_CNA       |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | CNADY       | Date assessed - Day                                    | TextBox                      |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | CNAMO       | Date assessed - Month                                  | DropDownList C_MONTH         |           | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | CNARES      | CNA Result   | DropDownList C_CNA_CNARES    |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | CNASAMP     | Type of Sample   | DropDownList C_CNA_TYPE      |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | CNAYR       | Date assessed - Year                                   | TextBox                      |           | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | COPYNUM     | Average Gene Copy Number                               | TextBox                      |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | CUSTPLAT    | Customized Platform                                    | DropDownList C_CNA_CUST-PLAT |           | VARCHAR (150) | VARCHAR (150)   | ACTIVE   |
|         |   | GENOTYPE    | Genotype   | DropDownList C_GENO          |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | PLATFORM    | Platform   | DropDownList C_CNA_PLATCNA   |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
| 10      | Genetic Biomarkers (FM_BIOMARKER-GENE)                    | AMNDCMT     | Amendment Comments                                     | TextBox                      |           | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR     | Error Correction                                       | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB    | Entire form submitted in error                         | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOOTH    | Reason(s) for Amending Record: Other                   | CheckBox                     |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Record: Other, Specify          | TextBox                      |           | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | DNAVAR      | DNA Variant  | DropDownList C_GEN_DNAVAR    |           | VARCHAR (12)  | VARCHAR (12)    | ACTIVE   |
|         |   | GENE        | Gene   | DropDownList C_GEN_GENPLAT   |           | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name) | Column Name | Column Description   | Control Type         | Code List     | Date Type     | Validation Type | Status   |
|---------|------------------------|-------------|--|----------------------|---------------|---------------|-----------------|----------|
| 11      | (FM_PROTEINBIO)        | GENEABNORM  | Were any results positive or inconclusive for genetic abnormalities? | RadioButton-List     | C_GEN_YN      | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | GENECUS     | Customized platform/panel  | DropDownList         |               | VARCHAR (150) | VARCHAR (150)   | ACTIVE   |
|         |                        | GENEDY      | Date assessed - Day  | TextBox              |               | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |                        | GENEMO      | Date assessed - Month  | DropDownList         | C_MONTH       | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |                        | GENEPLAT    | Platform   | DropDownList         | C_GEN_PLATBIO | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | GENESAMP    | Type of Sample   | DropDownList         | C_GEN_TYPE    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | GENETICAB   | Genetic abnormality  | DropDownList         | C_GEN_GENEAB  | VARCHAR (30)  | VARCHAR (30)    | ACTIVE   |
|         |                        | GENEYR      | Date assessed - Year   | TextBox              |               | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |                        | GENSEQAB    | Gene Sequence Abnormality, if applicable                             | TextBox              |               | VARCHAR (30)  | VARCHAR (30)    | ACTIVE   |
|         |                        | OTHVARSP    | Other variant, specify   | TextBox              |               | VARCHAR (30)  | VARCHAR (30)    | ACTIVE   |
|         |                        | TMBURDEN    | Total mutation burden  | TextBox              |               | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
| 12      | (FM_LABVALUES)         | AMNDCMT     | Amendment Comments   | TextBox              |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |                        | AMNDERR     | Error Correction   | CheckBox             |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDESUB    | Entire form submitted in error                                       | CheckBox             |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDMISS    | Entry of missing or previously unavailable information               | CheckBox             |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTH     | Reason(s) for Amending Record: Other                                 | CheckBox             |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTH_P   | Reason(s) for Amending Record: Other, Specify                        | TextBox              |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |                        | ANTIBODY    | Antibody   | DropDownList         | C_PRO_ANTI    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | HSCORE      | H-Score  | TextBox              |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | PCNTIMMC    | % immune cells   | TextBox              |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | PCNTTUMC    | % Tumor cells  | TextBox              |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | PROEXP      | Expression   | DropDownList         | C_PRO_EXP     | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | PROSAMP     | Type of Sample   | DropDownList         | C_PRO_TYPE    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | PROSEQAB    | Protein Sequence Abnormality:  | TextBox              |               | VARCHAR (30)  | VARCHAR (30)    | ACTIVE   |
|         |                        | PROTDY      | Date assessed - Day  | TextBox              |               | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |                        | PROTEIN     | Protein  | DropDownList         | C_PRO_PROT    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | PROTMO      | Date assessed - Month  | DropDownList         | C_MONTH       | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |                        | PROTPLAT    | Platform   | DropDownList         | C_PRO_PLATPA  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | PROTYR      | Date assessed - Year   | TextBox              |               | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
| 13      | (FM_DIAGNOSIS)         | AGE         | Age  | Label                |               | NUMBER (3)    | NUMBER (3)      | INACTIVE |
|         |                        | ALBUM       | Albumin Result   | TextBox              |               | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |                        | ALBUMLHI    | Albumin Lab Upper Limit of Normal                                    | LabUpper-TextBox     |               | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |                        | ALBUMLLO    | Albumin Lab Lower Limit of Normal                                    | LabLower-TextBox     |               | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |                        | ALBUMLU     | Albumin Lab Unit   | LabUnitDrop-DownList | C_LAB_GL      | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | ALBUMND     | Albumin Not Done   | CheckBox             |               | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | ALKPH       | Alkaline phosphatase (ALP) Result                                    | TextBox              |               | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |                        | ALKPHLHI    | Alkaline phosphatase (ALP) Lab Upper Limit of Normal                 | LabUpper-TextBox     |               | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |                        | ALKPHLLO    | Alkaline phosphatase (ALP) Lab Lower Limit of Normal                 | LabLower-TextBox     |               | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |                        | ALKPHLU     | Alkaline phosphatase (ALP) Lab Unit                                  | LabUnitDrop-DownList | C_LAB_IULUKAT | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name)                           | Column Name | Column Description                                     | Control Type         | Code List       | Date Type     | Validation Type | Status   |
|---------|--|-------------|--|----------------------|-----------------|---------------|-----------------|----------|
| 12      | Laboratory Values at Diagnosis<br>(FM_LABVALUES) | ALKPHND     | Alkaline phosphatase (ALP) Not Done                    | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | AMNDCMT     | Amendment Comments                                     | TextBox              |                 | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDRERR    | Error Correction                                       | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB    | Entire form submitted in error                         | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOOTH    | Reason(s) for Amending Form: Other                     | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOOTP    | Reason(s) for Amending Form: Other, Specify            | TextBox              |                 | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |  | ASSESSDY    | What was the lab specimen collection date? - Day       | TextBox              |                 | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |  | ASSESSMO    | What was the lab specimen collection date? - Month     | DropDownList         | C_MONTH         | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |  | ASSESSYR    | What was the lab specimen collection date? - Year      | TextBox              |                 | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |  | CALC        | Calcium Level Result                                   | TextBox              |                 | VARCHAR (5)   | NUMBER (4,2)    | ACTIVE   |
|         |  | CALCHI      | Calcium Level Lab Upper Limit of Normal                | LabUpper-TextBox     |                 | VARCHAR (5)   | NUMBER (4,2)    | ACTIVE   |
|         |  | CALCLLO     | Calcium Level Lab Lower Limit of Normal                | LabLower-TextBox     |                 | VARCHAR (5)   | NUMBER (4,2)    | ACTIVE   |
|         |  | CALCLU      | Calcium Level Lab Unit                                 | LabUnitDrop-DownList | C_LAB_MGDLM-MOL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | CALCND      | Calcium Level Not Done                                 | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | FEVIS       | Forced Expiratory Volume in 1 Second (FEV1)            | TextBox              |                 | VARCHAR (3)   | NUMBER (2,1)    | ACTIVE   |
|         |  | FVC         | Forced Vital Capacity (FVC)                            | TextBox              |                 | VARCHAR (3)   | NUMBER (2,1)    | ACTIVE   |
|         |  | HEMO        | Hemoglobin Result                                      | TextBox              |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | HEMOLHI     | Hemoglobin Lab Upper Limit of Normal                   | LabUpper-TextBox     |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | HEMOLLO     | Hemoglobin Lab Lower Limit of Normal                   | LabLower-TextBox     |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | HEMOLU      | Hemoglobin Lab Unit                                    | LabUnitDrop-DownList | C_LAB_GDLM-MOL  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | HEMOND      | Hemoglobin Not Done                                    | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | LABID       | Lab Name plus any qualifiers                           | DropDownList         |                 | NUMBER        | NUMBER          | INACTIVE |
|         |  | LDH         | LDH Result   | TextBox              |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | LDHLHI      | LDH Lab Upper Limit of Normal                          | LabUpper-TextBox     |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | LDHLLO      | LDH Lab Lower Limit of Normal                          | LabLower-TextBox     |                 | VARCHAR (7)   | NUMBER (6,2)    | ACTIVE   |
|         |  | LDHLU       | LDH Lab Unit   | LabUnitDrop-DownList | C_LAB_IULUKAT   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | LDHND       | LDH Not Done   | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | LYMPH       | Absolute Lymphocyte Count Result                       | TextBox              |                 | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |  | LYMPHLHI    | Absolute Lymphocyte Count Lab Upper Limit of Normal    | LabUpper-TextBox     |                 | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |  | LYMPHLLO    | Absolute Lymphocyte Count Lab Lower Limit of Normal    | LabLower-TextBox     |                 | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |  | LYMPHLU     | Absolute Lymphocyte Count Lab Unit                     | LabUnitDrop-DownList | C_LAB_CELLS     | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | LYMPHND     | Absolute Lymphocyte Count Not Done                     | CheckBox             |                 | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | NEUT        | Neutrophil Count Result                                | TextBox              |                 | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME) | COLUMN NAME | COLUMN DESCRIPTION   | CONTROL TYPE         | CODE LIST    | DATE TYPE     | VALIDATION TYPE | STATUS   |
|---------|------------------------|-------------|--|----------------------|--------------|---------------|-----------------|----------|
| 12      | (FM_LABVALUES)         | NEUTLHI     | Neutrophil Count Lab Upper Limit of Normal                       | LabUpper-TextBox     |              | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |                        | NEUTLLO     | Neutrophil Count Lab Lower Limit of Normal                       | LabLower-TextBox     |              | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |                        | NEUTLU      | Neutrophil Count Lab Unit  | LabUnitDrop-DownList | C_LAB_CELLS  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | NEUTND      | Neutrophil Count Not Done  | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | PLT         | Platelet Count Result  | TextBox              |              | VARCHAR (10)  | NUMBER (9,3)    | ACTIVE   |
|         |                        | PLTLHI      | Platelet Count Lab Upper Limit of Normal                         | LabUpper-TextBox     |              | VARCHAR (10)  | NUMBER (9,3)    | ACTIVE   |
|         |                        | PLTLLO      | Platelet Count Lab Lower Limit of Normal                         | LabLower-TextBox     |              | VARCHAR (10)  | NUMBER (9,3)    | ACTIVE   |
|         |                        | PLTLU       | Platelet Count Lab Unit  | LabUnitDrop-DownList | C_LAB_CELLS  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | PLTNDA      | Platelet Count Not Done  | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | PREFEV1S    | % Predicted FEV1   | TextBox              |              | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | PREFVC      | % Predicted FVC  | TextBox              |              | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | SODI        | Sodium Result  | TextBox              |              | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | SODILHI     | Sodium Lab Upper Limit of Normal                                 | LabUpper-TextBox     |              | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | SODILLO     | Sodium Lab Lower Limit of Normal                                 | LabLower-TextBox     |              | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |                        | SODILU      | Sodium Lab Unit  | LabUnitDrop-DownList | C_LAB_MMOL   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | SODIND      | Sodium Not Done  | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |                        | SUVAPP      | Maximum SUV (nodes) applies to                                   | DropDownList         | C_LAB_SUVAPP | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | SUVNODE     | Maximum SUV Nodes  | TextBox              |              | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |                        | SUVPRIM     | Maximum SUV Primary Tumour                                       | TextBox              |              | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |                        | TRIALDY     | Date of trial entry if database is from a clinical trial - Day   | TextBox              |              | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |                        | TRIALMO     | Date of trial entry if database is from a clinical trial - Month | DropDownList         | C_MONTH      | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |                        | TRIALYR     | Date of trial entry if database is from a clinical trial - Year  | TextBox              |              | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |                        | WBC         | White Cell Count Result  | TextBox              |              | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |                        | WBCLHI      | White Cell Count Lab Upper Limit of Normal                       | LabUpper-TextBox     |              | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |                        | WBCLLO      | White Cell Count Lab Lower Limit of Normal                       | LabLower-TextBox     |              | VARCHAR (9)   | NUMBER (8,3)    | ACTIVE   |
|         |                        | WBCLU       | White Cell Count Lab Unit  | LabUnitDrop-DownList | C_LAB_CELLS  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |                        | WBCND       | White Cell Count Not Done  | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
| 13      | (FM_FOLLOWUP)          | AMNDCMT     | Amendment Comments   | TextBox              |              | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |                        | AMNDERR     | Error Correction   | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDESUB    | Entire form submitted in error                                   | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDMISS    | Entry of missing or previously unavailable information           | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTH     | Reason(s) for Amending Form: Other                               | CheckBox             |              | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |                        | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify                      | TextBox              |              | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |                        | CAUSDTH     | Cause of Death, if Deceased                                      | DropDownList         | C_CAUSDTH    | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name)  | Column Name         | Column Description  | Control Type     | Code List | Date Type     | Validation Type | Status   |
|---------|---|---------------------|---|------------------|-----------|---------------|-----------------|----------|
| 13      | Follow-up<br>(FM_FOLLOWUP)  | LAST_CONTACT_DY     | Date of Last Contact with patient - Day   | TextBox          |           | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | LAST_CONTACT_MO     | Date of Last Contact with patient - Month   | DropDownList     | C_MONTH   | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | LAST_CONTACT_YR     | Date of Last Contact with patient - Year  | TextBox          |           | NUMBER (4)    | NUMBER (4)      | ACTIVE   |
|         |   | MOLERES             | Check here if results of molecular studies are available for this case  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | MOLETISS            | Check here if tissue is available for molecular studies for this case   | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | PT_VST              | Vital Status at Last Contact  | RadioButton-List | C_VST     | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | VISITNO             | Follow-up visit   | Label            |           | NUMBER        | NUMBER          | ACTIVE   |
| 14      | T-Descriptors,<br>by Post Surgical-<br>Pathological<br>Findings<br>(FM_POSTTDE-<br>SCRIPTORS) | AMNDCMT             | Amendment Comments  | TextBox          |           | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR             | Error Correction  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB            | Entire form submitted in error  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS            | Entry of missing or previously unavailable information  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTH             | Reason(s) for Amending Form: Other  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP            | Reason(s) for Amending Form: Other, Specify   | TextBox          |           | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | POSTT0              | No evidence of primary tumour (T0)  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT1CM3LESS       | Tumour 3 cm or less in greatest dimension, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion more proximal than the lobar bronchus (i.e., not in the main bronchus). (T1) | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT1SPREAD-TUM    | Superficial spreading tumour of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus. (T1)  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2BRONC         | Involves main bronchus regardless of distance to the carina, but without involving the carina. (T2)   | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2PLO           | Depth of visceral pleura invasion (T2) - PLO  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2PL1           | Depth of visceral pleura invasion (T2) - PL1  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2PL2           | Depth of visceral pleura invasion (T2) - PL2  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2PNEUM         | Associated with atelectasis or obstructive pneumonitis that extends to the hilar region, either involving part of the lung or the entire lung (T2)  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT2VISCPLEU      | Involves visceral pleura (T2)   | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT3APICAL-CHEST  | Apical chest wall invasion, stellate ganglion, inferior branches of the brachial plexus (below C8) (T3)   | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT3CHEST-WALL    | Chest wall invasion (T3)  | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |   | POSTT3HISTSEP-NODE  | Histology of separate nodules confirmed?  | DropDownList     | C_YN      | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTT3PARI-ETALPERI | Parietal pericardium involvement (T3)   | CheckBox         |           | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)  | COLUMN NAME         | COLUMN DESCRIPTION  | CONTROL TYPE | CODE LIST        | DATE TYPE   | VALIDATION TYPE | STATUS |
|---------|---|---------------------|---|--------------|------------------|-------------|-----------------|--------|
| 14      | T-Descriptors, by Post Surgical-Pathological Findings<br><br>(FM_POSTTDE-SCRIPTORS) | POSTT3PHRENIC-NERVE | Phrenic nerve involvement (T3)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT3PLEUR-INV     | Parietal Pleura Invasion (PL3) (T3)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT3SEPTUM-NODE   | Associated separate tumour nodule(s) in the same lobe as the primary  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4APICAL-CHEST  | Apical chest wall invasion (T4): evidence of invasion of the vertebral body or spinal canal, encasement of the subclavian vessels, or unequivocal involvement of the superior branches of the brachial plexus (c8 or above). (T4) | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4CARINA-INV    | Carina invasion (T4)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4DIAPH-INV     | Diaphragm invasion (T4)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4ESOPH-INV     | Esophageal invasion (T4)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTAORTA      | Aorta   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTINFER      | Inferior vena cava  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTPULART     | Pulmonary artery  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTPULVEIN    | Pulmonary vein  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTSUPER      | Superior vena cava  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTTRUNK      | Main trunk of pulmonary artery  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4GRTVESS       | Great vessel invasion (T4)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4HEART-INV     | Heart invasion (T4)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4HISTSEP-NODE  | Histology of separate nodules confirmed?  | DropDownList | C_YN             | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |   | POSTT4LARYN-INV     | Recurrent laryngeal nerve invasion (T4)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4MEDIA-INV     | Mediastinum invasion (T4)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4SEPTUM-NODE   | Separate tumour nodule(s) in a different ipsilateral lobe to that of the primary (T4)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTT4TRACH-INV     | Tracheal invasion (T4)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTTCAT            | Lung tumour T Category by post-surgical/pathological findings   | DropDownList | C_POST_TCAT      | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |   | POSTTIS             | Carcinoma in situ (Tis)   | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTTLEPSIZE        | Combined invasive and noninvasive (lepidic) size  | TextBox      |                  | VARCHAR (4) | NUMBER (3,1)    | ACTIVE |
|         |   | POSTTLYMPHINV       | Lymphatic vessel invasion   | DropDownList | C_POST_LYMPH-INV | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |   | POSTTMI             | Minimally invasive adenocarcinoma (T1mi)  | CheckBox     |                  | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |   | POSTTPERICYTO       | Perineural invasion   | DropDownList | C_YNU            | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |   | POSTTPLEURCYTO      | Pleural lavage cytology   | DropDownList | C_POST_PLEU-CYTO | VARCHAR (8) | VARCHAR (8)     | ACTIVE |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)   | COLUMN NAME        | COLUMN DESCRIPTION   | CONTROL TYPE | CODE LIST           | DATE TYPE     | VALIDATION TYPE | STATUS   |
|---------|--|--------------------|--|--------------|---------------------|---------------|-----------------|----------|
| 14      | T-Descriptors, by Post Surgical-Pathological Findings<br><br>(FM_POSTTDESCRIPTORS) | POSTTPRIMSIZE      | Size of primary tumour, by post-surgical/pathological findings   | TextBox      |                     | VARCHAR (4)   | NUMBER (3,1)    | ACTIVE   |
|         |  | POSTTSTAS          | Spread through the air spaces (STAS)   | DropDownList | C_POST_TSTAS        | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | POSTTSTATFISS      | Status of the fissures   | DropDownList | C_POST_STAT-FISSION | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | POSTTVASCINV       | Vascular invasion  | DropDownList | C_POST_VASC-INV     | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | POSTTX             | Primary tumour cannot be assessed, or tumour proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy (TX)                                | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | VISITNO            | Tumour visit   | Label        |                     | NUMBER        | NUMBER          | ACTIVE   |
| 15      | T-Descriptors, by Pre-Treatment/Evaluative Findings<br><br>(FM_PRETDESCRIPTIONS)   | AMNDCMT            | Amendment Comments   | TextBox      |                     | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDERR            | Error Correction   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB           | Entire form submitted in error   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDMISS           | Entry of missing or previously unavailable information   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTH            | Reason(s) for Amending Form: Other   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTHP           | Reason(s) for Amending Form: Other, Specify  | TextBox      |                     | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |  | PRETO              | No evidence of primary tumour (T0)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET1CM3LESS       | Tumor 3 cm or less in greatest dimension, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion more proximal than the lobar bronchus (i.e., not in the main bronchus). (T1) | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET1SPREAD-TUM    | Superficial spreading tumour of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus. (T1)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET2BRONC         | Involves main bronchus regardless of distance to the carina, but without involving the carina. (T2)  | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET2PNEUM         | Associated with atelectasis or obstructive pneumonitis that extends to the hilar region, either involving part of the lung or the entire lung (T2)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET2VISCPLEU      | Invades visceral pleura (T2)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3APICAL-CHEST  | Apical chest wall invasion, stellate ganglion, inferior branches of the brachial plexus (below C8) (T3)  | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3CHEST-WALL    | Chest wall invasion (T3)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3HISTSEP-NODE  | Histology of separate nodules confirmed?   | DropDownList | C_YN                | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRET3PARI-ETALPERI | Parietal pericardium involvement (T3)  | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3PHRENIC-NERVE | Phrenic nerve involvement (T3)   | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3PLEURINV      | Parietal Pleura Invasion (PL3) (T3)  | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |
|         |  | PRET3SEPTUM-NODE   | Associated separate tumour nodule(s) in the same lobe as the primary (T3)  | CheckBox     |                     | VARCHAR (1)   | VARCHAR (1)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)   | COLUMN NAME       | COLUMN DESCRIPTION  | CONTROL TYPE     | CODE LIST  | DATE TYPE   | VALIDATION TYPE | STATUS |
|---------|--|-------------------|---|------------------|------------|-------------|-----------------|--------|
| 15      | T-Descriptors, by Pre-Treatment/<br>Evaluative Findings<br><br>(FM_PRETDESCRIP-TORS) | PRET4APICAL-CHEST | Apical chest wall invasion (T4): evidence of invasion of the vertebral body or spinal canal, encasement of the subclavian vessels, or unequivocal involvement of the superior branches of the brachial plexus (c8 or above). (T4) | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4CARINA-INV   | Carina invasion (T4)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4DIAPHINV     | Diaphragm invasion (T4)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4ESOPHINV     | Esophageal invasion (T4)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTAORTA     | Aorta   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTINFER     | Inferior vena cava  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTPU-LART   | Pulmonary artery  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTPUL-VEIN  | Pulmonary vein  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTSUPER     | Superior vena cava  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTTRUNK     | Main trunk of pulmonary artery  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4GRTVESS      | Great vessel invasion (T4)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4HEARTINV     | Heart invasion (T4)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4HISTSEP-NODE | Histology of separate nodules confirmed?  | DropDownList     | C_YN       | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | PRET4LARYNINV     | Recurrent laryngeal nerve invasion (T4)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4MEDIAINV     | Medastinum invasion (T4)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4SEPTUM-NODE  | Separate tumour nodule(s) in a different ipsilateral lobe to that of the primary (T4)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRET4TRACHINV     | Tracheal invasion (T4)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETCAT           | Lung tumour T Category by pre-treatment/evaluative findings   | DropDownList     | C_PRE_TCAT | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | PRETGGO           | Is this a part-solid tumour with a GGO/lepidic component?   | RadioButton-List | C_YN       | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | PRETIS            | Carcinoma in situ (Tis)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETLYMADJPRI     | Adjacent to primary   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETLYMELSEL-OBE  | Elsewhere in lobe   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETLYMIPSLOBE    | In other ipsilateral lobes  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETLYMLUNG       | Contralateral lung  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PRETLYMPHANG      | Lymphangitis present?   | RadioButton-List | C_YN       | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | PRETMI            | Minimally invasive adenocarcinoma (T1mi)  | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | PREPRIMSIZE       | Size of primary tumour (solid component), by pre-treatment/evaluative findings:   | TextBox          |            | VARCHAR (4) | NUMBER (3,1)    | ACTIVE |
|         |  | PRETSIZECOMB      | If Yes, provide size of combined solid and part solid component together:   | TextBox          |            | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | PRETX             | Primary tumour cannot be assessed, or tumour proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy (TX)   | CheckBox         |            | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | VISITNO           | Tumour visit  | Label            |            | NUMBER      | NUMBER          | ACTIVE |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name)   | Column Name | Column Description                                     | Control Type | Code List     | Date Type     | Validation Type | Status   |
|---------|--|-------------|--|--------------|---------------|---------------|-----------------|----------|
| 16      | Pre-treatment/<br>Evaluative N<br>Category<br><br>(FM_PRETXNCATE-GORY) | AMNDCMT     | Amendment Comments                                     | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |  | AMNDERR     | Error Correction                                       | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDESUB    | Entire form submitted in error                         | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNMDMISS   | Entry of missing or previously unavailable information | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOOTH    | Reason(s) for Amending Form: Other                     | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |  | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify            | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |  | PRENCAT     | N Category   | DropDownList | C_PRE_NCATOR  | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT10L  | Hilar #10L   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT10R  | Hilar #10R   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT11L  | Interlobar #11L  | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT11R  | Interlobar #11R  | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT12L  | Lobar #12L   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT12R  | Lobar #12R   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT13L  | Segmental #13L   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT13R  | Segmental #13R   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT14L  | Subsegmental #14L                                      | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT14R  | Subsegmental #14R                                      | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT1L   | Supraclavicular #1L                                    | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT1R   | Supraclavicular #1R                                    | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT2L   | Upper paratracheal #2L                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT2R   | Upper paratracheal #2R                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT3L   | Pre-vascular #3aL                                      | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT3P   | Retrotracheal #3p                                      | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT3R   | Pre-vascular #3aR                                      | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT4L   | Lower paratracheal #4L                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT4R   | Lower paratracheal #4R                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT5    | Sub-aortic #5  | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT6    | Para-aortic #6   | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT7    | Subcarinal #7  | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT8L   | Paraoesophageal #8L                                    | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT8R   | Paraoesophageal #8R                                    | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT9L   | Pulmonary ligament #9L                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCAT9R   | Pulmonary ligament #9R                                 | DropDownList | C_PRE_NCATORL | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENCATSZ   | Size of largest node                                   | TextBox      |               | VARCHAR (10)  | VARCHAR (10)    | ACTIVE   |
|         |  | PRENEXT     | Extracapsular involvement?                             | DropDownList | C_YNU         | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENMEAS    | Method of measurement                                  | DropDownList | C_PRE_NMEAS   | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENN1EXPL  | Number of N1 nodes explored                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PRENN1EXT   | If 'Yes', N1 extracapsular involvement                 | DropDownList | C_YNU         | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENN1POS   | Number of positive N1 nodes                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PRENN2EXPL  | Number of N2 nodes explored                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |  | PRENN2EXT   | If 'Yes', N2 extracapsular involvement                 | DropDownList | C_YNU         | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |  | PRENN2POS   | Number of positive N2 nodes                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| Form ID | Form Name (Table Name)  | Column Name | Column Description                                     | Control Type | Code List     | Date Type     | Validation Type | Status   |
|---------|---|-------------|--|--------------|---------------|---------------|-----------------|----------|
| 16      | Pre-treatment/<br>Evaluative N<br>Category<br><br>(FM_PRETXNCATE-GORY)  | PRENN3EXPL  | Number of N3 nodes explored                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
|         |   | PRENN3EXT   | If 'Yes', N3 extracapsular involvement                 | DropDownList | C_YNU         | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | PRENN3POS   | Number of positive N3 nodes                            | TextBox      |               | NUMBER (3)    | NUMBER (3)      | ACTIVE   |
| 17      | Post Surgical/<br>Pathologic N<br>Category<br><br>(FM_POSTTXNCATE-GORY) | AMNDCMT     | Amendment Comments                                     | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR     | Error Correction                                       | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB    | Entire form submitted in error                         | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTH     | Reason(s) for Amending Form: Other                     | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify            | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | POSTN1DIR   | Direct invasion of N1 nodes:                           | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTN2DIR   | Direct invasion of N2 nodes:                           | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTN3DIR   | Direct invasion of N3 nodes:                           | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT    | N Category:  | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT10L | Hilar #10L   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT10R | Hilar #10R   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT11L | Interlobar #11L  | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT11R | Interlobar #11R  | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT12L | Lobar #12L   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT12R | Lobar #12R   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT13L | Segmental #13L   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT13R | Segmental #13R   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT14L | Subsegmental #14L                                      | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT14R | Subsegmental #14R                                      | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT1L  | Supraclavicular #1L                                    | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT1R  | Supraclavicular #1R                                    | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT2L  | Upper paratracheal #2L                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT2R  | Upper paratracheal #2R                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT3L  | Pre-vascular #3aL                                      | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT3P  | Retrotracheal #3p                                      | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT3R  | Pre-vascular #3aR                                      | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT4L  | Lower paratracheal #4L                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT4R  | Lower paratracheal #4R                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT5   | Sub-aortic #5  | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT6   | Para-aortic #6   | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT7   | Subcarinal #7  | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT8L  | Paraoesophageal #8L                                    | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT8R  | Paraoesophageal #8R                                    | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT9L  | Pulmonary ligament #9L                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNCAT9R  | Pulmonary ligament #9R                                 | DropDownList | C_POST_NCATOR | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTCATSZ   | Size of largest node                                   | TextBox      |               | VARCHAR (10)  | VARCHAR (10)    | ACTIVE   |
|         |   | POSTNDIR    | Direct nodal invasion from tumour?                     | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | POSTNEXT    | Extracapsular involvement?                             | DropDownList | C_YN          | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)   | COLUMN NAME  | COLUMN DESCRIPTION  | CONTROL TYPE | CODE LIST     | DATE TYPE   | VALIDATION TYPE | STATUS |
|---------|--|--------------|---|--------------|---------------|-------------|-----------------|--------|
| 17      | Post Surgical/<br>Pathologic N<br>Category<br><br>(FM_POSTTXNCATE-<br>GORY)                              | POSTNN1EXPL  | Number of N1 nodes removed:   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | POSTNN1EXT   | If 'Yes', N1 extracapsular involvement:   | DropDownList | C_YN          | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | POSTNN1POS   | Number of positive N1 nodes:  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | POSTNN2EXPL  | Number of N2 nodes removed:   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | POSTNN2EXT   | If 'Yes', N2 extracapsular involvement:   | DropDownList | C_YN          | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | POSTNN2POS   | Number of positive N2 nodes:  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | POSTNN3EXPL  | Number of N3 nodes removed:   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | POSTNN3EXT   | If 'Yes', N3 extracapsular involvement:   | DropDownList | C_YN          | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | POSTNN3POS   | Number of positive N3 nodes:  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
| 18      | M-Descriptors, After<br>Attempted Resection<br>of the Primary<br>Tumour<br><br>(FM_AFTMDESCRIP-<br>TORS) | AFTMABLYMNO  | Number of lesions - Abdominal lymph nodes   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMABLYMPR  | Presence/Number of Lesions - Abdominal lymph nodes  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMADRNO    | Number of lesions - Adrenals  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMADRRP    | Presence/Number of Lesions - Adrenals   | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMBONENO   | Number of lesions - Bone  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMBONEPR   | Presence/Number of Lesions - Bone   | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMBRAINNO  | Number of lesions - Brain   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMBRAINPR  | Presence/Number of Lesions - Brain  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMCATAFT   | M Category After Attempted Resection of the Primary Tumour:   | DropDownList | C_AFT_MCAT    | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMCATBEF   | M Category Before Attempted Resection of the Primary Tumour:  | Label        |               | VARCHAR (3) | VARCHAR (3)     | ACTIVE |
|         |  | AFTMDISLYMNO | Number of lesions - Other distant lymph nodes   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMDISLYMPR | Presence/Number of Lesions - Other distant lymph nodes  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMDISMET   | Were there any additional sites of metastasis that were identified during surgery or post-surgical staging? | DropDownList | C_YN          | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMLIVERNO  | Number of lesions - Liver   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMLIVERPR  | Presence/Number of Lesions - Liver  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMLUNGMET  | Contralateral lung metastasis:  | CheckBox     |               | VARCHAR (1) | VARCHAR (1)     | ACTIVE |
|         |  | AFTMMARRNO   | Number of lesions -Bone Marrow  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMMARRPR   | Presence/Number of Lesions - Bone Marrow  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMOTHNO    | Number of lesions - Other   | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMOTHPH    | Presence/Number of Lesions - Other  | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPERCYT   | Pericardial effusion - Cytology   | DropDownList | C_AFT_CYTO    | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPEREFF   | Pericardial effusion:   | DropDownList | C_AFT_MPERI   | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPERITNO  | Number of lesions - Peritoneum  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |
|         |  | AFTMPERITPR  | Presence/Number of Lesions - Peritoneum   | DropDownList | C_AFT_DISTMET | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPERNOD   | Pericardial nodules:  | DropDownList | C_AFT_MPERI   | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPLECTY   | Pleural effusion - Cytology   | DropDownList | C_AFT_CYTO    | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPLEEFF   | Pleural effusion:   | DropDownList | C_AFT_MPLEU   | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMPLENOD   | Pleural nodules:  | DropDownList | C_AFT_MPLEU   | VARCHAR (8) | VARCHAR (8)     | ACTIVE |
|         |  | AFTMSKINNO   | Number of lesions - Skin  | TextBox      |               | NUMBER (3)  | NUMBER (3)      | ACTIVE |

# IASLC Lung Cancer Staging Project Forms and Fields in the Lung Cancer Electronic Data Capture System (v1.11)

(continued)

| FORM ID | FORM NAME (TABLE NAME)  | COLUMN NAME | COLUMN DESCRIPTION                                     | CONTROL TYPE | CODE LIST     | DATE TYPE     | VALIDATION TYPE | STATUS   |
|---------|---|-------------|--|--------------|---------------|---------------|-----------------|----------|
| 18      | M-Descriptors, After Attempted Resection of the Primary Tumour<br><br>(FM_AFTMDESCRIP-TORS) | AFTMSKINPR  | Presence/Number of Lesions - Skin                      | DropDownList | C_AFT_DISTMET | VARCHAR (8)   | VARCHAR (8)     | ACTIVE   |
|         |   | AMNDCMT     | Amendment Comments                                     | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR     | Error Correction                                       | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB    | Entire form submitted in error                         | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOOTH    | Reason(s) for Amending Form: Other                     | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify            | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
| 19      | Progression/Recurrence<br><br>(FM_PROGRESSION-RECURR)                                       | AMNDCMT     | Amendment Comments                                     | TextBox      |               | VARCHAR (300) | VARCHAR (300)   | INACTIVE |
|         |   | AMNDERR     | Error Correction                                       | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDESUB    | Entire form submitted in error                         | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDMISS    | Entry of missing or previously unavailable information | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOOTH    | Reason(s) for Amending Form: Other                     | CheckBox     |               | VARCHAR (1)   | VARCHAR (1)     | INACTIVE |
|         |   | AMNDOTHP    | Reason(s) for Amending Form: Other, Specify            | TextBox      |               | VARCHAR (200) | VARCHAR (200)   | INACTIVE |
|         |   | PRGREL_DY   | Date of progression or recurrence - Day                | TextBox      |               | NUMBER (2)    | NUMBER (2)      | ACTIVE   |
|         |   | PRGREL_MO   | Date of progression or recurrence - Month              | DropDownList | C_MONTH       | VARCHAR (3)   | VARCHAR (3)     | ACTIVE   |
|         |   | PRGREL_YR   | Date of progression or recurrence - Year               | TextBox      |               | NUMBER (4)    | NUMBER (4)      | ACTIVE   |



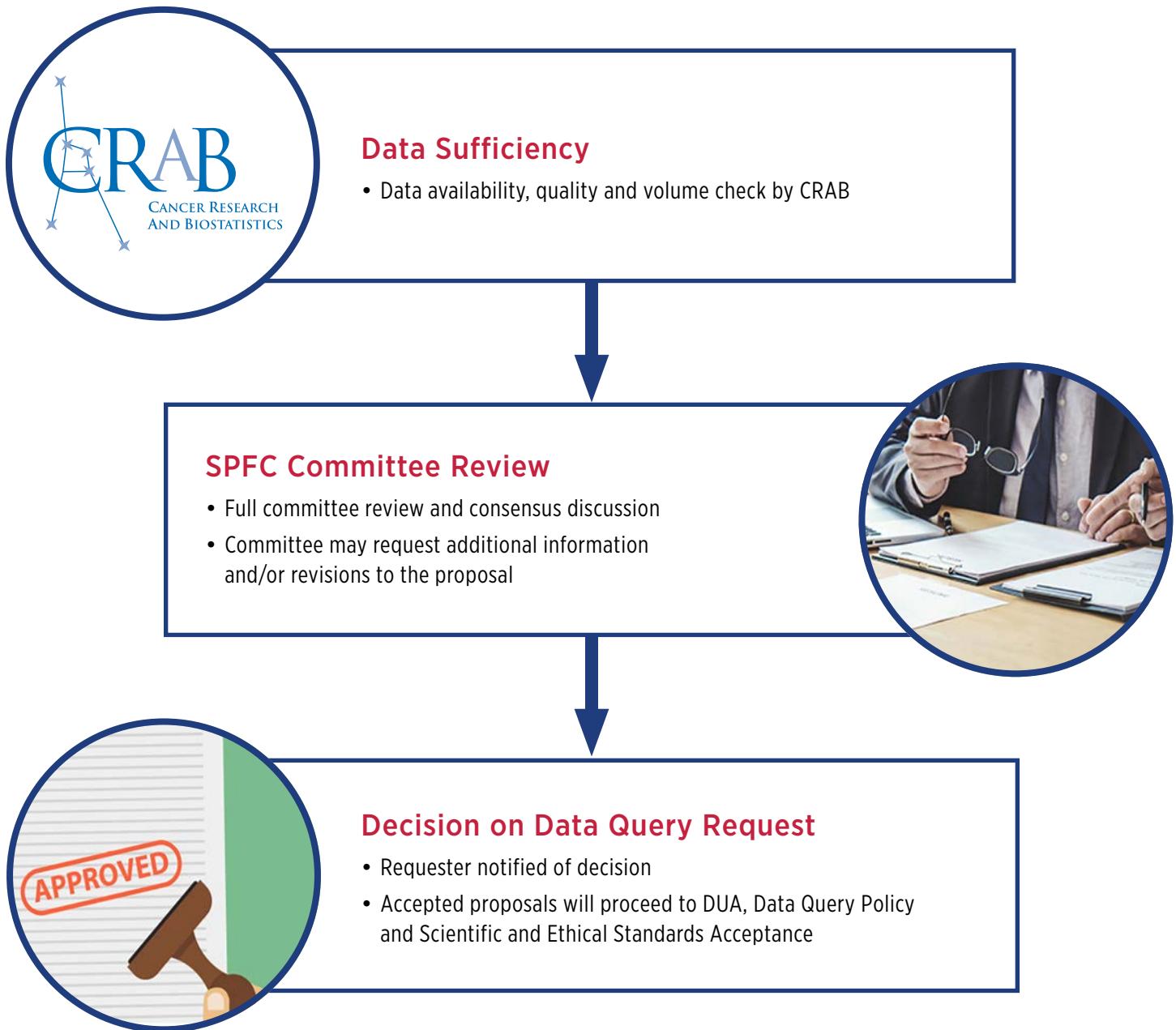
DATA  
QUERY

## DATA QUERY PROCESS

---

Access to the combined dataset is restricted, however an investigator may propose a research question for analysis. Such analyses are done collaboratively by CRAB, the IASLC SPFC, and the requestor. An investigator with a research question will complete an initial form outlining the question and the proposed data requirements. A sample of this form can be found on page 29 of the toolkit. If you are ready to apply, the electronic form can be found [here](#). If you are unable to access the electronic form, please visit [www.iaslc.org/Research-Education/IASLC-Staging-Project](http://www.iaslc.org/Research-Education/IASLC-Staging-Project) to access the PDF version. Based on the proposal, feasibility will be determined and a cost will be determined for the analysis effort. Once it is determined to be feasible, the research question will be submitted for approval to the SPFC and the IASLC.

# DATA QUERY PROCESS OVERVIEW





INTERNATIONAL  
ASSOCIATION  
FOR THE STUDY  
OF LUNG CANCER  
Conquering Thoracic Cancers Worldwide



## IASLC International Staging Project Data Query Application

Please email the completed form and required attachments (biosketches and proposal) to  
[staging@iaslc.org](mailto:staging@iaslc.org) and [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org)

### Submitter Name

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title      First Name      Last Name

### Submitter Institution

### Submitter Phone Number

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Country Code   Area Code   Phone Number

### Submitter Email Address

example@example.com

### Are you a contributor to the IASLC International Staging Project?

- Yes  
 No

### Are you an IASLC member?

- Yes  
 No

### IASLC Contact (if applicable)

**Name**

|                      |                      |                      |
|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|

Title

First Name

Last Name

**Email Address**

example@example.com

**Proposal Details****Project Title****Proposed Project Start Date**

|                      |                      |                      |   |
|----------------------|----------------------|----------------------|---|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |  |
|----------------------|----------------------|----------------------|---|

Month Day Year

**Proposed Project End Date**

|                      |                      |                      |   |
|----------------------|----------------------|----------------------|---|
| <input type="text"/> | <input type="text"/> | <input type="text"/> |  |
|----------------------|----------------------|----------------------|---|

Month Day Year

Please attach your proposal which highlights the following areas:

Relevant background and previous studies

State of the science

Justification for the analysis

Project goals and specific aims

Project benefits and public interest value

Summary of research design, proposed analytic methods and tools

This document should not exceed **3 pages single spaced**

## Research Team

### Principal Investigator \*

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

Title      First Name      Last Name

### Institution/Organization \*

|  |
|--|
|  |
|--|

### Email

|  |
|--|
|  |
|--|

example@example.com

### Is the Principal Investigator an IASLC member?

- Yes  
 No

### If yes, please provide the member ID

|  |
|--|
|  |
|--|

Please attach the Principal Investigator's biosketch

### Do you have a Co-Principal Investigator?

- Yes  
 No

**Co-Principal Investigator Name**

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

Title      First Name      Last Name

**Co-Principal Investigator Institution/Organization**

|  |
|--|
|  |
|--|

**Co-Principal Investigator Email Address**

|  |
|--|
|  |
|--|

example@example.com

**Is the Co-Principal Investigator an IASLC member?**

- Yes  
 No

**If yes, please provide the member ID**

|  |
|--|
|  |
|--|

**Please attach the Co-Principal Investigator's biosketch****Do you have other senior or key personnel to include?**

- Yes  
 No

**Name**

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

Title      First Name      Last Name

**Email**

example@example.com

**Is the individual an IASLC member?**

- Yes  
 No

**If yes, please provide the member ID****Data Query Request****What types of queries will be performed?****Additional Proposal Details**

**Dissemination Plan - How will this data be shared with the scientific community? (e.g. a manuscript submission, scholarly presentation, etc.)**

**Do you accept that any publication must be reviewed by the committee prior to submission? \***

- Yes  
 No

**Do you accept that all publications must be first submitted to the Journal of Thoracic Oncology? \***

- Yes  
 No

**Do you accept that the primary authors of the study include at least one medical member of the SPFC and one member of CRAB? \***

- Yes  
 No

**Do you accept that the IASLC, CRAB and any identified sponsors must be acknowledged in the presentation of data (e.g. manuscript, scholarly presentation, etc.) \***

- Yes  
 No

**Do you accept that any manuscript must contain an appendix that lists all contributing institutions? \***

- Yes  
 No

## Project Funding Details

Submit

SAMPLE

## **Data Access Policy**

The International Association for the Study of Lung Cancer (IASLC) is a global organization dedicated to the study of lung cancer that has compiled an extensive staging and clinical lung cancer dataset. That dataset is maintained by Cancer Research and Biostatistics (CRAB) and is referred to herein as the Staging Data.

The IASLC Staging and Prognostic Factors Committee (SPFC) has a duty to ensure that the data within its database are used to the maximum benefit for the good of patients and the lung cancer community, within ethical constraints and the agreements entered into with individual databases. Consistent with this duty, the SPFC wishes to offer the Staging Data for secondary uses under the following terms.

### **A. Permitted Secondary Uses**

1. Researchers may submit a proposal with a research query that can be run against the Staging Data to obtain an output result (a Report).
2. IASLC shall only consider non-commercial research purposes.
3. At no time will a Researcher have access to the Staging Data. Instead, upon successful approval of a proposal, CRAB will run a query and provide a Report to the Researcher.
4. The Report must be limited to the original proposal. If anything in the original proposal changes, the Researcher must seek approval for the new use and a new query must be run.

### **B. Approval Process**

#### **1. Initial Proposal**

- a. Any Researcher may submit an initial, outline proposal that includes the research query and explains how the Staging Data would aid in addressing such question.
- b. Please submit the initial proposal online or by email to IASLC at [staging@iaslc.com](mailto:staging@iaslc.com). IASLC will submit the initial proposal to CRAB for its certification that the Staging Data is sufficient to be responsive to the research query and an estimate of the cost to run the query. After receiving CRAB's certification that the Staging Data is sufficient, as well as the Researcher's agreement to pay the related cost, either directly or through funding sources, the initial proposal shall be provided to the chairperson of the SPFC.
- c. The initial proposal will be reviewed by email by a subcommittee comprised of the chairperson, a CRAB member of the committee and the chairperson of the relevant subcommittee.
- d. If the request is considered to be a reasonable proposal that is of value and can be addressed by the dataset, the applicant will be asked to submit a full proposal.

#### **2. Full Proposal**

- a. The full proposal must be submitted online or by email to IASLC at [staging@iaslc.com](mailto:staging@iaslc.com)[]. IASLC will submit the full proposal to the chairperson of the SPFC for review by the steering committee.
- b. The full proposal must set out the details of the study, methods, population under study, data required from the Staging Data and proposed timelines. In addition, the application must include a full list of the participants to the study and proposals for involvement by

members of the SPFC and CRAB. The study should include as primary authors at least one medical member and one CRAB member of the SPFC.

- c. The full application must include the following, additional documentation:
  - i. A supportive letter from CRAB confirming that the necessary data are obtainable from the database and that the quality and volume of those data are adequate to answer the question posed.
  - ii. All raw data will remain in the IASLC database, as maintained by CRAB, and all extraction, analysis and validation will be conducted by CRAB. The application must be accompanied by an estimate from CRAB of the additional costs of extracting and analyzing the data. The applicant must explain all sources of funding and give assurances that IASLC and/or the SPFC will be reimbursed for the additional cost of this work.
  - iii. Confirmation that the applicant and all other parties who may be considered to hold intellectual property rights will adhere to the highest scientific and ethical standards, including, but not limited to, the following:
    - (a) Will respect IASLC ownership of the data and will not seek to use the information provided for any other use without the agreement of IASLC.
    - (b) Will respect the anonymity of the clinical data.
    - (c) Will submit any publication or presentation for scrutiny by the SPFC, and in addition, by those database proprietors with whom there exist prior agreements, before submission. The SPFC reserves the right to deny publication in extreme situations.
    - (d) Will publish any submission in a format agreed with the SPFC, including the format of the title, and acknowledging the participation of IASLC, the SPFC members, CRAB, and the database proprietors. The acknowledgement of Staging Data project sponsors will be recognized in a format agreed with them from time to time.
    - (e) Will submit publications, in the first place, to the *Journal of Thoracic Oncology*, the official journal of IASLC.
- d. The full proposal will be circulated to the full SPFC by email. The committee members' views will be collected by the chair of the SPFC. If consensus cannot be reached using electronic mail, the proposal will be discussed at the next meeting of the SPFC. Revisions or additional material may be requested before a final decision is reached.
- e. The SPFC's decision is final and there will be no appeal structure.

#### C. General Principles

- 1. Researchers must comply with all applicable laws, regulations, and contractual obligations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations at 45 C.F.R. Parts 160, 162, and 164, as amended by the Health Information Technology for Economic and Clinical Health Act (HIPAA).
- 2. Researchers are specifically prohibited from linking Staging Data with any other dataset, public or private.
- 3. The Staging Data dataset is a non-exclusive resource. IASLC may, at its option, permit multiple unrelated, but similar or identical, requests or analyses by different Researchers.

4. Enhancement and enlargement of the Staging Data dataset is ongoing. However, the Staging Data are provided “as-is.” Each of IASLC, the SPFC, and CRAB disclaim and exclude any and all representations and warranties, conditions or other terms, whether written or oral, expressed or implied, of any kind, including any representations and warranties, conditions or other terms with respect to the Staging Dataset, including any representation or warranty of noninfringement, quality, performance, merchantability or fitness for a particular use or purpose. Nor does IASLC, the SPFC, or CRAB give any assurance about the accuracy, completeness, or fitness for purpose of the data included in any Report. Likewise, IASLC, the SPFC, and CRAB make no guarantees as to the availability or quality of data included in any Report.
5. IASLC reserves the right to disclose the general parameters of any research performed on the Staging Data. Such right of disclosure shall extend to any information other than the related raw data.

D. Publication Review

1. Any Publication resulting from the proposal, Report, or otherwise based on the Staging Data must be reviewed and approved by IASLC or the SPFC before it is submitted to the *Journal of Thoracic Oncology* or to any other congress or journal as approved by IASLC or the SPFC or otherwise released beyond the Researcher.
2. IASLC will review the Publication to assure that it is consistent with the approved project, that it accurately characterizes the Staging Data, that authorship is appropriately acknowledged, and that there is no express or implied IASLC endorsement of an external Researchers’ work or product.
3. An IASLC disclaimer may be required to be included with the Publication.
4. IASLC review will not assess or validate research methods or results. IASLC review is not a substitute for peer review, which is independently performed by relevant associations, congresses, and journals.
5. IASLC approval of a Publication does not assure acceptance of the Publication by the *Journal of Thoracic Oncology* or any other IASLC meeting or journal. IASLC educational programs and publications are independent and peer reviewed, and have sole discretion over the work accepted.

**IASLC**  
**DATA USE AGREEMENT**

This Data Use Agreement (this “**Agreement**”) dated [day, month, year] (the “**Effective Date**”)

**BETWEEN**

\_\_\_\_\_, a \_\_\_\_\_, located at \_\_\_\_\_ (“**Researcher**”);

INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER, a Colorado nonprofit corporation, (“**IASLC**”) located at 13100 East Colfax Avenue, Unit 10, Aurora, Colorado 80011 USA;

**AND**

CANCER RESEARCH AND BIOSTATISTICS, a Washington non-profit corporation (“**CRAB**”), located at 1505 Westlake Ave. N., Suite 750, Seattle, Washington 98109-3050 USA.

**RECITALS:**

- A. IASLC is a global organization dedicated to the study of lung cancer that has compiled an extensive staging and clinical lung cancer dataset (the “**Staging Data**”), which is maintained by CRAB.
- B. Researcher desires to submit a proposal with a research query (a “**Proposal**”) to be run by CRAB against the Staging Data to obtain an output result (a “**Report**”).
- C. By this Agreement, the parties seek to set out the terms under which they will cooperate in good faith to perform their respective obligations hereunder.

IN CONSIDERATION OF THE MUTUAL COOPERATION BETWEEN THE PARTIES, IT IS AGREED BETWEEN THE PARTIES AS FOLLOWS:

1. Definitions.

- a. “**Authorized User**” means any individual under the control of Researcher, who is given permission by Researcher to access the Report, subject to the terms and conditions of this Agreement.
- b. “**Confidential Information**” means, subject to Section 4.b, all written, electronic or oral information, disclosed by IASLC or the Researcher (the “**Discloser**”) to the other or its designee (the “**Recipient**”), identified as confidential or proprietary, as well as information that, based on its nature and the circumstances surrounding its disclosure, a reasonable person would consider to be confidential or proprietary. The parties agree that the Staging Data and the Report shall be deemed Confidential Information of IASLC.

- c. “**Data Access Policy**” means the IASLC Data Access Policy for the staging and clinical lung cancer dataset maintained by CRAB, which may be updated from time to time.
- d. “**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations at 45 C.F.R. Parts 160, 162 and 164, as amended by the Health Information Technology for Economic and Clinical Health Act, which is at Section 13400, *et. seq.* of ARRA, 42 U.S.C. §§ 17921, *et. seq.*, and guidance promulgated thereunder.
- e. “**Publication**” means, any report or work describing, stemming from, or based in whole or in part on, the Report, including, without limitation, articles published in print or online journals or repositories, electronic journals, reviews, books, abstracts, posters and other written, digital and verbal presentations and representations of the Report.
- f. “**SPFC**” means the IASLC Staging and Prognostic Factors Committee.

2. Report Creation.

- a. Researcher shall submit the Proposal for approval in accordance with the Data Access Policy. If approved at each stage in the approval process, Researcher shall pay all costs associated with generating the Report. CRAB will conduct all extraction, analysis and validation with respect to the Staging Data that is necessary to generate the Report. The Report will be limited to the information requested in the Proposal. Researcher agrees that if there are any modifications to the Proposal at any stage in the approval process or if the Researcher desires any additional information after a Proposal is submitted for final approval, Researcher must submit a new proposal in accordance with the Data Access Policy.
- b. CRAB will provide Researcher with an estimate of the cost to create the Report after reviewing the initial proposal, which must be submitted in accordance with the Data Access Policy. Researcher agrees to pay such cost, which must be paid before the Report is created. Any changes in the estimated cost will be communicated by CRAB to Researcher.

3. Ownership.

- a. *Ownership.* The parties agree that, as between IASLC and Researcher, IASLC shall be the sole owner of all right, title and interest, including all intellectual property rights, in and to the Staging Data and any Report generated from the Staging Data. Researcher shall own all rights, title, and interest in any Publication, subject to the limitations included in the Data Access Policy. Researcher acknowledges and agrees that IASLC reserves the right to disclose the general parameters of any research performed on the Staging Data. Each party shall retain all rights to and title in any other intellectual, proprietary or property rights owned by, or otherwise controlled by that party.

- b. *License to Report.* IASLC grants Researcher a non-exclusive, royalty-free license to use the Report consistent with the Proposal as approved by the SPFC, including for use in any Publication, consistent with the requirements in the Data Access Policy.
- c. *Researcher Right to Staging Data.* Researcher is granted no right, title, interest or license of any kind in or to the Staging Data and may not access or use the Staging Data for any reason.

4. Confidential Information.

- a. In addition to the parties' other obligations under this Agreement and with respect to any Confidential Information received by the Recipient from the Discloser, except as otherwise provided in this Agreement, the Recipient shall: (i) protect and maintain the confidentiality of the Confidential Information using the same care that it would use for its own confidential information, but in any event no less than reasonable care; (ii) use the Confidential Information solely for the purposes of fulfilling its obligations under the Agreement and only for the benefit of the Discloser; (iii) not disclose any Confidential Information of Discloser to third parties or to Recipient's employees, except where employees of Recipient have a need to know about the Confidential Information and are subject to obligations of confidentiality at least as restrictive as those in this Agreement, and, with respect to disclosure of the Report by Researcher, such third party is an Authorized User; (iv) cease use of such Confidential Information immediately upon termination or expiration of the Agreement and either return or permanently destroy all Confidential Information upon request of the Discloser; and (v) not attempt to reverse engineer, decompile or create derivative works from or using the Confidential Information.
- b. The confidentiality obligations of this Section 4 shall terminate with respect to any Confidential Information when the Recipient can prove that such information was (i) in the public domain at the time of Discloser's communication to the Recipient, or it subsequently entered the public domain through no fault of the Recipient, (ii) in the Recipient's possession free of any obligation of confidence at the time of the Discloser's communication to the Recipient, (iii) subsequently rightfully communicated to the Recipient free of any obligation of confidence, or (iv) was or is independently developed by the Recipient without reference or recourse to the Discloser's Confidential Information.
- c. Notwithstanding the foregoing, each party may disclose Confidential Information to the limited extent required in order to comply with the order of a court or other governmental body, or as otherwise necessary to comply with applicable laws, provided that the party making the disclosure pursuant to the order shall first have given written notice to the other in order to seek protective relief, if legally permissible, and provided such assistance as may be reasonably requested to limit or prevent such disclosure.

5. Representations and Warranties; Disclaimer.

- a. *Mutual Representations and Warranties.* Each party hereby represents and warrants that such party is duly organized, validly existing and in good standing under the laws of the state of its incorporation or organization and has all requisite power and authority to enter into this Agreement. The parties agree to comply with all applicable law, including laws, rules and regulations, including U.S. federal and state law (e.g., HIPAA) in the performance of their obligations under this Agreement. In the event of a conflict between the requirements of any applicable law, rule or regulation and the requirements stated in this Agreement, the applicable law, rule or regulation under a conflict-of-law analysis, including the preemption analysis required under HIPAA, shall prevail.
- b. *Researcher Representations and Warranties.* Researcher hereby represents and warrants that:
  - i. Researcher will, and will cause all Authorized Users to, adhere to the highest scientific and ethical standards;
  - ii. Researcher acknowledges that the Staging Data is a non-exclusive resource and IASLC may, at its option, permit multiple unrelated, but similar or identical requests or analyses by different researchers;
  - iii. All information contained in the Proposal is true, correct, and complete;
  - iv. Researcher will not use the Report for commercial research purposes or for any use other than as contemplated by this Agreement;
  - v. Researcher will comply, and will cause all Authorized Users to comply, with the Data Access Policy;
  - vi. Researcher will not attempt to re-identify any data provided in the Report or link the Report or Staging Data with any other dataset, public or private;
  - vii. Researcher will submit any Publication to the SPFC, IASLC and *Journal of Thoracic Oncology* for review, approval and publication in accordance with the Data Access Policy;
  - viii. Researcher's use of the Report for the purposes contemplated by this Agreement will not violate any law, rule or regulation or conflict with, result in any breach of, or constitute a default (or an event which would, with the passage of time or the giving of notice or both, constitute a default) under, or give rise to a right to terminate, amend, modify, abandon or accelerate, any contract which is applicable to, binding upon or enforceable against Researcher; and
  - ix. Researcher shall implement administrative, physical and technical safeguards to protect the Report that are no less rigorous than accepted industry practices, and shall ensure that all such safeguards, including the manner in which the Report is accessed, used, stored, processed, disposed of and disclosed, comply with applicable data protection and privacy laws, as well as the terms and conditions of this Agreement.
- c. *Disclaimer.* THE REPORT GENERATED FROM THE STAGING DATA IS PROVIDED "AS-IS." EXCEPT AS OTHERWISE PROVIDED HEREIN AND

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IASLC, CRAB, AND THE SPFC HEREBY DISCLAIM AND EXCLUDE ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, OF ANY KIND, INCLUDING ANY REPRESENTATIONS AND WARRANTIES, CONDITIONS OR OTHER TERMS WITH RESPECT TO THE REPORT, INCLUDING ANY REPRESENTATION OR WARRANTY OF NONINFRINGEMENT, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. NEITHER IASLC NOR CRAB GIVES ANY ASSURANCE REGARDING THE ACCURACY, COMPLETENESS OR FITNESS FOR PURPOSE OF THE DATA INCLUDED IN ANY REPORT, NOR DO IASLC OR CRAB MAKE ANY GUARANTEES AS TO THE AVAILABILITY OR QUALITY OF DATA INCLUDED IN ANY REPORT.

- d. NEITHER IASLC NOR RESEARCHER WILL BE LIABLE FOR INDIRECT, CONSEQUENTIAL, OR INCIDENTAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF PROFITS, REVENUE, DATA, OR USE) ARISING OUT OF THIS AGREEMENT AND/OR ANY DISCLOSURES OF DATA RECEIVED OR CREATED UNDER THIS AGREEMENT, WHETHER IN A LEGAL ACTION IN CONTRACT OR TORT, EVEN IF THE APPLICABLE PARTY IS ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE ENTIRE LIABILITY OF IASLC AND ITS AFFILIATES, DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS UNDER THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT OF FEES AND COSTS PAID BY RESEARCHER HEREUNDER.

6. Term; Termination.

- a. *Term.* This Agreement shall be binding on IASLC and Researcher from the Effective Date until the date when this Agreement is terminated in accordance with this Section. This Agreement shall be binding on CRAB from the Effective Date until the termination of all then applicable agreements between CRAB and IASLC in accordance with their terms.
- b. *Termination.* This Agreement may be terminated by either IASLC or Researcher, but not CRAB, (i) immediately if the other party breaches a material term of this Agreement and cure of such breach is not possible, or (ii) if the other party breaches a material term of this Agreement that is subject to cure and fails to cure such breach within thirty (30) days of receiving notice of such breach from the non-breaching party. This Agreement may be terminated by Researcher, but not IASLC or CRAB, (i) immediately if CRAB breaches a material term of this Agreement and cure of such breach is not possible, or (ii) if CRAB breaches a material term of this Agreement that is subject to cure and fails to cure such breach within thirty (30) days of receiving notice of such breach from the non-breaching party. CRAB shall not have any termination rights under this Agreement; however, to the extent that CRAB ceases to provide services with respect to the Staging Data pursuant to one

or more then applicable agreements between IASLC and CRAB, CRAB shall have no liability for the acts or omissions of its successor.

- c. *Knowledge of Non-compliance.* Any non-compliance by Researcher with this Agreement or with HIPAA, or any equivalent laws or regulations, automatically will be considered a breach or violation of a material term of this Agreement if Researcher knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.
- d. *Effect of Termination.*
  - i. Upon termination of this Agreement by IASLC, Researcher shall confirm that all Reports and all Confidential Information received from IASLC have been destroyed or returned to IASLC, and Researcher shall provide written confirmation of such destruction to IASLC.
  - ii. All of the terms of the Agreement which by their nature extend beyond the expiration or termination of the Agreement, including indemnification obligations, confidentiality obligations, shall survive expiration or termination of the Agreement and remain in full force and effect.

## 7. Indemnification.

- a. Researcher shall indemnify, defend and hold harmless IASLC and its affiliates, and their respective licensors, officers, directors, employees and contractors (each, an “**Indemnitee**” and collectively “**Indemnites**”), from and against any and all third-party claims (including, but not limited to, labour claims), liabilities, demands, causes of action, judgments, settlements and expenses (including, but not limited to, reasonable attorneys’ fees and court costs) arising out of or in connection with any breach of any covenant, representation or warranty made by Researcher (each a “**Claim**”).
- b. If any Claim is initiated against any Indemnitee, the Indemnitee shall give prompt written notice of such Claim to the Researcher. Indemnitee may elect to assume the defense of a Claim and Researcher shall reimburse Indemnitee for all reasonable expenses (including reasonable attorneys’ fees which may include, without limitation, an allocation for in-house counsel) as such expenses are incurred, relating to the defense of such Claim. If Indemnitee elects not to assume the defense of a Claim, then Researcher, at Researcher’s own expense, shall assume the defense of such Claim. If Researcher assumes the defense of such Claim, (i) Researcher shall keep the Indemnites informed of all material developments and events relating to such Claim, (ii) the Indemnites shall have the right to participate, at their own expense, in the defense of such Claim (but such participation shall not be deemed to give the Indemnites the right to control such defense), (iii) the Indemnites shall cooperate as reasonably requested by Researcher in the defense of such Claim, and (iv) Researcher shall not settle such Claim without the prior written consent of the Indemnites, which consent shall not be unreasonably withheld.

8. Miscellaneous.

- a. *Equitable Relief.* Each party agrees that any other party's breach of any provision of this Agreement will cause immediate and irreparable harm to the other party for which money damages are not an adequate remedy at law. Therefore, the parties agree that, in the event either party breaches or threatens to breach this Agreement, the other party shall be entitled to an injunction to restrain said breach or threatened breach, without posting any bond or other security.
- b. *Binding Effect.* This Agreement shall be legally binding as between the parties until such time as it has been expressly superseded by a more detailed agreement should one be duly signed.
- c. *Applicable Law.* The validity and interpretation of this Agreement shall be governed by the laws of the State of Colorado. The parties agree that any conflict of law provisions, where applicable, are hereby excluded by this express agreement to an applicable law and jurisdiction.
- d. *Assignment.* Neither IASLC nor Researcher shall transfer, delegate, or assign this Agreement to any other person or legal entity, whether by written agreement, operation of law or otherwise, without the prior written consent of the other party. To the extent that CRAB ceases to provide services with respect to the Staging Data pursuant to any then applicable agreement or agreements between IASLC and CRAB, CRAB's rights and obligations under this Agreement on and after the date when CRAB ceases to provide such services shall be automatically assigned to its successor; however, such successor shall not have any liability for the acts or omissions of any of its predecessors or successors. Any assignment or transfer by a party hereto that is not in compliance with the terms and conditions set forth in this Section shall be void and of no effect. Any permitted assignment or transfer of or under this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assigns of the assigning or transferring party hereto.
- e. *Entire Agreement.* Subject to this Section 8.e, this Agreement embodies the entire understanding of the parties with respect to the subject matter hereof and shall supersede all previous communications, representations, or understandings, either oral or written, between the parties relating to the subject matter hereof. This Agreement and the subject matter hereof may not be modified except by a written agreement signed on behalf of IASLC, Researcher and, if the amendment directly impacts CRAB's representations, rights or obligations under this Agreement, CRAB, by their respective duly authorized representatives. Only with respect to IASLC and CRAB, to the extent of any conflict or inconsistency between the provisions in the body of this Agreement and any other then applicable agreement or agreements between CRAB and IASLC, the terms of such other agreement or agreements between CRAB and IASLC will prevail. The terms of any agreement or agreements between CRAB and IASLC will not impact the rights and obligations of Researcher under this Agreement.

- f. *Independent Contractor Status.* In connection with this Agreement, each party is an independent contractor and as such will not have any authority to bind or commit the other. Furthermore, neither this Agreement, nor any terms and conditions contained herein, shall be construed as creating a partnership, joint venture or agency relationship or as granting a franchise.
- g. *Severability; No Waiver.* To the extent that any term, condition or provision of this Agreement is held to be invalid, illegal or otherwise unenforceable under applicable law, rule, or regulation then such term, condition or provision shall be deemed excluded from this Agreement and the other terms, conditions and provisions hereof shall remain in full force and effect as if such unenforceable term, condition or provision had not been included herein. The failure of a party to prosecute its rights with respect to a default or breach hereunder shall not constitute a waiver of the right to enforce its rights with respect to any other or later breach. No waiver of any right or remedy available to a party under this Agreement, at law, or in equity shall be effective unless signed in writing by the waiving party. Unless otherwise specifically limited under this Agreement, all rights and remedies reserved to either party shall be cumulative and shall not be in limitation of any other right or remedy which such party may have at law or in equity.

[Signature page follows]

IN WITNESS WHEREOF, as of the Effective Date, an authorised representative of each party has duly executed this Data Use Agreement.

RESEARCHER

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

CANCER RESEARCH AND  
BIOSTATISTICS

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

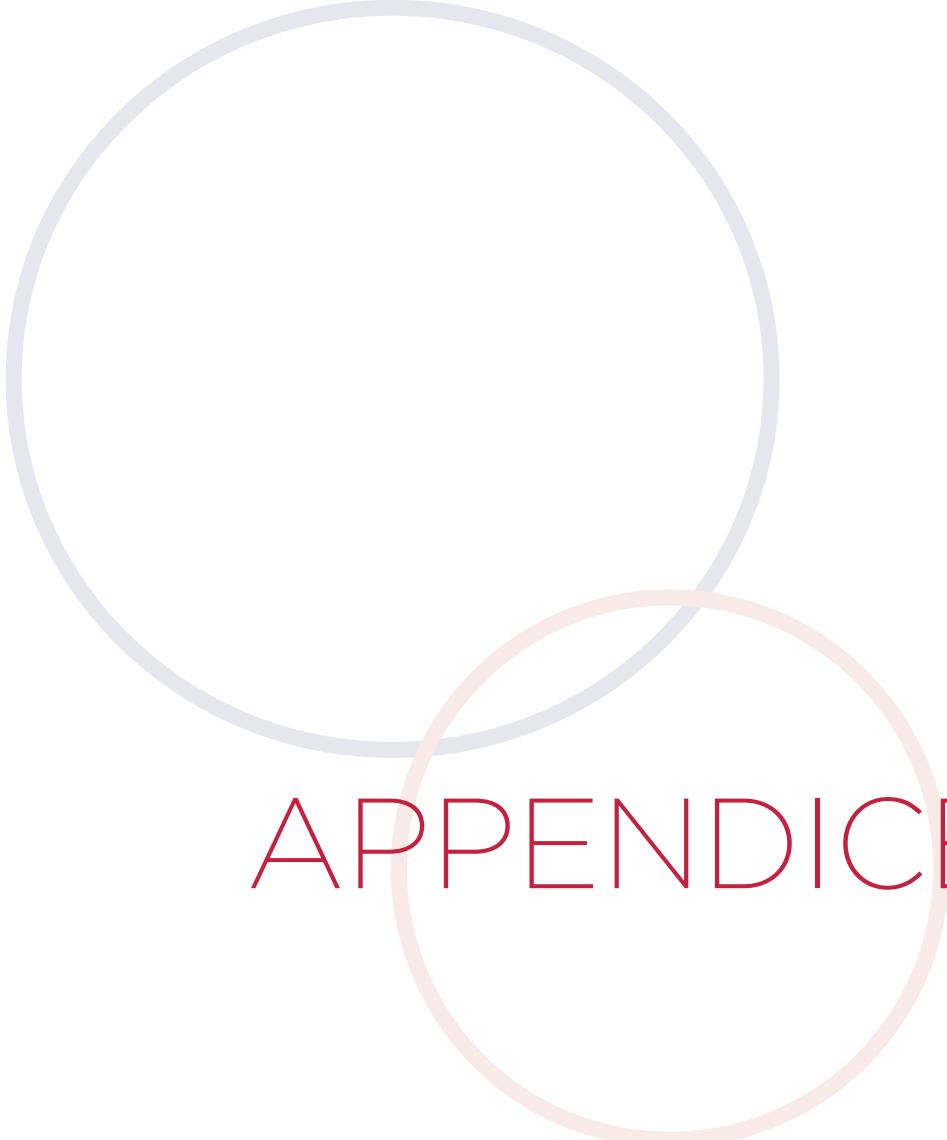
INTERNATIONAL ASSOCIATION FOR  
THE STUDY OF LUNG CANCER

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

SAMPLE



# APPENDICES

**PRIVILEGED COMMUNICATION**

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

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

**IASLC Staging and Prognostic Factors Committee, Full Committee Chair**

Hisao Asamura, MD

Keio University School of Medicine, Tokyo, Japan

**IASLC Staging and Prognostic Factors Committee, Full Committee Vice Chair**

Kemp Kernstine, MD, PhD

The University of Texas Southwestern Medical Center, Dallas, Texas, United States of America

**T Subcommittee Chair**

Ayten K Cangir, MD

Ankara University School of Medicine, Ankara, Turkey

**N Subcommittee Chair**

James Huang, MD

Memorial Sloan-Kettering Cancer Center, New York, New York, United States of America

**M Subcommittee Chair**

Kwun Fong, MBBS, FRACP, PhD

Prince Charles Hospital, Brisbane, Australia

**Ground Glass Opacities (GGO) and Adenocarcinoma In Situ (AIS) Subcommittee Chair**

William Travis, MD

Memorial Sloan-Kettering Cancer Center, New York, New York, United States of America

**Neuroendocrine Tumors Subcommittee Chair**

Ming Tsao, FRCPC, MD

Princess Margaret Cancer Centre, Toronto, Ontario, Canada

**Stage Subcommittee Chair**

Hisao Asamura, MD

Keio University School of Medicine, Tokyo, Japan

**Lymph Node Chart Subcommittee Chair**

Shun-ichi Watanabe, MD  
National Cancer Center Hospital, Tokyo, Japan

**Validation and Methodology Subcommittee Chair**

Frank Detterbeck, MD  
Yale University School of Medicine, New Haven, Connecticut, United States of America

**Prognostic Factors Subcommittee Chair**

Frank Detterbeck, MD  
Yale University School of Medicine, New Haven, Connecticut, United States of America

**R Factor Subcommittee Chair**

John Edwards, MD  
University of Leicester, Glenfield Hospital, Leicester, United Kingdom

**Molecular Database Taskforce Chair**

David Carbone, MD, PhD  
Ohio State University, Columbus, Ohio, United States of America

**Statistics and Data Management**

John Crowley, PhD  
Cancer Research and Biostatistics (CRAB), Seattle, Washington, United States of America

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## **1.0 OBJECTIVES**

1.1. The primary objectives of this study are:

- 1.1.1. To assess the prognostic value and validity of each component of the eighth edition of the tumor, node, metastasis (TNM) classification for lung cancer with respect to the overall survival of patients with newly diagnosed lung cancer.
- 1.1.2. To identify and validate additional descriptors for possible inclusion in future revisions to the TNM classification.

1.2. T-Component objectives:

- 1.2.1. To assess the prognostic impact of tumor size
- 1.2.2. To assess the classification capacity of each descriptor defining T-status.
- 1.2.3. To study new conditions not included in the present T (e.g., differences between parietal pleura invasion and rib invasion).

1.3. N-Component objectives:

- 1.3.1 To assess the prognostic impact of N-status.
- 1.3.2 To assess the prognostic impact of:
  - a. Nodal extent (single vs multiple station involvement in N1 and N2 locations),
  - b. Nodal size, i.e. the largest involved node within the relevant N category, and
  - c. Individual nodes being involved in each nodal category.
- 1.3.3 To assess the prognostic impact of extracapsular extension.
- 1.3.4 To assess the prognostic impact of the N3 nodal location, i.e. contralateral mediastinum, ipsilateral or contralateral supraclavicular fossa.

1.4 M-Component objectives:

- 1.4.1 To assess the prognostic impact of M-status.
- 1.4.2 To assess the prognostic impact of:
  - 1.4.2.1 Single metastasis in a single organ
  - 1.4.2.2 Multiple metastases in a single organ, and
  - 1.4.2.3 Multiple metastases in several organs.

1.5 Objectives regarding other prognostic factors:

- 1.5.1 To assess the prognostic impact of histologic type and grade.
- 1.5.2 To assess the reliability of staging methods utilized in clinical staging (for those tumors with pre-treatment and post-surgical classification).
- 1.5.3 To assess the prognostic impact of complete, incomplete, and uncertain resections, according to the proposed definitions of the IASLC.
- 1.5.4 To assess the prognostic impact of clinical factors, including co-morbidity and pulmonary function tests.

- 1.5.5 To assess the prognostic impact of maximum standard uptake value (SUV max), at the primary site and in any positive nodal sites, for those patients with positron emission tomography (PET) scans in the pre-treatment staging.

## **2.0 BACKGROUND**

The objectives of the first iteration of the Lung Cancer Staging Project of the International Association for the Study of Lung Cancer (IASLC)<sup>1</sup> were achieved in 2007 with the submission of recommendations for the seventh edition of the tumor, node, metastasis (TNM) classification for lung cancer to the International Union Against Cancer (UICC) and to the American Joint Committee on Cancer (AJCC). The UICC and AJCC accepted these recommendations. These core recommendations and the methodology used in the analysis of the retrospective database were published<sup>2, 3, 4, 5, 6</sup> in 2007, along with additional publications on small cell lung cancer, carcinoid tumors, and prognostic factors<sup>7, 8, 9</sup>.

The limitations of the analysis of the retrospective database derived from the fact that most databases that contributed cases to the international database were not designed to study the TNM classification of lung cancer. The most important consequence was that, while the clinical or pathologic T status was recorded in most of the databases, few included the finer details, such as the specific anatomic sites of tumor extension. For this reason, most of the descriptors that define T3 and T4 tumors could not be validated in this retrospective study<sup>2</sup>. The same was true for the potential subdivision of the N1 and N2 nodal spread based on the number of involved nodes/nodal stations or nodal zones<sup>3</sup>, and for the differences in the various forms of M1 disease<sup>4</sup>. In addition, subtle differences between nodal maps used in different parts of the world – e.g. the Mountain and Dressler 1997 modification to the American Thoracic Society (ATS)<sup>10</sup> map and the Naruke-Japan Lung Cancer Society map<sup>11, 12</sup> – complicated previous attempts to analyze international data on nodal involvement.

To overcome the limitations of the previous, retrospectively amalgamated database, the Staging and Prognostic Factors Committee (SPFC) of the IASLC launched a web-based Electronic Data Capture (EDC) system for staging and survival data in 2009<sup>13</sup> with the general objective to refine future editions of the TNM classification for lung cancer. The EDC was designed to facilitate validation of all T, N, and M descriptors, with special attention to those that could not be validated with the analysis of the retrospective database, and the investigation of the prognostic value of other descriptors of interest to the SPFC that were not included in the TNM classification.

As a result of this web-based data collection effort, supplemented by other large, external data sources, a database of 94,708 patients diagnosed around the world from 1999-2010 was constructed, from which the IASLC SPFC developed recommendations toward the eighth edition of the TNM staging system. These recommendations were published in

2015<sup>14, 15, 16, 17, 18, 19</sup> and were accepted by the UICC and AJCC in 2017 (with AJCC implementation effective in 2018).

As the project enters its third cycle, with the goal of developing recommendations for the 9<sup>th</sup> edition of TNM, its continued success will depend on the extent of the international participation and the quality of the data. The initial retrospective staging project showed that quality of the data is even more important than its size. In the second iteration of the project, the superior quality of TNM descriptor data from the EDC relative to retrospectively amalgamated data was clearly demonstrated. The subset of cases that were entered via the EDC was instrumental in the development of the 8<sup>th</sup> edition recommendations due to the level of detail and consistency of the submitted data. For example, the distinction between cases with multiple distant metastatic lesions and those with a single distant metastasis could not have been identified without the EDC dataset.

Useful information not related to the anatomic extent of the disease can also be derived from the newly revised data elements. Including the methods used in clinical staging allows exploration of their reliability in those patients undergoing lung resection, in whom the pre-treatment and post-surgical classifications can be compared. The IASLC has published consensus guidelines on clinical staging based on the best evidence available in clinical practice<sup>21, 22, 23</sup>. With continued collection of the data elements related to clinical staging methods, the previously developed guidelines can be validated, and future staging recommendations can be made in the context of adherence to those guidelines.

One of the objectives of the TNM classification is to assign a prognosis based on the anatomical extent of the disease. However, there are other factors that influence prognosis of lung cancer that are not related to its anatomic extension. Sex, age and comorbidity<sup>24, 25, 26</sup>, biological parameters<sup>27</sup>, and molecular and genetic factors are known to influence prognosis, but have never been integrated, along with the TNM classification, into a valid, clinically useful prognostic system. Information on comorbidity and basic blood analyses is easily available from most patients. The maximum standard uptake value, which has shown prognostic relevance<sup>28</sup>, will also be registered in those patients undergoing PET scan in the pre-treatment staging of their tumors. The importance of molecular and genetic factors is now undisputed, both in terms of survival prognosis as well as interactions with treatment. Recognizing this importance, the collection of detailed biomarker information and specific systemic treatments, with emphasis on targeted agents, is a new feature of the revised EDC. This data collection system is designed to be easily expanded as new biomarkers and discovered, and as new drugs come to market.

Centralized collection of all these anatomic and non-anatomic parameters has been found to be most effective in addressing the research questions of the SPFC of the IASLC<sup>29</sup>. This document is provided to collaborating institutions so that we may standardize the processes and procedures for conducting this study across multiple institutions.

### **3.0 STUDY DESIGN**

This is an international, multi-institutional cohort study that will collect detailed information on the extent of disease, personal and demographic characteristics, comorbid illness status, treatment and survival of newly-diagnosed lung cancer patients.

Ideally, an inception cohort will be enrolled prospectively at each site, and data will be collected using a standardized abstraction tool. However, because it is unlikely that accrual goals will be met using this option alone, sites may alternatively petition the SPFC to transfer data from an existing database.

Data completeness and logic checks will be conducted on an ongoing basis. Analyses will be conducted at CRAB. Each participating institution will have access to their own patients' data and will be eligible to conduct secondary investigations of the larger database subject to approval by the IASLC<sup>30</sup>.

### **4.0 SAMPLE SELECTION**

Based on the experience from the original retrospective study, three types of study samples will be targeted, depending on the nature of the collaborating institution: population-based, institution-based and clinical series. In each case, the intention is to describe the experience of an unselected group of patients. Sample selection for each is described below.

- 4.1 Population-based sample selection will likely involve enhancement of a population-based cancer registry with the data elements required for this study. All patients diagnosed within the study period may be included, or a random sample from the registry within the study period may be included. Documentation of the population coverage of the registry will be required for a sample to fall into this category.
- 4.2 Institution-based sample selection will likely involve the capture of information on all newly-diagnosed lung cancer patients seen at that institution during the period of the study. Usually, this involves the use of an institution's tumor registry that will be enhanced with the data elements required for this study. Description of the institution's referral pattern will be required.
- 4.3 Clinical series sample selection will capture information on an inception cohort of all newly-diagnosed patients presenting to a defined clinical service during the period of the study. All such patients will be tracked with documentation regarding data completeness and losses to follow up.

In considering applications for participation in the project, the SPFC will grant preference to sites which implement one of the above methods of sample selection.

## **5.0 INTERVENTION**

Subjects will not be assigned to any specific intervention as a result of inclusion in this observational data base.

## **6.0 ELIGIBILITY CRITERIA**

- 6.1 Subjects must have newly diagnosed non-small or small cell bronchogenic carcinomas, including neuroendocrine and carcinoid tumors of the lung.
- 6.2 Lung cancer must be confirmed by histology or cytology, with a diagnosis date no earlier than January 1, 2011.
- 6.3 For a subject to be eligible for inclusion, there must be sufficient information available to classify the subject according to the eighth edition of the TNM classification for lung cancer.

## **7.0 DESCRIPTIVE FACTORS**

Patients will be described by pretreatment T, N, and M status, treatment (surgically managed vs not), by country of origin and study sample type. Enrollment will be monitored with respect to these descriptive factors, with two objectives in mind: 1) to track recruitment of specific subgroups defined by geography, stage, or treatment modality with a view to targeting additional institutions and/or clinical settings if under-representation exists and 2) to demonstrate that the study sample is unbiased with regard to subject selection.

## **8.0 STATISTICAL CONSIDERATIONS**

Participation in the previous two database cycles was high, with approximately 100,000 cases submitted for each of the last two revisions. During the most recent effort, 4,631 cases were submitted via electronic data capture. Based upon the number of new participants expressing interest and the expectation of past participants to continue using the EDC or to convert to it, we anticipate a larger proportion of cases to be submitted in this fashion for the next revision. The data derived from EDC submission are uniformly complete, and therefore the calculations below consider only the number of cases that we expect to accrue via the EDC.

The EDC accrual expectation is 20,000 non-small cell lung cancer (NSCLC) cases diagnosed between the beginning of 2011 and the end of 2019, and a smaller proportion of small cell lung cancer (SCLC) and other histologic types. This database is not a population-based registry and the stage distribution is not expected to reflect the distribution of lung

cancer stage in the general population. Based on the previous database, we expect the stage distribution for NSCLC to be approximately 40% stage I, 10% stage II, 25% stage III, and 25% stage IV. For each of the existing ten stage groups of the 8<sup>th</sup> edition (IA, IB, IC, IIA, IIB, IIIA, IIIB, IIIC, IVA, IVB), the smallest anticipated stage groups would be the stage IIA and IIB, with approximately 1000 cases in each of these two group from the EDC. Previously, the 24 month overall survival rate in stage IIA was 81%, and 75% in the stage IIB (HR=1.2) according to the full NSCLC analysis set in the IASLC database. (The difference was similar in the National Cancer Database, although the absolute survival rates were lower.)<sup>19</sup> A difference smaller than this would not be expected to warrant separate stage categories. In a comparison of two groups of 1000 cases each, after 10 years of accrual and an additional 2 years of follow-up, and assuming exponentially distributed survival times, there would be 92% power to detect a hazard ratio of 1.2 with an alpha level of 5% in a one-sided test. This is a worst case scenario as we expect the stage II to be the smallest group of subjects. For example in the stage III, we expect 1600 cases in each of 3 groups. If we wish to detect at minimum a hazard ratio of 1.2 between the potential stage IIIA and IIIB, we would have 99% power to do so at an alpha level of 5% in a one-sided test. Applying a Bonferroni correction to account for multiple comparisons under the assumption of 9 separate between-group tests, power would range from 70% to 92% for the above scenarios.

These power calculations address the simplified case of formally confirming up to 10 overall stage categories. Initially, more exploratory analyses will be conducted to inform the stage categories, and subsequently other subsets will be separately considered, such as the SCLC and neuroendocrine histologic types. Additionally, we anticipate a substantial number of cases submitted by participating sites will be transferred to the project rather than entered directly into the EDC system. These datasets will vary in terms of data elements, and some may only be used to answer some of the questions that arise as part of the initial analyses. Although some of these datasets will be sufficiently complete and utilized in the primary analyses, we do not include them in the power calculations.

## **9.0 DE-IDENTIFICATION OF DATA**

All sites must agree to gather identifiable private information of research subjects in compliance with applicable law and with respect and regards for human subjects. Each participating institution will secure approval of the project from their local Research Ethics Board.

Participating sites must agree unequivocally to prohibit release of individually identifiable private data to CRAB for research purposes. CRAB will receive only ‘coded’ data for analysis. The ‘coded’ data sent to CRAB must not be able to be linked to individual research subjects, either directly or indirectly through the coding system, by any member of CRAB’s research team . Where personal identifiers might inadvertently be included with data received, CRAB will delete/destroy this identified data, and immediately notify the site to replace with de-identified data.

If ever visiting the site, CRAB staff may access or utilize individually private information but these activities become subject to the oversight of the site's Institutional Review Board. At no time will CRAB employees record any private information.

CRAB, as an institution, is not considered to be "engaged" in human subjects research for this project.

## **10.0 SITE APPLICATION MATERIALS**

This section includes the necessary application materials for any site interested in contributing data to the staging project. These application materials and other supportive documentation for the project can be accessed online at <https://iaslc.crab.org/LC/LCStagingProject.pdf>.

### **10.1 Site Cohort Description Form**

### **10.2 Data Use Agreement**

### **10.3 Account Request Form**

## **11.0 PROPERTY OF THE DATA BASE AND PUBLICATION POLICY**

Each institution will retain full access and publishing rights to its own data; however, the collective database will be the property of the IASLC, and CRAB will be responsible for its management, storage, and analysis.

Publications related to the objectives of the Lung Cancer Staging Project of the IASLC SPFC (i.e., publications providing recommendations for changes in the TNM classification) will be planned, researched, analysed, and written by the members of the respective Subcommittees, and will follow the same authorship pattern used for the publications on the retrospective data: chairperson of the subcommittee, members of the subcommittee in alphabetical order, Chairman of the Staging and Prognostic Factors Committee, on behalf of the IASLC Staging Committee, and participating institutions.

## **12.0 DATA COLLECTION PROCESSES**

Identification and training of data collectors will be left to the discretion of the participating institution. With the exception of the outcome data, most of the data collected for this study will occur around the time of diagnosis and treatment. The last date of follow up and vital status of each study subject will be updated at each follow-up visit with a frequency of no less than once per year.

Institutions approved by the SPFC for participation in the project will enter the data online using the secure, web-based EDC system or transfer data from an existing database.

Designed and administered by Cancer Research and Biostatistics (CRAB), the system will incorporate extensive, between-field logic checks and provide a query system enabling communication between CRAB and the institutions regarding the data. The system will provide users the ability to download all data entered by that institution.

Transfer of existing, external data will be initially limited to selected partners from the retrospective project and centers that facilitate correction of geographical gaps identified in the retrospective data. Additional sites may be recruited to meet the accrual goals, provided standards regarding data quality and completeness are met.

It is the intent of the project to follow each subject until death, provided there is sufficient funding to maintain this follow-up. As of the date of activation of this protocol, the IASLC has agreed to sponsor collection of data via the EDC through the year 2024.

### **13.0 OVERSIGHT BY VALIDATION AND METHODOLOGY COMMITTEE**

The SPFC Validation and Methodology Committee will monitor population coverage, losses to follow up, and missing data rates at each site and report their findings to the full committee.

### **14.0 SECONDARY USE OF THE IASLC LUNG CANCER DATA BASE**

The IASLC SPFC has a duty to ensure that the data within its database are used to maximum benefit for the good of patients and the lung cancer community, within ethical constraints and the agreements entered into with individual databases. All requests for the secondary use of the database will be subjected to the following review mechanism:  
An initial, outline proposal should be submitted to the chair of the committee. This will be reviewed by e-mail by a sub-committee consisting of the chair person, a CRAB member of the committee, and the chair of the relevant sub-committee. If the request is considered to be a reasonable proposal, the applicant will be asked to submit a full application containing the following, additional documents:

- a) A full proposal setting out the details of the study, methods, population under study, data required from the database and proposed time lines.
- b) A full list of the participants to the study and proposals for involvement by members of the committee and CRAB. The study should include as primary authors at least one medical member of the committee and one CRAB member of the committee.
- c) A supportive letter from CRAB confirming that the necessary data is obtainable from the data base and that the quality and volume of that data is adequate to answer the question posed.
- d) Confirmation that the applicant and all other parties who may be considered to hold intellectual property rights will adhere to the highest scientific and ethical standards, including but not exclusively:

- i. Will respect the IASLC ownership of the data and will not seek to use the information provided for any other use without the agreement of the IASLC.
- ii. Will respect the anonymity of the clinical data.
- iii. Will submit any publication or presentation for scrutiny by the committee, and in addition, by those database proprietors with whom there exists prior agreements, before submission. The committee reserves the right to deny publication in extreme situations.
- iv. Will publish any submission in a format agreed with the committee, including the format of the title, and acknowledging the participation of the IASLC, the committee members, CRAB and the database proprietors. The acknowledgment of our sponsors will be recognized in a format agreed with them from time to time.
- v. Will submit publications, in the first place, to the Journal of Thoracic Oncology, the official journal of the IASLC.

The full proposal will be circulated to the full committee by e-mail and the committee's view collected by the chairman. If consensus is not reached the proposal will be discussed at the next meeting of the committee. Revisions or additional material may be requested before a final decision is reached. The committee's decision is final and there will be no appeal structure.

## **15.0 REFERENCES**

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**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

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**The International Association for the Study of Lung Cancer (IASLC)**  
**Lung Cancer Staging Project, Data Elements**

### 1.1. Registration

---

Institution: -

Principal Investigator: -

Patient Code:

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

Birth Date:  -  -  (dd-mmm-yyyy)

Sex:  Male  Female

Race (check all that apply):

- |   |   |
|---|---|
| <input type="checkbox"/> East, Central, and Southeast Asian | <input type="checkbox"/> South Asian (India, Pakistan, Nepal, Bhutan, Bangladesh) |
| <input type="checkbox"/> Asian, NOS                         | <input type="checkbox"/> Caucasian (including Middle East and North African)      |
| <input type="checkbox"/> North American or African Descent  |   |
| <input type="checkbox"/> African                            |   |
| <input type="checkbox"/> Native North or South American     |   |
| <input type="checkbox"/> Pacific Islander (Oceania)         |   |
| <input type="checkbox"/> Other                              |   |

If Other, Specify (Race):

---

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## 1.2. Patient Characteristics

---

Subject ID: 999900022

Site Number: 9999 - PRACTICE INSTITUTION

Principal Investigator: PRACTICE Principal Investigator

Patient Code: ZZZ1111

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TAB: Patient

Smoking history:

If a former smoker, number of years since quitting?

Number of years smoked:

Average number:  packs per day

Weight loss in previous six months:

Zubrod Performance Status:

Height:  cm

Weight:  kg

### Comorbidity [hyperlink to definitions with citation]

Tobacco consumption:

Diabetes mellitus:

Renal insufficiency:

Respiratory comorbidity:

Cardiovascular comorbidity:

Previously treated malignancy (Other than basal cell skin carcinoma and in situ carcinoma of the cervix):

Alcoholism:

---

eCRF Version: 1.0

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Lung Cancer Staging Project, Data Elements**

Code List Values: "Patient Characteristics" form

**Form Question:** Smoking History

| Display Value  |
|----------------|
| Never smoked   |
| Former smoker  |
| Current smoker |
| No Data        |

**Form Question:** Weight loss in the previous six months

| Display Value             |
|---------------------------|
| < 5% of body weight       |
| ≥ 5% - 10% of body weight |
| ≥ 10 % of body weight     |
| No Data                   |

**Form Question:** Zubrod Performance Status

| Display Value           |
|-------------------------|
| 0 – Fully active        |
| 1 – Restricted          |
| 2 – No work, ambulatory |
| 3 – Limited self-care   |
| 4 – Completely disabled |
| No Data                 |

**Form Question:** Comorbidity options from 'Diabetes mellitus' to 'Alcoholism'

| Display Value |
|---------------|
| Yes           |
| No            |
| No Data       |

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Lung Cancer Staging Project, Data Elements**

### 1.3. Laboratory Values at Diagnosis

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

TAB: Patient

What was the lab specimen collection date?:  -  -  (dd-mmm-yyyy)

Gender: Male

Age: Unknown

Please select an existing lab, or create one by using the shaded box below.

[Lab Limits of Normal Instructions](#)

Lab Name plus any qualifiers (ex effective dates, patient sex, age ranges):

|   |
|---|
| Create New Lab  |
| Lab Name plus any qualifiers (ex effective dates, patient sex, age ranges):<br><input type="text"/> |
| Copy values from an existing lab:<br><input checked="" type="checkbox"/> No, create blank set       |
| <input type="button" value="Create Lab"/>   |

Complete the following data items. Enter or update limits of normal values and lab units as necessary. The lab data will be updated upon form submission

|                             | Not Done                 | Result               | Lab Lower Limit of Normal | Lab Upper Limit of Normal | Lab Unit             |
|-----------------------------|--------------------------|----------------------|---------------------------|---------------------------|----------------------|
| LDH:                        | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Hemoglobin:                 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Calcium Level:              | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Alkaline Phosphatase (ALP): | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Sodium, NA:                 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| White Cell Count:           | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Neutrophil Count:           | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Platelet Count:             | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Absolute Lymphocyte Count:  | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |
| Albumin:                    | <input type="checkbox"/> | <input type="text"/> | <input type="text"/>      | <input type="text"/>      | <input type="text"/> |

PET Standardized Uptake Value (SUV)

Maximum SUV Primary Tumour:

Maximum SUV Nodes:

Maximum SUV (nodes) applies to:

Pulmonary Function Test

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

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

Date of trial entry if database is from a clinical trial:  -  -  (dd-mmm-yyyy)

eCRF Version: 1.0

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

Code List Values: "Laboratory Values at Diagnosis" form

**Form Question:** Lab Units – LDH

Field size: XX.XX (NUMBER 6,2)

| Display Value | Range  |
|---------------|--------|
| ukat/L        | 0-50   |
| IU/L          | 0-3000 |

**Form Question:** Lab Units – Hemoglobin;

Field size: XX.XX (NUMBER 6,2)

| Display Value | Range |
|---------------|-------|
| g/dl          | 0-20  |
| mmol/L        | 0-4   |

**Form Question:** Lab Units – Calcium Level

Field size: XX.XX (NUMBER 4,2)

| Display Value | Range |
|---------------|-------|
| mmol/L        | 0-20  |
| mg/dl         | 0-80  |

**Form Question:** Lab Units – Alkaline Phosphatase

Field size: XX.XX (NUMBER 6,2)

| Display Value | Range  |
|---------------|--------|
| ukat/L        | 0-20   |
| IU/L          | 0-1200 |

**Form Question:** Lab Units – Sodium, NA

Field size: XXX (NUMBER 3)

| Display Value | Range |
|---------------|-------|
| mmol/L        | 0-500 |

**Form Question:** Lab Units – White Cell Count

Field size: XX.XXX (NUMBER 8,3)

| Display Value             |
|---------------------------|
| 10 <sup>9</sup> X cells/L |

**Form Question:** Lab Units – Neutrophil Count

Field size: XX.XXX (NUMBER 8,3)

| Display Value             |
|---------------------------|
| 10 <sup>9</sup> X cells/L |

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**Form Question:** Lab Units – Platelet Count

Field size: XXX.XXX (NUMBER 9,3)

| Display Value             |
|---------------------------|
| 10 <sup>9</sup> X cells/L |

**Form Question:** Lab Units – Absolute Lymphocyte Count

Field size: XX.XXX (NUMBER 8,3)

| Display Value             |
|---------------------------|
| 10 <sup>9</sup> X cells/L |

**Form Question:** Lab Units – Albumin

Field size: XX (NUMBER 2)

| Display Value | Range |
|---------------|-------|
| g/L           | 0-99  |

**Form Question:** Maximum SUV applies to

| Display Value          |
|------------------------|
| Hilar/interlobar nodes |
| Mediastinal nodes      |
| Supraclavicular nodes  |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

#### 1.4. Lung Cancers with Multiple Lesions

Are there multiple lung lesions?

If yes, complete the section below. Check only one of the first five choices.

- Synchronous primary tumour(s)
- Separate Tumour Nodules with similar histopathologic features in same lung (intrapulmonary metastases)
- Separate Tumour Nodules with similar histopathologic features in opposite lung (interpulmonary metastases)
- Multifocal adenocarcinoma with GGO/lepidic features

If checked, number of lesions:

- Diffuse pneumonic-type lung adenocarcinoma

If the tumors are diffuse pneumonic-type lung adenocarcinoma, complete the section below:

Select One:

- Single focus
- Multiple foci

If 'Multiple foci' checked, select one:

- All lesions are located in one lobe
- Lesions are located in more than one ipsilateral lobe
- Involvement of contralateral lung (M1a)

**Instructions:** Classify multiple lesions according to IASLC rules. [Click here for classification criteria](#):

**Instructions for synchronous tumours:** T-category is described for each primary tumour. Complete the Primary Tumour Description and T-Descriptor form(s) for each lesion. Then complete the node and metastasis sections for all nodal and metastatic disease. Describe the tumour with highest T-category first.

**Instructions for separate tumour nodules:** Apply the general T-classification for multiple nodules on the T-descriptor form. Complete the Primary Tumour Description and the T-Descriptor form. If there is contralateral involvement (M1a), T-category is defined by largest lesion. Apply general TNM classification.

**Instructions for multifocal adenocarcinoma with GGO/lepidic features:** Describe only the lesion with the highest T-category on the T-descriptor form.

**Instructions for diffuse pneumonic-type lung adenocarcinoma, single focus:** Apply general TNM classification.

**Instructions for diffuse pneumonic-type lung adenocarcinoma, multiple foci:** Complete the Primary Tumour Description form and the T-Descriptor form. T-category is defined by location of foci and size of largest lesion.

eCRF Version: 1.1

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

Code List Values: "Lung Cancers with Multiple Lesions" form

**Form Question:** Are there multiple lung lesions?

| Display Value |
|---------------|
| Yes           |
| No            |

**The International Association for the Study of Lung Cancer (IASLC)**  
**Lung Cancer Staging Project, Data Elements**

### 1.5. Primary Tumour Description

TUMOUR:1

TAB: Primary Tumour

Instructions: For patients undergoing resection, use final description of tumour (post-resection) to complete this form.

Method of detection:

Diagnosed by:

- Cytology
- Histology

Date histolog or cytology obtained:  -  -  (dd-mmm-yyyy)

Please specify the location of primary tumour. Do not include the locations of the involved nodes or additional nodules. Select all that apply.

- Right Main Bronchus
- Right Upper Lobe
- Right Middle Lobe
- Right Lower Lobe
- Right Upper Lobar Bronchus
- Right Middle Lobar Bronchus
- Intermediate Bronchus
- Right Lower Lobar Bronchus
- Main Bronchus, Side Not Specified
- Trachea
- Carina
- Left Main Bronchus
- Left Upper Lobe
- Left Lower Lobe
- Left Upper Lobar Bronchus
- Left Lower Lobar Bronchus

Differentiation grade:

Histologic Type, WHO 2015 edition:

Paraneoplastic syndrome:

Pleural Effusion:

eCRF Version: 1.0

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Lung Cancer Staging Project, Data Elements**

Code List Values: "Primary Tumour Description" form

**Form Question:** Method of detection

| Display Value |
|---------------|
| Symptoms      |
| Screening     |
| Incidental    |
| Unknown       |

**Form Question:** Differentiation grade

| Display Value                 |
|-------------------------------|
| Gx: Cannot be assessed        |
| G1: Well differentiated       |
| G2: Moderately differentiated |
| G3: Poorly differentiated     |
| G4: Undifferentiated          |
| Unknown                       |

**Form Question:** Histologic type, WHO 2015 edition

| Display Value  |
|--|
| Adenocarcinoma, noninvasive: Adenocarcinoma in situ                                |
| Adenocarcinoma: Minimally invasive adenocarcinoma                                  |
| Adenocarcinoma, Invasive: Lepidic adenocarcinoma                                   |
| Adenocarcinoma, Invasive: Acinar adenocarcinoma                                    |
| Adenocarcinoma, Invasive: Papillary adenocarcinoma                                 |
| Adenocarcinoma, Invasive: Micropapillary adenocarcinoma                            |
| Adenocarcinoma, Invasive: Solid adenocarcinoma                                     |
| Adenocarcinoma, Invasive: Invasive mucinous adenocarcinoma                         |
| Adenocarcinoma, NOS  |
| Squamous cell carcinoma: Squamous cell carcinoma in situ                           |
| Squamous cell carcinoma: Invasive squamous cell carcinoma                          |
| Neuroendocrine tumor: Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia |
| Neuroendocrine tumor: Small cell carcinoma   |
| Neuroendocrine tumor: Large cell neuroendocrine carcinoma                          |
| Carcinoid tumor: typical carcinoid   |
| Carcinoid tumor: atypical carcinoid  |
| Large cell carcinoma   |
| Adenosquamous carcinoma  |
| Sarcomatoid carcinomas: Pleomorphic carcinoma                                      |
| Sarcomatoid carcinomas: Giant cell carcinoma                                       |
| Sarcomatoid carcinoma: Carcinosarcoma  |
| Salivary gland type tumors: Mucoepidermoid carcinoma                               |
| Salivary gland type tumors: Adenoid cystic carcinoma                               |
| Non Small Cell Lung Cancer – Not otherwise specified                               |
| Other  |

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**Lung Cancer Staging Project, Data Elements**

**Form Question:** Paraneoplastic syndrome

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** Pleural Effusion

| Display Value               |
|-----------------------------|
| Present – cytology positive |
| Present – cytology negative |
| Present – cytology unknown  |
| Absent                      |
| Unknown                     |

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Lung Cancer Staging Project, Data Elements**

**1.6. Pre-Treatment TNM Tests**

From the list below, please select the test that best determined the T, the N and the M categories.

Select "Data not available" if this determination cannot be made.

T    N    M

- Physical examination
- Standard radiology (e.g. chest x-rays)
- CT of chest/upper abdomen
  - CT of the brain
- MRI of chest/upper abdomen
  - MRI of the brain
- PET or PET/CT
- Percutaneous needle biopsy or cytology
- Bronchoscopy with or without ultrasonography (EBUS), with biopsy or cytology
- Oesophagoscopy with or without ultrasonography (EUS), with biopsy or cytology
- Mediastinoscopy with biopsy or cytology
- Mediastinoscopy with or extended cervical mediastinoscopy
- Transcervical lymphadenectomy
- Thoracoscopic biopsy or cytology
- Laparoscopy
- Diagnostic thorascopy
  - Videomediastinoscopy
  - Video-assisted mediastinal lymphadenectomy (VAMLA)
  - Transcervical extended mediastinal lymphadenectomy (TEMLA)
- Data not available
- Other

If 'Other', specify:

The International Association for the Study of Lung Cancer (IASLC)  
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## 1.7. Treatments

---

Subject ID: 999900022

Site Number: 9999 - PRACTICE INSTITUTION

Principal Investigator: PRACTICE Principal Investigator

Patient Code: ZZZ1111

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TAB: Evaluation and Treatment

Was removal of the primary tumour attempted?

Date of resection attempt:  -  -  (dd-mmm-yyyy)

If resection of the primary tumour was attempted:

Extent of resection:

Status of resection margin:

Carcinoma in situ at the bronchial resection margin

Completeness of resection:

(For completeness of resection definitions: [click here](#))

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

Systemic therapy:

Immunotherapy:

Radiation administered to thorax:

Radiation administered to other sites as part of first line therapy. (Select all that apply)

- Brain
- Bone
- Spine
- Other

---

eCRF Version: 1.0

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Code List Values: "Treatments" form

**Form Question:** Was the removal of the primary tumour attempted?

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** Extent of resection

| Display Value  |
|--|
| Thoracotomy, no resection                                  |
| Resection of the airway without removal of lung parenchyma |
| Resection of the airway with removal of lung parenchyma    |
| Endoscopic resection                                       |
| Segmentectomy  |
| Wedge resection  |
| Lobectomy  |
| Bilobectomy  |
| Pneumonectomy  |
| Other  |

**Form Question:** Status of resection margin

| Display Value                |
|------------------------------|
| Negative free margins        |
| Microscopic residual disease |
| Macroscopic residual disease |

**Form Question:** Completeness of resection

| Display Value |
|---------------|
| R0            |
| R1            |
| R2            |
| Unknown       |

**Form Question:** Systemic therapy

| Display Value   |
|---|
| No Systemic therapy   |
| Systemic therapy, no resection attempt                            |
| Systemic therapy before attempted resection                       |
| Systemic therapy after attempted resection                        |
| Systemic therapy before and after attempted resection             |
| Sequence unknown, but both systemic therapy and resection attempt |

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**Form Question:** Immunotherapy

**Display Value**

- |  |
|--|
| No Immunotherapy   |
| Immunotherapy, no resection attempt                            |
| Immunotherapy before attempted resection                       |
| Immunotherapy after attempted resection                        |
| Immunotherapy before and after attempted resection             |
| Sequence unknown, but both Immunotherapy and resection attempt |

**Form Question:** Radiation administered to thorax

**Display Value**

- |  |
|--|
| No radiation therapy   |
| Radiation therapy, no resection attempt: standard or stereotactic  |
| Radiation therapy before attempted resection                       |
| Radiation therapy after attempted resection                        |
| Radiation therapy before and after attempted resection             |
| Sequence unknown, but both radiation therapy and resection attempt |

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**Lung Cancer Staging Project, Data Elements**

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

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TUMOUR:1

TAB: Primary Tumour

**Instructions:** Indicate T-category. [\[Click here for the 8th edition criteria\].](#)

Lung tumour T Category  by pre-treatment/evaluative findings

Size of primary tumour (solid component), by pre-treatment/evaluative findings:  cm, longest dimension

Is this a part-solid tumour with a GGO/lepidic component?  Yes  
 No

If 'Yes', provide size of combined solid and part solid component together:  cm

Lymphangitis present?  Yes  
 No

Specify all locations of lymphangitis, if present:

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

**Instructions: T-Descriptors. Check ALL that apply, regardless of final T-category:**

- Primary tumour cannot be assessed, or tumour proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy (TX)
- No evidence of primary tumour (T0)
- Carcinoma in situ (Tis)
- Minimally invasive adenocarcinoma (T1mi)
- Tumor 3 cm or less in greatest dimension, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion more proximal than the lobar bronchus (i.e., not in the main bronchus). (T1)
- Superficial spreading tumour of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus. (T1)
- Involves main bronchus regardless of distance to the carina, but without involving the carina. (T2)
- Invades visceral pleura (T2)
- Associated with atelectasis or obstructive pneumonitis that extends to the hilar region, either involving part of the lung or the entire lung (T2)
- Parietal Pleura Invasion (PL3) (T3)
- Chest wall invasion (T3)
- Apical chest wall invasion, stellate ganglion, inferior branches of the brachial plexus (below C8) (T3)
- Phrenic nerve involvement (T3)
- Parietal pericardium involvement (T3)
- Associated separate tumour nodule(s) in the same lobe as the primary (T3)

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Lung Cancer Staging Project, Data Elements**

- Diaphragm invasion (T4)
- Mediastinum invasion (T4)
- Heart invasion (T4)
- Great vessel invasion (T4)
  - Superior vena cava
  - Inferior vena cava
  - Pulmonary vein
  - Pulmonary artery
  - Aorta
  - Main trunk of pulmonary artery
- Tracheal invasion (T4)
- Recurrent laryngeal nerve invasion (T4)
- Esophageal invasion (T4)
- Apical chest wall invasion (T4): evidence of invasion of the vertebral body or spinal canal, encasement of the subclavian vessels, or unequivocal involvement of the superior branches of the brachial plexus (c8 or above). (T4)
- Carina invasion (T4)
- Separate tumour nodule(s) in a different ipsilateral lobe to that of the primary (T4)

Histology of separate nodules confirmed?

eCRF Version: 1.0

Code List Values: "T-Descriptors, by Pre-Treatment/Evaluative Findings" form

**Form Question:** Lung tumour T Category

| Display Value |
|---------------|
| TX            |
| T0            |
| Tis           |
| T1mi          |
| T1a           |
| T1b           |
| T1c           |
| T2a           |
| T2b           |
| T3            |
| T4            |

**Form Question:** Histology of separate nodules confirmed?

| Display Value |
|---------------|
| Yes           |
| No            |

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Lung Cancer Staging Project, Data Elements**

**1.9. Pre-treatment/Evaluative N Category**

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

**TAB: Nodal Staging**

*Instructions: Indicate status for each nodal station using results from pre-treatment biopsy (e.g., mediastinoscopy) if available, otherwise use imaging results.*

**Key to nodal station results:**

+= At least one node examined in this region was considered to be metastatic.

-= All nodes examined in this region were considered to be nonmetastatic.

ND = No node examination done in this region or results were equivocal (none considered metastatic).

**Location of primary tumour (with highest T-category):**

N Category:

**Supraclavicular**

#1R  #1L

**Upper paratracheal**

#2R  #2L

**Pre-vascular**

#3aR  #3aL

**Retrotracheal**

#3p

**Lower paratracheal**

#4R  #4L

**Sub-aortic**

#5

**Para-aortic**

#6

**Subcarinal**

#7

**Paraoesophageal**

#8R  #8L

**Pulmonary ligament**

#9R  #9L

**Hilar**

#10R  #10L

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Lung Cancer Staging Project, Data Elements**

**Interlobar**

#11R  #11L

**Lobar**

#12R  #12L

**Segmental**

#13R  #13L

**Subsegmental**

#14R  #14L

**Size of largest node:**  cm

**Method of measurement:**

**Extracapsular involvement?**

If 'Yes', N3 extracapsular involvement:

If 'Yes', N2 extracapsular involvement:

If 'Yes', N1 extracapsular involvement:

**Number of N3 nodes explored:**  Number of positive N3 nodes:

**Number of N2 nodes explored:**  Number of positive N2 nodes:

**Number of N1 nodes explored:**  Number of positive N1 nodes:

eCRF Version: 1.0

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Lung Cancer Staging Project, Data Elements**

Code List Values: "Pre-Treatment/Evaluative N Category" form

**Form Question:** N Category

| Display Value |
|---------------|
| N0            |
| N1            |
| N2            |
| N3            |
| NX            |

**Form Question:** All staging questions before 'Size of largest node'

| Display Value |
|---------------|
| +             |
| -             |
| ND            |

**Form Question:** Method of measurement

| Display Value |
|---------------|
| X-ray         |
| CT            |
| Ultrasound    |
| Biopsy        |

**Form Question:** Extracapsular involvement?

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** N3 extracapsular involvement; N2 extracapsular involvement; N1 extracapsular involvement

| Display Value |
|---------------|
| Yes           |
| No            |
| Unknown       |

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Lung Cancer Staging Project, Data Elements**

**1.10. M-Descriptors, by Pre-Treatment/Evaluative Findings**

---

Subject ID: 999900022

Site Number: 9999 - PRACTICE INSTITUTION

Principal Investigator: PRACTICE Principal Investigator

Patient Code: ZZZ1111

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TAB: M Descriptors

**Instructions:** Indicate M-category. [\[Click here for the 8th edition criteria\]](#)

M Category by pre-treatment/evaluative findings:

Was cytologic or histologic evidence obtained for M1 Disease?

Pleural nodules:

Pericardial nodules:

Pleural effusion:  Cytology:

Pericardial effusion:  Cytology:

Contralateral lung metastasis:

Are there any distant (extrathoracic) metastases?

| Sites of distant metastases | Presence/Number of Lesions       | If multiple lesions, specify number of lesions |
|-----------------------------|----------------------------------|--|
| Bone:                       | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Liver:                      | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Brain:                      | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Abdominal lymph nodes:      | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Other distant lymph nodes:  | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Peritoneum:                 | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Adrenals:                   | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Skin:                       | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Bone Marrow:                | <input type="button" value="▼"/> | <input type="button" value=""/>                |
| Other:                      | <input type="button" value="▼"/> | <input type="button" value=""/>                |

---

eCRF Version: 1.0

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Lung Cancer Staging Project, Data Elements**

Code List Values: "M-Descriptors, by Pre-Treatment/Evaluative Findings" form

**Form Question:** M status by pre-treatment/evaluative finding

| Display Value |
|---------------|
| M0            |
| M1a           |
| M1b           |
| M1c           |

**Form Question:** Was cytologic or histologic evidence obtained for M1 Disease?; Are there any distant (extrathoracic) metastases?

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** Pleural nodules; Pleural effusion

| Display Value               |
|-----------------------------|
| None                        |
| Ipsilateral                 |
| Contralateral               |
| Bilateral                   |
| Present, side not specified |
| Unknown                     |

**Form Question:** Pericardial nodules; Pericardial effusion

| Display Value |
|---------------|
| Present       |
| Absent        |
| Unknown       |

**Form Question:** Cytology

| Display Value |
|---------------|
| Positive      |
| Negative      |
| Not done      |
| Unknown       |

**Form Question:** Sites of distant metastases

| Display Value                           |
|---|
| Single lesion                           |
| Multiple lesions                        |
| Present, number of lesion not specified |
| Absent                                  |

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Lung Cancer Staging Project, Data Elements**

### 1.11. T-Descriptors, by Post-Surgical Pathological Findings

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TUMOUR.1

TAB: Primary Tumour

**Instructions:** Indicate T-category. [\[Click here for the 8th edition criteria\]](#)

Lung tumour T Category  by post-surgical/pathological findings

Size of primary tumour, by post-surgical/pathological findings:  cm, longest dimension, invasive component only

Combined invasive and noninvasive (lepidic) size, if applicable:  cm, longest dimension

Vascular invasion:

Status of the fissures:

Lymphatic vessel invasion:

Pleural lavage cytology:  cm

Perineural invasion:

Spread through the air spaces (STAS):

**Instructions:** T-Descriptors. Check ALL that apply, regardless of final T-category:

- Primary tumour cannot be assessed, or tumour proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy (TX)
- No evidence of primary tumour (T0)
- Carcinoma in situ (Tis)
- Minimally invasive adenocarcinoma (T1mi)
- Tumour 3 cm or less in greatest dimension, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion more proximal than the lobar bronchus (i.e., not in the main bronchus). (T1)
- Superficial spreading tumour of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus. (T1)
- Involves main bronchus regardless of distance to the carina, but without involving the carina. (T2)
- Invades visceral pleura (T2)

Depth of visceral pleura invasion. [Click here](#) for definitions

- PL0
- PL1
- PL2

- Associated with atelectasis or obstructive pneumonitis that extends to the hilar region, either involving part of the lung or the entire lung (T2)
- Parietal Pleura Invasion (PL3) (T3)
- Chest wall invasion (T3)
- Apical chest wall invasion, stellate ganglion, inferior branches of the brachial plexus (below C8) (T3)

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- Phrenic nerve involvement (T3)
- Parietal pericardium involvement (T3)
- Associated separate tumour nodule(s) in the same lobe as the primary

Histology of separate nodules confirmed?

- Diaphragm invasion (T4)
- Mediastinum invasion (T4)
- Heart invasion (T4)
- Great vessel invasion (T4)
  - Superior vena cava
  - Inferior vena cava
  - Pulmonary vein
  - Pulmonary artery
  - Aorta
  - Main trunk of pulmonary artery
- Tracheal invasion (T4)
- Recurrent laryngeal nerve invasion (T4)
- Esophageal invasion (T4)
- Apical chest wall invasion (T4): evidence of invasion of the vertebral body or spinal canal, encasement of the subclavian vessels, or unequivocal involvement of the superior branches of the brachial plexus (c8 or above). (T4)
- Carina invasion (T4)
- Separate tumour nodule(s) in a different ipsilateral lobe to that of the primary (T4)

Histology of separate nodules confirmed?

---

eCRF Version: 1.0

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

Code List Values: "T-Descriptors, by Post-Surgical Pathological Findings" form

**Form Question:** Lung tumour T Category

| Display Value |
|---------------|
| TX            |
| T0            |
| Tis           |
| T1mi          |
| T1a           |
| T1b           |
| T1c           |
| T2a           |
| T2b           |
| T3            |
| T4            |

**Form Question:** Vascular invasion

| Display Value   |
|-----------------|
| V0: None        |
| V1: Microscopic |
| V2: Macroscopic |
| Unknown         |

**Form Question:** Status of the fissures

| Display Value             |
|---------------------------|
| Adjacent lobe invaded     |
| Adjacent lobe not invaded |
| Unknown                   |

**Form Question:** Lymphatic vessel invasion

| Display Value    |
|------------------|
| Ly0: No invasion |
| Ly1: Invasion    |
| Unknown          |

**Form Question:** Pleural lavage cytology

| Display Value |
|---------------|
| Positive      |
| Negative      |
| Not done      |
| No Data       |

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**Lung Cancer Staging Project, Data Elements**

**Form Question:** Perineural invasion

| Display Value |
|---------------|
| Yes           |
| No            |
| Unknown       |

**Form Question:** Histology of separate nodules confirmed?

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** Spread through the air spaces (STAS)

| Display Value |
|---------------|
| Present       |
| Absent        |
| Not evaluated |

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Lung Cancer Staging Project, Data Elements**

### 1.12. Post-Surgical/Pathologic N Category

---

**Subject ID:** 999900020

**Site Number:** 9999 - PRACTICE INSTITUTION

**Principal Investigator:** PRACTICE Principal Investigator

**Patient Code:** CFU1000ZBY

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

TAB: Nodal Staging

**Instructions:** Indicate nodal sampling results at each station based on pathology review of attempted resection of the primary tumor.

**Key to nodal station results:**

+ = At least one node examined in this region was considered to be metastatic.

- = All nodes examined in this region were considered to be nonmetastatic.

ND = No node examination done in this region or results were equivocal (none considered metastatic).

**Location of primary tumour (with highest T-category):**

**N Category:**

**Supraclavicular**

#1R  #1L

**Upper paratracheal**

#2R  #2L

**Pre-vascular**

#3aR  #3aL

**Retrotracheal**

#3p

**Lower paratracheal**

#4R  #4L

**Sub-aortic**

#5

**Para-aortic**

#6

**Subcarinal**

#7

**Paraoesophageal**

#8R  #8L

**Pulmonary ligament**

#9R  #9L

**Hilar**

#10R  #10L

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**Interlobar**  
 #11R  #11L

**Lobar**  
 #12R  #12L

**Segmental**  
 #13R  #13L

**Subsegmental**  
 #14R  #14L

**Size of largest node:**  cm

**Direct nodal invasion from tumour?**

Direct invasion of N3 nodes:

Direct invasion of N2 nodes:

Direct invasion of N1 nodes:

**Extracapsular involvement?**

If 'Yes', N3 extracapsular involvement:

If 'Yes', N2 extracapsular involvement:

If 'Yes', N1 extracapsular involvement:

**Number of N3 nodes removed:**  Number of positive N3 nodes:

**Number of N2 nodes removed:**  Number of positive N2 nodes:

**Number of N1 nodes removed:**  Number of positive N1 nodes:

eCRF Version: 1.0

Code List Values: "Post Surgical/Pathologic N Category" form

**Form Question: 'N Category'**

| Display Value |
|---------------|
| N0            |
| N1            |
| N2            |
| N3            |
| NX            |

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**Lung Cancer Staging Project, Data Elements**

**Form Question:** All staging questions excluding the 'N Category' question and the 'Direct nodal invasion from tumour?' and 'Extracapsular involvement?' questions

| Display Value |
|---------------|
| +             |
| -             |
| ND            |

**Form Question:** 'Direct nodal invasion from tumour?' and 'Extracapsular involvement?' questions

| Display Value |
|---------------|
| Yes           |
| No            |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**1.13. M-Descriptors, After Attempted Resection of the Primary Tumour**

Subject ID: 999900022

Site Number: 9999 - PRACTICE INSTITUTION

Principal Investigator: PRACTICE Principal Investigator

Patient Code: ZZZ1111

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

TAB: M Descriptors

**Instructions:** Indicate M-category. [Click here for 8th edition criteria]

Only new sites of disease, discovered during surgery or post-surgical staging, should be indicated on this form.

M Category Before Attempted Resection of the Primary Tumour:

M Category After Attempted Resection of the Primary Tumour:  ▾

Pleural nodules:  ▾

Pericardial nodules:  ▾

Pleural effusion:  ▾ Cytology:  ▾

Pericardial effusion:  ▾ Cytology:  ▾

Contralateral lung metastasis:

Were there any additional sites of metastasis that were identified during surgery or post-surgical staging?  ▾

| Sites of distant metastases | Presence/Number of Lesions | If multiple lesions, specify number of lesions |
|-----------------------------|----------------------------|--|
| Bone:                       | <input type="text"/> ▾     | <input type="text"/>                           |
| Liver:                      | <input type="text"/> ▾     | <input type="text"/>                           |
| Brain:                      | <input type="text"/> ▾     | <input type="text"/>                           |
| Abdominal lymph nodes:      | <input type="text"/> ▾     | <input type="text"/>                           |
| Other distant lymph nodes:  | <input type="text"/> ▾     | <input type="text"/>                           |
| Peritoneum:                 | <input type="text"/> ▾     | <input type="text"/>                           |
| Adrenals:                   | <input type="text"/> ▾     | <input type="text"/>                           |
| Skin:                       | <input type="text"/> ▾     | <input type="text"/>                           |
| Bone Marrow:                | <input type="text"/> ▾     | <input type="text"/>                           |
| Other:                      | <input type="text"/> ▾     | <input type="text"/>                           |

eCRF Version: 1.0

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Lung Cancer Staging Project, Data Elements**

Code List Values: "M-Descriptors, After Attempted Resection of the Primary Tumour" form

**Form Question:** M Category Before Attempted Resection of Primary Tumour; M Category After Attempted Resection of Primary Tumour

| Display Value |
|---------------|
| M0            |
| M1a           |
| M1b           |
| M1c           |

**Form Question:** Pleural nodules; Pleural effusion

| Display Value               |
|-----------------------------|
| None                        |
| Ipsilateral                 |
| Contralateral               |
| Bilateral                   |
| Present, side not specified |
| Unknown                     |

**Form Question:** Pericardial nodules; Pericardial effusion

| Display Value |
|---------------|
| Present       |
| Absent        |
| Unknown       |

**Form Question:** Cytology

| Display Value |
|---------------|
| Positive      |
| Negative      |
| Not done      |
| Unknown       |

**Form Question:** Were there any additional sites of metastasis that were identified during surgery or post-surgical staging?

| Display Value |
|---------------|
| Yes           |
| No            |

**Form Question:** Sites of distant metastases

| Display Value                           |
|---|
| Single lesion                           |
| Multiple lesions                        |
| Present, number of lesion not specified |
| Absent                                  |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

#### 1.14. Systemic Treatments

Subject ID: 20010001

Institution: University of Michigan

Principle Investigator: Smith, John

Patient Code: UM045-13

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

Therapy:  Other therapy, specify:

Line of Treatment:

Start Date of Systemic Treatment:  -  -  (dd-mmm-yyyy)

Ongoing:

End Date of Systemic Treatment:  -  -  (dd-mmm-yyyy)

#### Systemic Treatments for this Subject

To view complete information for a record, or to edit or delete an record, click on the entry in the Therapy column.

| Therapy    | Other therapy, specify | Line of Treatment | Start Date | Ongoing | End Date  |
|------------|------------------------|-------------------|------------|---------|-----------|
| Afatinib   |                        | First Line        | 3/1/2017   | N       | 3/14/2017 |
| Trametinib |                        | First Line        | 3/1/2017   | N       | 3/28/2017 |
| Other      | Free text              | Second Line       | 4/1/2017   | Y       |           |
| Nivolumab  |                        | Neoadjuvant       | 4/1/2017   | Y       |           |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Code List Values:** "Systemic Treatment" form

**Form Question:** Therapy

| Display Value |
|---------------|
| Afatinib      |
| Alectinib     |
| Atezolizumab  |
| Avelumab      |
| Bevacizumab   |
| Brigatinib    |
| Cabozantinib  |
| Carboplatin   |
| Ceritinib     |
| Cetuximab     |
| Cisplatin     |
| Crizotinib    |
| Dabrafenib    |
| Docetaxel     |
| Durvalumab    |
| Entrectinib   |
| Erlotinib     |
| Etoposide     |
| Gefitinib     |
| Gemcitabine   |
| Lorlatinib    |
| LOXO 101      |
| LOXO 292      |
| Necitumumab   |
| Nivolumab     |
| Osimertinib   |
| Paclitaxel    |
| Pembrolizumab |
| Pemetrexed    |
| Ponatinib     |
| Ramicirumab   |
| Trametinib    |
| Vemurafenib   |
| Vinorelbine   |
| Other         |

**Form Question:** Line of Treatment

| Display Value      |
|--------------------|
| First Line         |
| Second Line        |
| Third line or more |
| Neoadjuvant        |
| Adjuvant           |

**The International Association for the Study of Lung Cancer (IASLC)**  
**Lung Cancer Staging Project, Data Elements**

1.15. Follow-up

**Follow-up**

Logged in: Joan Smith (31023)

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

**Subject ID:** 20010001

**Site Number:** University of Michigan

**Principle Investigator:** Smith, John

**Patient Code:** UM045-13

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

FOLLOW-UP: 1

Date of Last Contact with patient:  -  -  (dd-mm-yyyy)

Vital Status at Last Contact:

- Alive
- Dead

If the patient's disease progressed or recurred after first-line (or neoadjuvant) treatment, please submit a Progression/Recurrence form documenting the date of progression/recurrence.

Please document the primary cause of death below:

Cause of Death, if Deceased:

Check here if results of molecular studies are available for this case.

Check here if tissue is available for molecular studies for this case.

eCRF Version: 1.1

Code List Values: "Follow-up" form

**Form Question:** Cause of Death, if Deceased

| Display Value   |
|---|
| Death due to lung cancer – locoregional relapse             |
| Death due to lung cancer – distant relapse                  |
| Death due to lung cancer – locoregional and distant relapse |
| Death due to lung cancer – Not otherwise specified          |
| Death due to second primary cancer                          |
| Death, non-cancer cause                                     |
| Cause of death unknown                                      |

**The International Association for the Study of Lung Cancer (IASLC)**  
**Lung Cancer Staging Project, Data Elements**

**1.16. Progression/Recurrence**

**Progression/Recurrence**

Logged in: Joan Smith (31023)

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

---

**Subject ID:** 20010001

**Site Number:** University of Michigan

**Principle Investigator:** Smith, John

**Patient Code:** UM045-13

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

If the patient's disease progressed or recurred after first-line (or neoadjuvant) treatment,  
please document the date of progression or recurrence below.

Date of progression or recurrence:  -  -  (dd-mm-yy)

---

eCRF Version: 1.0

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**1.17. Genetic Biomarkers**

**Genetic Biomarkers**

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

---

**Subject ID:** 20010001  
**Institution:** University of Michigan  
**Principle Investigator:** Smith, John  
**Patient Code:** UM045-13

---

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

---

Date assessed:  -  -  (dd-mmm-yyyy)

Type of Sample:

Total mutational burden:

OR

Gene:   If specific gene does not appear on the list, please contact us at: [wcbhclpiasl@crab.org](mailto:wcbhclpiasl@crab.org)

|   |   |                         |
|---|---|-------------------------|
| Platform:   | DNA Variant<br>(if applicable):                       | Other variant, specify: |
| <input type="text"/> <input type="button" value="▼"/> | <input type="text"/> <input type="button" value="▼"/> | <input type="text"/>    |

Gene Sequence Abnormality, if applicable:

---

---

**Genetic Biomarkers for this Subject**

To view complete information for a record, or to edit or delete a record, click on the entry in the Total mutational burden or Gene column.

| Date Assessed | Type of Sample | Total mutational burden | Gene                  | Platform | DNA Variant | Other variant | Gene Sequence Abnormality |
|---------------|----------------|-------------------------|-----------------------|----------|-------------|---------------|---------------------------|
| 12-JUN-2017   | Biopsy         |                         | <a href="#">ASXL1</a> | Sanger   |             |               | ASXL1 Exon 14             |
| 13-JUN-2017   | Plasma         | <a href="#">55</a>      |                       |          |             |               |                           |
| 15-JUN-2017   | Plasma         |                         | <a href="#">FGFR4</a> | FISH     |             |               | FGFR4 Mutation            |

---

eCRF Version 1.0

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Code List Values:** "Genetic Biomarkers" form

**Form Question:** Gene (NOTE: if gray- 'DNA Variant' dropdown is null)

| Display Value | Display Value | Display Value | Display Value |
|---------------|---------------|---------------|---------------|
| ABL1          | EPHA5         | KRAS          | RBM10         |
| AKT1          | EPHA7         | MAP2K1        | RECQL4        |
| ALK           | EPHB1         | MAP3K1        | RET           |
| AMER1         | ERBB2         | MED12         | RFWD2         |
| APC           | ERBB3         | MEN1          | ROS1          |
| AR            | ERBB4         | MET           | SETBP1        |
| ARAF          | ERCC2         | MGA           | SETD2         |
| ARID1A        | ERCC3         | MPL           | SF3B1         |
| ARID1B        | ERCC4         | MSH2          | SMAD4         |
| ARID2         | ERCC5         | MSH6          | SMARCA4       |
| ASXL1         | ESR1          | MTOR          | SMO           |
| ATM           | ETV1          | NBN           | SPEN          |
| ATR           | FANCA         | NF1           | STAG2         |
| ATRX          | FAT1          | NF2           | STK11         |
| AXL           | FBXW7         | NFE2L2        | TBX3          |
| BAP1          | FGFR1         | NOTCH1        | TCF3          |
| BCOR          | FGFR2         | NOTCH2        | TERT          |
| BCORL1        | FGFR3         | NOTCH3        | TET1          |
| BLM           | FGFR4         | NOTCH4        | TET2          |
| BRAF          | FLT1          | NRAS          | TLR4          |
| BRCA1         | FLT3          | NTRK1         | TP53          |
| BRCA2         | FLT4          | NTRK2         | TSC1          |
| BRIP1         | GATA3         | NTRK3         | TSC2          |
| CARD11        | GLI1          | PAK5          | WT1           |
| CBL           | GLI2          | PALB2         | ZFHX3         |
| CDC73         | GLI3          | PARK2         |               |
| CD74-NRG1     | GNAS          | PBRM1         |               |
| CDH1          | GRIN2A        | PDGFRA        |               |
| CDKN2A        | HGF           | PDGFRB        |               |
| CIITA         | HIST1H3F      | PIK3C2B       |               |
| CREBBP        | IGF1R         | PIK3C2G       |               |
| CSF1R         | IKZF1         | PIK3CA        |               |
| CTNNB1        | INPP4B        | PIK3CG        |               |
| CUX1          | JAK2          | PMS1          |               |
| DDR2          | JAK3          | PMS2          |               |
| DICER1        | KDM5C         | POLE          |               |
| DIS3          | KDM6A         | PRKDC         |               |
| DMD           | KDR           | PTCH1         |               |
| DNMT3A        | KEAP1         | PTEN          |               |
| EGFR          | KIT           | PTPN11        |               |
| EML4          | KMT2A         | PTPRD         |               |
| EP300         | KMT2C         | PTPRT         |               |
| EPHA3         | KMT2D         | RB1           |               |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Form Question:** Type of Sample

|               |
|---------------|
| Display Value |
| Biopsy        |
| Plasma        |

**Form Question:** Platform

|                    |
|--------------------|
| Display Value      |
| Sanger             |
| NGS                |
| NGS: COBAS         |
| NGS: Oncomine      |
| NGS: FoundationOne |
| qPCR               |
| RT-qPCR            |
| FISH               |
| FoundationOne CDx  |
| MSK-IMPACT         |
| Other              |

**Form Question:** DNA Variant

| Gene Value | Display Value                      |
|------------|------------------------------------|
| ALK        | AKT1 c.49G>A (E17K)                |
|            | ALK Fusions                        |
|            | I1151Tins                          |
|            | L1152R                             |
|            | C1156Y                             |
|            | I1171T/N/S                         |
|            | F1174L/C                           |
|            | V1180L                             |
|            | L1196M                             |
|            | L1198F                             |
|            | F1202R/del                         |
|            | S1206F                             |
|            | D1203N                             |
|            | S1206Y/C                           |
|            | G1269A                             |
|            | G1548E                             |
|            | BRAF c.1397G>T (G466V)             |
|            | BRAF c.1405_1406delGGinsTT (G469L) |
|            | BRAF c.1406G>C (G469A)             |
| BRAF       | BRAF c.1415A>G (Y472C)             |
|            | BRAF c.1789C>G (L597V)             |
|            | BRAF c.1799T>A (V600E)             |
|            | DDR2 DDR2 c2304T>A (S768R)         |
|            | EGFR Status Unknown                |
|            | EGFR No Mutation Detected          |
| EGFR       | EGFR Kinase Domain Duplication     |
|            | EGFR c.2156G>C (G719A)             |
|            | EGFR c.2155G>T (G719C)             |
|            | EGFR c.2156G>A (G719S)             |

|       |  |
|-------|--|
| EGFR  | EGFR Exon 19 Deletion                  |
|       | EGFR Exon 19 Insertion                 |
|       | EGFR Exon 20 Insertion                 |
|       | EGFR c.2290_2291ins (A763_Y764insFQEA) |
|       | EGFR c.2369C>T (T790M)                 |
|       | EGFR c.2573T>G (L858R)                 |
|       | EGFR c.2582T>A (L861Q)                 |
|       | EGFR c.2303G>T (S768I)                 |
|       | EGFR c.2390G>C (C797S)                 |
|       | EGFR c.2159C>T (S720F)                 |
|       | EGFR c.2281G>T (D761Y)                 |
|       | EGFR c.2294T>C (V765A)                 |
|       | EGFR c.2347A>G (T783A)                 |
|       | EGFR c.2305G>T (V769L)                 |
|       | EGFR c.2312A>C (N771T)                 |
|       | EGFR c.2582 T>G (L861R)                |
|       | EGFR D770_N771 (insNPG)                |
|       | EGFR D770_N771 (insSVO)                |
|       | EGFR D770_N771 (insG)                  |
| ERBB2 | HER2 Exon 20 Insertion                 |
| FGFR1 | FGFR1 Fusions                          |
| FGFR2 | FGFR2 Mutation                         |
| FGFR3 | FGFR3 Fusions                          |
|       | FGFR3 mutation at 248/249 pos.         |
|       | FGFR3 Rearrangement                    |
| FGFR4 | FGFR4 Mutation                         |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Form Question:** DNA Variant (cntd)

|      |                                |
|------|--------------------------------|
| KRAS | KRAS c.34G>T (G12C)            |
|      | KRAS c.34G>C (G12R)            |
|      | KRAS c.34G>A (G12S)            |
|      | KRAS c.35G>C (G12A)            |
|      | KRAS c.35G>A (G12D)            |
|      | KRAS c.35G>T (G12V)            |
|      | KRAS c.37G>T (G13C)            |
|      | KRAS c.37G>C (G13R)            |
|      | KRAS c.37G>A (G13S)            |
|      | KRAS c.38G>C (G13A)            |
|      | KRAS c.38G>A (G13D)            |
|      | KRAS c.181C>A (Q61K)           |
|      | KRAS c.182A>T (Q61L)           |
|      | KRAS c.182A>G (Q61R)           |
|      | KRAS c.183A>C (Q61H)           |
|      | KRAS c.183A>T (Q61H)           |
|      | MAP2K1                         |
|      | MEK1 c.167A>C (Q56P)           |
|      | MEK1 c.171G>T (K57N)           |
|      | MEK1 C.199G>A (D67N)           |
| MET  | MET Exon 14 Skipping Mutations |

|        |                           |
|--------|---------------------------|
| NRAS   | NRAS c.34G>T (G12C)       |
|        | NRAS c.34G>C (G12R)       |
|        | NRAS c.34G>A (G12S)       |
|        | NRAS c.35G>C (G12A)       |
|        | NRAS c.35G>A (G12D)       |
|        | NRAS c.181C>A (Q61K)      |
|        | NRAS c.182A>T (Q61L)      |
|        | NRAS c.182A>G (Q61R)      |
|        | NRAS c.183A>C (Q61H)      |
|        | NRAS c.183A>T (Q61H)      |
| NTRK1  | NTRK1 (TRKA) Fusions      |
| PIK3CA | PIK3CA c.1624G>A (E542K)  |
|        | PIK3CA c.1633G>A (E545K)  |
|        | PIK3CA c.1633G>C (E545Q)  |
|        | PIK3CA c.3140A>T (H1047L) |
|        | PIK3CA c.3140A>G (H1047R) |
| PTEN   | PTEN c.697C>T (R233*)     |
| RET    | RET Fusions               |
| ROS1   | S1986Y/F                  |
|        | G2032R                    |
|        | D2033N                    |
|        | D2155S                    |
|        | ROS1 Fusions              |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**1.18. Copy Number Alteration (CNA) Biomarkers**

**Subject ID:** 20010001

**Institution:** University of Michigan

**Principle Investigator:** Smith, John

**Patient Code:** UM045-13

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

Copy Number Alteration:  If specific CNA does not appear on the list, please contact us at: [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org)

Date assessed:  -  -  (dd-mmm-yyyy)

Type of Sample:

|                      |                             |                      |                                   |
|----------------------|-----------------------------|----------------------|-----------------------------------|
| Platform:            | Average Gene<br>Copy Number | Genotype:            | Average Gene:<br>Centromere Ratio |
| <input type="text"/> | <input type="text"/>        | <input type="text"/> | <input type="text"/> %            |

**CNA Biomarkers for this Subject**

To view complete information for a record, or to edit or delete an record, click on the entry in the CNA column.

| CNA                               | Date Assessed | Type of Sample | Platform | Average Gene Copy Number | Genotype     | Average Gene: Centromere Ratio | Centromere Copy Number |
|-----------------------------------|---------------|----------------|----------|--------------------------|--------------|--------------------------------|------------------------|
| <a href="#">CCND1 11q13 AMP</a>   | 12-JUN-2017   | Biopsy         | OncoScan | 42                       | Homozygous   | 19.27%                         | 40                     |
| <a href="#">FOXA1 14q21.1 AMP</a> | 15-JUN-2017   | Plasma         | FISH     | 38                       | Heterozygous | 24.65%                         | 24                     |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Code List Values:** "Copy Number Alteration (CAN) Biomarkers" form

**Form Question:** Copy Number Alteration

| Display Value            |
|--------------------------|
| CCND1 11q13 AMP          |
| CCNE1 19q12 AMP          |
| CDK4 12q14 AMP           |
| CDKN2A 9p21 DEL          |
| CDKN2B 9p21 DEL          |
| CEBPA 19q13.1 AMP        |
| EGFR 7p12 AMP            |
| ERBB2 17q12 AMP          |
| ETV1 7p21.3 AMP          |
| FGF19 11q13.1 AMP        |
| FGF3 11q13 AMP           |
| FGF4 11q13.3 AMP         |
| FGFR1 8p11.23-p11.22 AMP |
| FGFR1 Amplification      |
| FGFR2 Amplification      |
| FGFR3 Amplification      |
| FGFR4 Amplification      |
| FOXA1 14q21.1 AMP        |
| KRAS 12p12.1 AMP         |
| MCL1 1q21 AMP            |
| MDM2 12q14.3-q15 AMP     |
| MET 7q31 AMP             |
| MYC 8q24.21 AMP          |
| NFKBIA 14q13 AMP         |
| NKX2-1 14q13 AMP         |
| PIK3CA 3q26.3 AMP        |
| PTEN 10q23.3 DEL         |
| RECQL4 8q24.3 AMP        |
| RICTOR AMP               |

**Form Question:** Type of Sample

| Display Value |
|---------------|
| Biopsy        |
| Plasma        |

**Form Question:** Platform

| Display Value |
|---------------|
| FISH          |
| NGS           |
| CISH          |
| OncoScan      |

**Form Question:** Genotype

| Display Value |
|---------------|
| Homozygous    |
| Heterozygous  |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

### 1.19. Protein Alterations

**Subject ID:** 20010001

**Institution:** University of Michigan

**Principle Investigator:** Smith, John

**Patient Code:** UM045-13

**IMPORTANT:** This form has a 20 minute timeout period. You can click or type on the form at any time to reset your timeout period.

Protein:   If specific protein does not appear on the list, please contact us at: [webhelpiaslc@crab.org](mailto:webhelpiaslc@crab.org)

Date assessed:  -  -  (dd-mmm-yyyy)

Type of Sample:

Platform:

Antibody:

% Tumor Cells:

% Immune cells:

H-Score:

Protein Sequence Abnormality:

#### Protein Alterations for this Subject

To view complete information for a record, or to edit or delete an record, click on the entry in the Protein column.

| Protein | Date Assessed | Type of Sample | Platform          | Antibody  | % Tumor Cells | % Immune Cells | H-Score | Protein Sequence Abnormality |
|---------|---------------|----------------|-------------------|-----------|---------------|----------------|---------|------------------------------|
| PD-L1   | 12-JUN-2017   | Biopsy         | Mass Spectrometry | DAKO 28-8 | 36            | 45             | 121     |                              |
| ALK     | 15-JUN-2017   | Plasma         | IHC               | Dako ALK1 | 32            | 42             | 181     |                              |

**The International Association for the Study of Lung Cancer (IASLC)  
Lung Cancer Staging Project, Data Elements**

**Code List Values:** "Protein Alterations" form

**Form Question:** Protein

| Display Value |
|---------------|
| PD-L1         |
| ALK           |
| ROS           |
| EGFR          |

**Form Question:** Type of Sample

| Display Value |
|---------------|
| Biopsy        |
| Plasma        |

**Form Question:** Platform

| Display Value     |
|-------------------|
| IHC               |
| Mass spectrometry |

**Form Question:** Antibody

| Protein | Display Value                               |
|---------|---|
| PD-L1   | DAKO 28-8                                   |
|         | DAKO 22-C3                                  |
|         | DAKO 73-10                                  |
|         | Ventana SP142                               |
|         | Ventana SP263                               |
|         | Cell Signaling E1L3N                        |
| ALK     | Dako ALK1                                   |
|         | Ventana D5F3 CDx                            |
|         | Cell Signaling D5F3                         |
|         | Novocastra/Abcam/Leica/Novus 5A4            |
| ROS     | Cell Signaling D4D6                         |
| EGFR    | Cell Signaling 43B2 (L858R Mutant Specific) |
|         | Cell Signaling D6B6 (E746-A750del Specific) |

**IASLC Lung Cancer Staging Project**  
**T, N, and M Descriptors for the 8<sup>th</sup> edition of the TNM classification of lung cancer**

| <b>T – Primary Tumor</b> |             |  |
|--------------------------|-------------|--|
| Category                 | Subcategory | Descriptors  |
| TX                       |             | Primary tumor cannot be assessed, or tumor proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy   |
| T0                       |             | No evidence of primary tumor   |
| Tis                      |             | Carcinoma in situ:<br>Tis(AIS): adenocarcinoma<br>Tis(SCIS): squamous cell carcinoma   |
| T1                       |             | Tumor 3 cm or less in greatest dimension, surrounded by lung or visceral pleura, without bronchoscopic evidence of invasion more proximal than the lobar bronchus (i.e., not in the main bronchus). The uncommon superficial spreading tumor of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus, is also classified as T1a.   |
|                          | T1mi        | Minimally invasive adenocarcinoma  |
|                          | T1a         | Tumor 1 cm or less in greatest dimension   |
|                          | T1b         | Tumor more than 1 cm but not more than 2 cm in greatest dimension  |
|                          | T1c         | Tumor more than 2 cm but not more than 3 cm in greatest dimension  |
| T2                       |             | Tumor more than 3 cm but not more than 5 cm; or tumor with <i>any</i> of the following features. T2 tumors with these features are classified T2a if 4 cm or less, or if size cannot be determined; and T2b if greater than 4 cm but not larger than 5 cm. <ul style="list-style-type: none"> <li>• Involves main bronchus regardless of distance to the carina, but without involving the carina</li> <li>• Invades visceral pleura</li> <li>• Associated with atelectasis or obstructive pneumonitis that extends to the hilar region, either involving part of the lung or the entire lung</li> </ul> |
|                          | T2a         | Tumor more than 3 cm but not more than 4 cm in greatest dimension  |
|                          | T2b         | Tumor more than 4 cm but not more than 5 cm in greatest dimension  |
| T3                       |             | Tumor more than 5 cm but not more than 7 cm in greatest dimension or one that directly invades any of the following: parietal pleura (PL3), chest wall (including superior sulcus tumours), phrenic nerve, parietal pericardium; or associated separate tumor nodule(s) in the same lobe as the primary  |
| T4                       |             | Tumors more than 7 cm or one that invades any of the following: diaphragm, mediastinum, heart, great vessels, trachea, recurrent laryngeal nerve, esophagus, vertebral body, carina; separate tumor nodule(s) in a different ipsilateral lobe to that of the primary   |

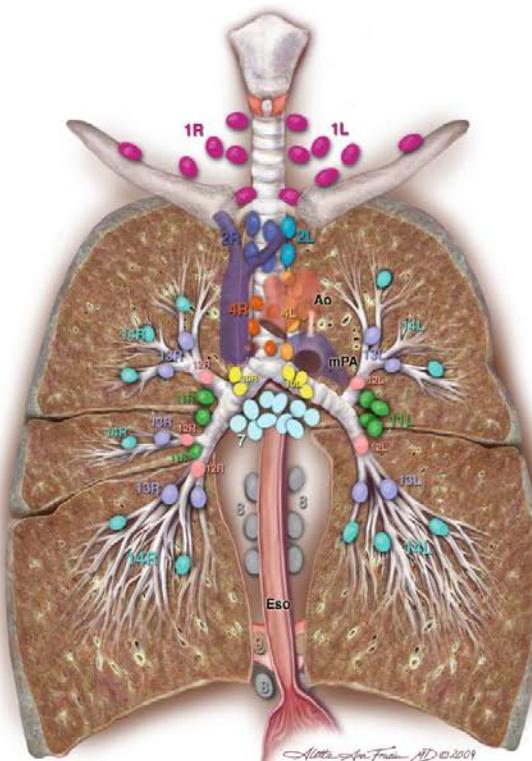
**IASLC Lung Cancer Staging Project**

**T, N, and M Descriptors for the 8<sup>th</sup> edition of the TNM classification of lung cancer**

| <b>N – Regional Lymph Nodes</b> |     |   |
|---------------------------------|-----|---|
| NX                              |     | Regional lymph nodes cannot be assessed   |
| N0                              |     | No regional lymph node metastasis   |
| N1                              |     | Metastasis in ipsilateral peribronchial and/or ipsilateral hilar lymph nodes and intrapulmonary nodes, including involvement by direct extension  |
| N2                              |     | Metastasis in ipsilateral mediastinal and/or subcarinal lymph node(s)   |
| N3                              |     | Metastasis in contralateral mediastinal, contralateral hilar, ipsilateral or contralateral scalene, or supraclavicular lymph node(s)  |
| <b>M- Distant Metastasis</b>    |     |   |
| M0                              |     | No distant metastasis   |
| M1                              |     | Distant metastasis  |
|                                 | M1a | Separate tumor nodule(s) in a contralateral lobe; tumor with pleural nodules or malignant pleural or pericardial effusion. Most pleural (pericardial) effusions with lung cancer are due to tumor. In a few patients, however, multiple microscopic examinations of pleural (pericardial) fluid are negative for tumor, and the fluid is non-bloody and is not an exudate. Where these elements and clinical judgment dictate that the effusion is not related to the tumor, the effusion should be excluded as a staging descriptor. |
|                                 | M1b | Single extrathoracic metastasis in a single organ and involvement of a single distant (non-regional) node   |
|                                 | M1c | Multiple extrathoracic metastases in one or several organs  |

Besides the descriptor ‘tumor size’, it should be indicated that, for part-solid tumors, the size of the solid component on CT and the size of the invasive component at pathologic examination are the ones to be used to define the T category based on tumor size.

**IASLC Lung Cancer Staging Project**  
**IASLC 2009 NODAL MAP**



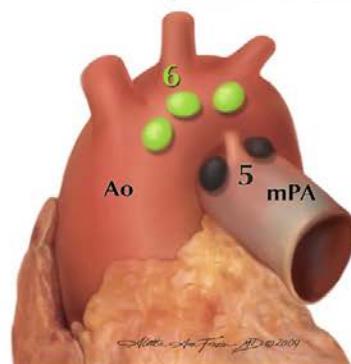
**Supraclavicular zone**

- 1 Low cervical, supraclavicular, and sternal notch nodes

**SUPERIOR MEDIASTINAL NODES**

*Upper zone*

- 2R Upper Paratracheal (right)
- 2L Upper Paratracheal (left)
- 3a Prevascular
- 3p Retrotracheal
- 4R Lower Paratracheal (right)
- 4L Lower Paratracheal (left)



**AORTIC NODES**

*AP zone*

- 5 Subaortic
- 6 Para-aortic (ascending aorta or phrenic)

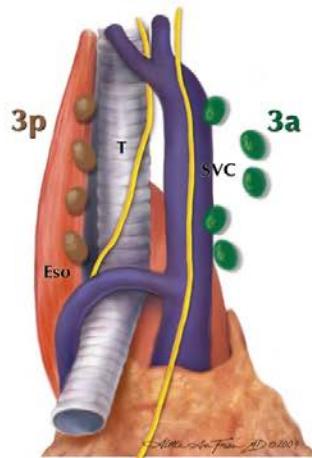
**INFERIOR MEDIASTINAL NODES**

*Subcarinal zone*

- 7 Subcarinal

*Lower zone*

- 8 Paraesophageal (below carina)
- 9 Pulmonary ligament



**N1 NODES**

*Hilar/Interlobar zone*

- 10 Hilar
- 11 Interlobar

*Peripheral zone*

- 12 Lobar
- 13 Segmental
- 14 Subsegmental

# We Probably have the Answer: Now What is the Question?

*Peter Goldstraw, MB, FRCS,\* Ramón Rami-Porta, MD,† and John Crowley, PhD‡*

The International Staging Project of the International Association for the Study of Lung Cancer (IASLC)<sup>1</sup> created a data base containing information on over 100,000 cases of lung cancers, enrolled between 1990 and 2000, treated by all modalities of care, from over 46 data bases in over 19 countries around the world. The analysis of this data has informed the forthcoming 7th edition of TNM in Lung Cancer, and has resulted in 13 peer-reviewed articles in the *Journal of Thoracic Oncology*.<sup>2–14</sup> The thrust of these articles has understandably focused on staging issues in non-small cell lung cancer, small-cell lung cancer, and carcinoid tumors. However, there has been one other study by a member of the committee which has demonstrated the possibility of using this data for purposes other than that for which it was collected by the IASLC.<sup>15</sup> Now that this first phase of the project is complete the committee will be focusing on accumulating more retrospective and prospective data to inform the 8th edition of TNM and beyond. However, the committee feels that it has a responsibility to the IASLC, the contributing data bases, the lung cancer community and, not least, patients and their relatives around the world, to offer this data base for wider secondary uses. The committee has developed guide lines on this use:

All requests for the secondary use of the database will be subjected to the following review mechanism:

An initial, outline proposal should be submitted to the chair of the committee. This will be reviewed by e-mail by a subcommittee consisting of the chair person, a member of our statistical team at Cancer Research And Biostatistics (CRAB) and the chair of the relevant subcommittee. If the request is considered to be of value, and one which can be addressed by the data base, the applicant will be asked to submit a full application containing the following, additional documentation:

- a. A full proposal setting out the details of the study, methods, population under study, data required from the database and proposed time lines.
- b. A full list of the participants to the study and proposals for involvement by members of the committee and CRAB. The study should include as primary authors at least one medical member of the committee and one CRAB member of the committee.
- c. A supportive letter from CRAB confirming that the necessary data is obtainable from the data base and that the quality and volume of that data is adequate to answer the question posed.
- d. All raw data will remain in the IASLC database and all extraction, analysis and validation will be conducted by CRAB. The application must be accompanied by an estimate from CRAB of the additional costs of extracting and analyzing the data. The applicant must explain all sources of funding and give assurances that the committee will be reimbursed for the additional cost of this work unless, in exceptional circumstances, the committee agrees to waive such charges.
- e. Confirmation that the applicant and all other parties who may be considered to hold intellectual property rights will adhere to the highest scientific and ethical standards, including but not exclusively:

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- a. Will respect the IASLC ownership of the data and will not seek to use the information provided for any other use without the agreement of the IASLC.
- b. Will respect the anonymity of the clinical data.
- c. Will submit any publication or presentation for scrutiny by the committee, and in addition, by those database proprietors with whom there exists prior agreements, before submission. The committee reserves the right to deny publication in extreme situations.
- d. Will publish any submission in a format agreed with the committee, including the format of the title, and acknowledging the participation of the IASLC, the committee members, CRAB and the database proprietors. The acknowledgment of our sponsors will be recognized in a format agreed with them from time to time.
- e. Will submit publications, in the first place, to the *Journal of Thoracic Oncology*, the official journal of the IASLC. In exceptional circumstances this requirement may be waived if, in the opinion of the committee, another journal is more appropriate for the format or topic under study.

The full proposal will be circulated to the full committee by e-mail and the committee's view collected by the chairman. If consensus cannot be reached using electronic mail the proposal will be discussed at the next meeting of the committee. Revisions or additional material may be requested before a final decision is reached. The committee's decision is final and there will be no appeal structure.

The data fields contained within the data base, and other information, can be obtained by e-mailing [information@crab.org](mailto:information@crab.org) with "IASLC Staging Project" in the subject line.

All applications should be sent to the chairman, Peter Goldstraw, at [p.goldstraw@rbht.nhs.uk](mailto:p.goldstraw@rbht.nhs.uk) or the vice-chair, Dr. Ramon Rami-Porta at [r.ramip@terra.es](mailto:r.ramip@terra.es). We look forward to receiving your proposals. While our first obligation is to those who contributed data to the project, proposals from all other individuals will be considered on merit.

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