

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

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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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Disclosure: The authors declare no conflicts of interest.

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ISSN: 1556-0864/09/0408-0939

- 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 with "IASLC Staging Project" in the subject line.

All applications should be sent to the chairman, Peter Goldstraw, at p.goldstraw@rbht.nhs.uk or the vice-chair, Dr. Ramon Rami-Porta at rramip@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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