**PROGNOSTIC AND PREDICTIVE BIOMARKERS FOR ACT (ADJUVANT CHEMOTHERAPY) IN RESECTED NON-SMALL CELL LUNG CANCER (R-NSCLC): LACE-BIO**


1Queens University, NCIC Clinical Trials Group, Cancer Research Institute, Kingston, ON, CANADA
2Service de Biostatistique et d’Epidémiologie, Institut de Cancérologie Gustave-Roussy, Villejuif, FRANCE
3Pathology Department, University Health Network, Princess Margaret Cancer Centre, Toronto, ON, CANADA
4Département d’anatomie et Cytopathologie, Centre Hospitalier Universitaire de Grenoble, Grenoble, FRANCE
5Department of Medical Oncology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, CANADA
6South-Paris University, Département de Médecine Gustave Roussy, Villejuif, FRANCE
7Oncology, University of Minnesota, Minneapolis, MN, USA
8Hematology and Internal Medicine, SUNY Upstate Medical University Hospital, Syracuse, NY, USA
9Medical Oncology, ICO Institut de Cancérologie de l’Ouest René Gauduchau, Nantes, FRANCE
10Medical Oncology Service, Catalan Institute of Oncology, Hospital Germans Trias i Pujol, Badalona, SPAIN
11Service de Biostatistique et d’Épidémiologie, Institut Gustave-Roussy, Villejuif, FRANCE
12Dept. of Medicine, Institut Gustave Roussy, Villejuif, FRANCE
13Department of Medicine, Medical University of Vienna, Vienna, AUSTRIA
14Medicine, Medical University of Vienna, Vienna, AUSTRIA
15Thoracic Oncology, Dana-Farber Cancer Institute, Boston, MA, USA

**Aim:** The precise selection of patients for ACT is critical but there remain no validated molecular tools which are prognostic for relapse or predictive of benefit from ACT.

**Methods:** LACE-Bio, based on the LACE (Lung Adjuvant Cisplatin Evaluation) meta-analysis project, includes a fully annotated database and tissue bank from 4 randomised trials comparing ACT to non-treated control (IALT(1), ANITA(2), NCIC CTG JBR-10 (3) and CALGB 9633(4). It contains ∼1500 samples, including frozen tissue (JBR.10). Histochemical/immunohistochemical (HC) biomarkers shown in one trial to have a significant prognostic and/or predictive effect on overall survival, were cross-validated in the 3 other trials; when only a trend (T) for such effects was observed we performed a pooled analysis combining all 4 trials. All statistical analyses were conducted by the meta-analysis unit at Gustave Roussy. Biomarker assays for validation/pooled analyses were in general conducted by the group reporting the original biomarker results.

**Results:** Numerous issues were encountered during the attempted validation of promising assays, including method of fixation, storage, the use of TMAs vs. sections, stored vs. fresh sections, and reagent/antibody batches. Despite meticulous methodology, the majority of the promising biomarkers (other than mutations) could not be confirmed as of value.

**Conclusions:** Although inexpensive and widely available, HC based assays from single trials may be misleading and require validation before being implemented. Of particular concern are HC biomarkers which we could not validate, but which are being used as selection tools in open trials. LACE-Bio-2 is evaluating potential genomic biomarkers using next-generation sequencing that may allow more precise selection of NSCLC patients for ACT in NSCLC.

**Disclosure:** All authors have declared no conflicts of interest.

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**Table 1670**

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<th>Marker</th>
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<th>Predictive?</th>
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