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## **Press release**

### **Results of the IFCT-0302 phase III trial question the role of chest CT-scan for the follow-up of resected non-small cell lung cancer (NSCLC)**

Today, the French Cooperative Thoracic Intergroup (IFCT) announced the results of the IFCT-0302 trial, a large randomized controlled study conducted in France. It compared a minimal follow-up with regular clinic visits and chest X-rays and a CT-based follow-up including the same procedures with the addition of chest CT-scan, in patients with completely resected non-small cell lung cancer (NSCLC). The main objective of the study was to determine whether CT-based follow-up improved overall survival. Secondary endpoints included disease-free survival, survival from recurrence or 2<sup>nd</sup> primary cancer, quality of life, cost-effectiveness and prognostic value of gene signatures.

Despite a median survival (time after which 50% of patients are likely to be alive) of 8.2 years (95% CI: 7.4-9.6) in the control group, and 10.3 years (95% CI: 8.5-non reached) in the CT-based group, the study did not reach its statistical endpoint (HR=0.94, 95% CI: 0.81-1.08; p=0.37).

There was a trend for a shorter disease-free survival in the CT-based arm, showing that this follow-up detected recurrences and 2<sup>nd</sup> primary cancers earlier (median: not reached and 4.95 years (95% CI: 4.4-non reached) p=0.07), respectively. Exploratory analyses suggest that this earlier diagnosis does not translate into a survival improvement in the situation of recurrence, which occur mostly during the first two postoperative years, but might be of interest later in these patients at high risk of 2<sup>nd</sup> primary cancers.

**Prof. Virginie Westeel, the coordinating investigator of the study, Pulmonologist at the University Hospital Besançon, in France stated:** *“The IFCT-0302 trial is the first large randomized study of follow-up in resected NSCLC and the first trial evaluating the interest of chest CT-scan. The results of this study, which show that systematic chest CT-scan does not affect the chances of cure after surgery for NSCLC, are of particular interest in terms of cost saving from a health insurance perspective. This study shows that a chest CT-scan every 6 months is probably not useful during the first 2 years, although a yearly chest CT-scan might be kept for the earlier detection and treatment of second primary cancers”.*

The data, which may inform international lung cancer recommendations for optimal post-operative follow-up, will be featured today, September 9, at the Annual meeting of the European Society for Medical Oncology, Presidential Symposium (Abstract 12730).

## About IFCT-0302 trial

Between January 2005 and November 2012, 1775 patients were enrolled in 159 centers in France. Eligible patients, with complete resection of stage I, II, IIIA NSCLC (6<sup>th</sup> TNM classification), were randomized into two groups (1.1). In the control group, follow-up consisted of clinic visit and chest X-rays. In the experimental group, patients underwent clinic visit, chest X-rays, with the addition of thoraco-abdominal CT scan and fiberoptic bronchoscopy (optional for adenocarcinomas). In both groups, patients completed follow-up every 6 months for 2 years and yearly until 5 years. Supplementary procedures were allowed in case of symptoms. Median follow-up was 8 years 10 months.

## Rationale of the study

Lung cancer is the leading cause of cancer death globally. NSCLC is the most commonly diagnosed type of lung cancer, accounting for approximately 85% of all cases. The 5-year survival rate following complete resection of lung cancer is stage dependent and varies from 20% to 75%. In patients operated on for NSCLC, the majority of clinical practice guidelines recommend follow-up visits including history and physical examination, and chest CT. However, evidence to support these recommendations is poor, in the absence of randomized data. A large randomized study was therefore necessary to evaluate a CT-based follow-up.

## About the French Cooperative Thoracic intergroup (IFCT)

The IFCT is an independent, non-profit academic research intergroup specialized in thoracic oncology. Its objective is to improve survival and quality of life for thoracic cancer patients. Established in 1999, the IFCT has its own operational infrastructure and is equipped to design, promote, and carry out clinical studies in France and internationally, and to communicate the findings thus obtained. The IFCT's activity regularly results in the introduction of new drugs or strategies that improve the efficacy, safety, and/or economic impact of anti-cancer therapies. All IFCT projects are coordinated by a Clinical Research Unit accredited by the National Cancer Institute (INCa) and the National League Against Cancer.

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