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Biomarkers France: a first and distinctive step in assessing the impact of non-small cell lung cancer (NSCLC) patients routine molecular profiling

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The French Cooperative Thoracic Intergroup (IFCT) recently published the results of the Biomarkers France study, the largest nationwide program of molecular profiling for non-small cell lung cancer (NSCLC) patients (1). As highlighted in the three editorials published by *Translational Cancer Research* regarding these results, the Biomarkers France study not only shows that a routine molecular profiling is already feasible for all of our advanced NSCLC patients, but also that identification of a molecular alteration changes their outcomes by decreasing their risk of death by 22%.

This program, launched by the French NCI, was initially designed on the basis of available actionable molecular alterations in 2006 and then improved by the addition of emerging biomarkers in 2010. The results reported in the *Lancet* are based on the molecular profiling done during 2012/2013. Obviously, several changes occurred since 2010 and multiplex testing by NGS is becoming more and more frequent, but mainly in selected centers. Indeed, the number of NSCLC patients really acceding to a molecular profiling by next-generation sequencing (NGS), across US or EU, in daily practice, has still to be assessed, and only very few examples are available to date outside clinical trials (2).

One of the main drawbacks of global health initiatives is often the lack of a comprehensive assessment on the changes provided regarding patients' outcomes. This is the justification of nationwide studies such the Biomarkers France study. In the same time, collecting data on more than 17,600 patients treated routinely by more than 3,800 physicians was not an easy task. In order to succeed, the choice was made to collect selected data only in order to maximize the chance to get the case reported forms completed by the treating physician(s). Despite some gaps in the data collected, the Biomarkers France study succeeded. This study was able to provide data regarding epidemiological characteristics, turnover time, response rates or survival for prespecified molecular alterations. Furthermore the Biomarkers France study also provided the scientific community and the health authorities with unexpected results (less than the half of EGFR mutated patients receiving an EGFR-TKI in first line, 3% and 2% of patients enrolled in clinical trials in 1st and 2nd lines, respectively, etc.). All these data will now be used to adapt the French NCI guided national initiatives but also give the background to set up comparable molecular profiling

programs in other countries. Additional improvements will come from the expanded use of NGS to identify additional molecular alterations, from the use of cfDNA to better identify and/or potentially monitor molecular alterations (resistance), from the increasing access to drugs in development across the early phases trials cancer units network (CLIP²) (3), etc. All these improvements will be benchmarked against the data collected via the Biomarkers France initiative.

The IFCT Biomarkers France #2 project, hopefully starting in 2017, will collect all these newly routinely available data in order to assess the impact of these technical and medical changes for NSCLC patients, including the advent of immune-oncology options. A second step toward precision medicine for NSCLC patients!

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