

# Determination of essential biomarkers in lung cancer: a real-world data study in Spain

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## BACKGROUND

- The survival of patients with lung cancer has increased in the last decade due to targeted therapies available for advanced stages and immunotherapy.
- The Thoracic Tumours Registry (TTR) is an observational, prospective, registry-based study that included patients diagnosed with lung cancer and other thoracic tumours, from September 2016 to date. This TTR study was sponsored by the Spanish Lung Cancer Group (SLCG), an independent, scientific, multidisciplinary oncology group that coordinates more than 550 experts and 182 hospitals across the Spanish territory.
- The main objective is to study the situation biomarker testing in Spain.

## METHODS

- The TTR was classified by the Spanish Agency for Drugs and Medical Devices (AEMPS) in 2016, and it is registered on the ClinicalTrials.gov database (NCT02941458).
- Protocol approval was obtained from the institutional ethics committee at Puerta de Hierro-Majadahonda University Hospital (No. PI 148/15)
- Patients with histologically confirmed non-small cell lung cancer (NSCLC) stage IV were eligible.

## METHODS

- Research teams collected data from patient electronic health records (EHR) using an electronic data capture system (EDC).
- Sociodemographic, epidemiological, clinical, molecular and treatment outcome variables were recorded in an electronic case report form (eCRF).

## RESULTS

- 9,239 patients diagnosed with stage IV NSCLC were analyzed.
- 7,467 (80.8%) were non-squamous and 1,772 (19.2%) were squamous.

Characteristics	Total	Non-squamous	Squamous
<b>Sex</b>			
-Male	6,623 (71.7%)	5,085 (68.1%)	1,538 (86.8%)
-Female	2,616 (28.3%)	2,382 (31.9%)	234 (13.2%)
<b>Mean age (years)</b>	64.3	63.6	67.5
<b>Smoking status</b>			
-Never smokers	1,344 (14.5%)	1,277 (17.3%)	67 (3.8%)
-Former smokers	3,989 (43.2%)	3,133 (41.6%)	856 (49.0%)
-Smokers	3,776 (40.9%)	2,953 (40.1%)	823 (47.1%)
-Unknown	130 (1.4%)	104 (1%)	26 (0.1%)
<b>Performance status</b>			
-ECOG 0	2,385 (25.8%)	1,976 (26.5%)	409 (23.1%)
-ECOG 1	4,976 (53.9%)	3,989 (53.5%)	987 (55.7%)
-ECOG ≥ 2	1,878 (20.3%)	1,502 (20.0%)	376 (21.2%)
<b>Comorbidities</b>			
-No	1,530 (17.4%)	1,334 (18.7%)	196 (11.7%)
-Yes	7,266 (82.6%)	5,785 (81.3%)	1,481 (88.3%)

## RESULTS

- Tumour marker testing was performed in 85.0% of patients with non-squamous tumours vs 56.3% in those with squamous tumours (p-value <0.001).
- In non-squamous histology, the global testing of EGFR, ALK and ROS1 was 78.9%, 64.7% and 35.6% respectively.
- PDL1 was determined globally in the same period (46.9%), although if we focus on the last 3 years it exceeds 85%.
- 4,115 cases had a positive result (44.5%) for either EGFR, ALK, KRAS, BRAF, ROS1, or PDL1.

## CONCLUSIONS

- Despite the lack of a national project and standard protocol in Spain that regulates the determination of biomarkers, the situation is similar to other European countries.
- Given the growing number of different determinations and their high positivity, national strategies are urgently needed to implement next-generation sequencing in an integrated and cost-effective way in lung cancer.

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