Aim: In the last decade, we have witnessed a revolution in the molecular genetics of NSCLC (Non Small Cell Lung Cancer). These advances have led to the development of a multitude of prognostic and predictive biomarkers. Somatic mutations in EGFR (Epidermal Growth Factor Receptor) gene & ALK (Anaplastic Lymphoma Kinase) translocation are two “actionable” biomarkers that have passed clinical validation and are incorporated into current treatment paradigms. This abstract contributes towards understanding the epidemiology of ALK mutation in NSCLC patients in India.

Methods: This was an observational study within the cohort of NSCLC patients. Pfizer Ltd supported this study as a part of Diagnostic Assistance Program. A total of 3351 patients of lung adenocarcinoma were tested from Jan 2013 to Mar 2014. These samples were collected from various locations across the country. ALK mutation was studied using the FDA approved Vysis ALK Gene Breakapart Probe Kit and the EGFR mutation testing (exons 18-21) was done using PCR followed by bidirectional Sanger sequencing.

Results: Of the 3351 samples tested, 2146 (64.04%) were male & 1205 (35.96%) were females. Patients ranged in age from 25-90yrs with a median age of 57.94yrs. Biomarker testing for EGFR and ALK was performed on FFPE specimen of patients with confirmed adenocarcinoma histology. ALK testing was performed on 3351 samples and EGFR analysis on 3079. Of samples received for EGFR, 2653 (86.16%) were successfully analyzed & reported, 177 (5.75%) showed unsatisfactory results, and test could not be performed in 249 cases (8.09%). 2810 (83.86%) samples received for ALK testing by FISH could be successfully reported, 287 (8.56%) showed unsatisfactory results and 254 samples (7.58%) could not be tested. Common reasons for unsatisfactory results were presence of high degree of necrosis, scanty tumor or suboptimal fixation. Of the successfully reported cases, 28.19% were positive for presence of EGFR mutations. Mutations were observed in exon 18 (2.27%), exon 19 (72.99%), exon 20 (3.48%) and exon 21 (21.26%). 71 (2.53%) of the 2810 successfully reported cases were found Positive for ALK Gene Rearrangement. None of the samples showed a concomitant mutation.

Conclusions: This study on 3351 adenocarcinoma enriched NSCLC patients of Indian origin, shows an ALK positivity of 2.53% & EGFR mutation positivity of 28.19%.

Disclosure: All authors declare that he study was funded by Pfizer Ltd as a part of its Diagnostic Assistance Program. Other than that there is no disclosure to declare.