Patients With PD on Brigatinib (n=107)	n	1-Year OS Post-PD,[a] % (95% CI)	Unadjusted HR (95% CI)	Adjusted HR[b] (95% CI)
Continued brigatinib	84	66(53—99)	0.32(0.17—0.62)	0.53(0.26—1.08)
At 90 mg qd (arm A without escalation)	23	62(38—99)	0.49(0.22—1.11)	0.61(0.25—1.46)
At 180 mg qd	61	68 (51—99)	0.26(0.13—0.54)	0.48(0.21—1.06)
Arm A with escalation	23	70(44—99)	0.29(0.12—0.72)	0.51(0.19—1.33)
Arm B	38	66(44—99)	0.25(0.11—0.57)	0.45(0.18—1.16)
Did not continue brigatinib	23	31(13—100)	Reference	Reference

[a]Kaplan-Meier estimate from time of first PD [b]Adjusted for duration of prior crizotinib exposure, number of prior treatment regimens (1, 2, or ≥3), time to investigator-assessed PD, PD due to new lesions only (yes/no), and ECOG performance status at PD (0, 1, or ≥2)

P1.01-006
Effect of EML-Alk Fusion Variant and Fusion Abundance on the Efficacy of Crizotinib in Non-Small Cell Lung Cancer

T. Lv, Q. Zou, Y. Song *Respiratory Medicine, Jinling Hospital, Nanjing/CN*

Background: EML4-ALK fusion gene is a molecular subtype of non-small cell lung cancer (NSCLC), which is carcinogenic both in vitro and in vivo. Most of the EML4-ALK-positive NSCLC patients have effectively sensitivity with an ALK tyrosine kinase inhibitor (TKI), such as crizotinib. However, the treatment outcomes and duration of response are heterogeneous. EML4-ALK has several variants. The effects of ALK fusion variants on the efficacy of crizotinib is still unclear, although many scientists are committed to this work. In addition, we also unknown the effects of ALK variants allele fraction (AF) on the efficacy of crizotinib. **Method:** Among 54 patients with advanced NSCLC were treated with crizotinib as the first-line or further-line ALK-TKI between 2013 and 2017, eventually, we identified 48 patients whose the tumor samples were detected by IHC(38), FISH(2), NGS(5),PCR(1) and ARMS(2). Through retrospective analysis, we assumed the efficacy of crizotinib on the basis of the PFS according to the ALK variants and its allele fraction. **Result:** Among the 29 ALK-positive patients, the most common ALK variants was variant 1 in 13 patients (44.9%), followed by variant 3 in 7 patients (24.1%), variants 2 in 2 patients (6.9%), other variants in 7 patients (24.1%). We divided all variants into two subgroups: V1/3 and V2/others. We found 35.4% of the samples test results between the next generation sequencing (NGS) and hospital immunohistochemical were not concordance. Further analysis found that patients who did not match that PFS were shorter (p=0.036). By the NGS, we observed from the figure that the variant 2/others group, the median PFS had a longer trend than V1/3 group, although not statistically significant (p>0.05). The level of AF was no correlated with PFS (P=0.346). **Conclusion:** The above results show that next-generation sequencing (NGS) can identify ALK variants and AF, therefore, NGS can be used as a supplement to a detection method. The type of EML4-ALK fusion variants may has a certain correlation with PFS in patients who oral crizotinib treatment. Since the sample size of this study is small, we have not yielded accurate results and found only these phenomena. We believe that in the near future, most NSCLC patients can be detected by NGS detection of gene mutations, especially EML4-ALK fusion gene, and according the different of the fusion gene variant type which can be estimated the efficacy of the ALK-TKIs, to provide the basis of individualized treatment options for NSCLC patients. **Keywords:** Effect, EML-Alk fusion variant, fusion abundance, efficacy of Crizotinib, NSCLC

P1.01-007
ALK Testing Trends and Patterns Among Community Practices in the United States

P. Illei,[1] W. Wong,[2] N. Wu,[2] L. Chu,[2] K. Schulze,[2] M. Gubens[3]
[1]Pathology, Johns Hopkins University School of Medicine, Baltimore, MD/US, [2]Genentech, South San Francisco, CA/US, [3]Thoracic Oncology, University of California, San Francisco, San Francisco, CA/US

Background: The CAP/IASLC/AMP molecular testing guidelines recommend ALK testing on patients with lung adenocarcinoma, regardless of clinical characteristics. FISH is the recommended assay to detect ALK rearrangement, however other assays, such as NGS and IHC, are available. There have been limited published data to assess adherence to ALK testing guidelines using large real-world data sources. The objective of this study was to assess real-world ALK testing patterns among community practices in the United States. **Method:** The Flatiron database provides real-world clinical data collected from EHRs used by US cancer care providers. The Flatiron network comprises ~15% of US cancer patients and is geographically and demographically diverse. Patients with ≥2 visits within the Flatiron Network after Jan 1, 2011, ≥18 years of age, and an stage IIIB/IV NSCLC diagnosis from 2011 through 2017 Q1 were included in this analysis. Logistic regression was used to identify patient characteristics associated with receiving ALK testing. **Result:** Of 29,903 patients identified from community-based clinics (mean age: 71.6, 52.2% male), ALK testing rates have steadily increased over time from 32.2% in 2011 to 61.0% in 2016 for all NSCLC patients, and 41.0% in 2011 to 74.0% in non-squamous patients. Patients that are younger, no history of smoking, women and living in the West region were more likely to be tested for ALK. Patients with Medicaid insurance, recurrent disease and squamous histology were less likely to be tested. The most common first assay to test for ALK was FISH (70%) followed by NGS (8%), PCR (4%) and IHC (1%). The median time from specimen receipt by lab to test result ranged from 6 days (FISH) to 11 days (NGS). Patients who had NGS testing were more likely to initiate chemotherapy prior to test result (34% of patients tested with NGS) than FISH (20%). 1235 patients had at least one FISH and another ALK test, with the percent agreement between FISH and other assays (NGS, PCR, IHC) ranging from 92% to 97%. **Conclusion:** Several patient characteristics predicted ALK testing indicating that some subgroups of patients may be under tested, according to guidelines. Consistent with guidelines, FISH was the most common assay and turnaround times from lab receipt to test result was under 2 weeks. There was a high agreement between FISH and NGS, indicating the potentially clinical utility of NGS, however NGS had also the longest turnaround time and the highest proportion of patients initiating treatment prior to test results. **Keywords:** ALK, biomarker testing

P1.01-008
Real-World Patient Characteristics, Testing and Treatment Patterns of ALK+ NSCLC

M. Gubens,[1] W. Wong,[2] N. Wu,[2] L. Chu,[2] K. Schulze,[2] P. Illei[3]
[1]Thoracic Oncology, University of California, San Francisco, San Francisco, CA/US, [2]Genentech, South San Francisco, CA/US, [3]Pathology, Johns Hopkins University School of Medicine, Baltimore, MD/US

Background: Based on clinical trials, ALK+ patients have been described as typically younger and never/former smokers, however patients enrolled in clinical trials may be different than those in the real-world. While the ALK positivity rate has been described as about 4% among all NSCLC patients, limited information is available on the positivity rates in patient subgroups. The objective of this study is to describe the real-world ALK positivity rates, patient characteristics and treatment patterns in ALK+ NSCLC patients. **Method:** The Flatiron database provides real-world clinical data collected from EHRs used by US cancer care providers. The Flatiron network comprises ~15% of US cancer patients and is geographically and demographically diverse. Patients with ≥2 visits within the Flatiron Network after Jan 1, 2011, ≥18 years of age, ≥1 ALK+ test result and an stage IIIB/IV NSCLC diagnosis from 2011 through 2017 Q1 were included in this analysis. Logistic regression was used to examine the association of ALK positivity and initiation of ALK inhibitor therapy based on patient characteristics. Survival model adjusting for censoring was used to estimate the time to ALK inhibitor order. **Result:** 599 out of 15,551 ALK tested patients were identified to have an ALK positive test result, for a positivity rate of 3.9%. The ALK positivity