Title: Prospective Advanced Non-small Cell lung cancer Holistic Registry (ANCHoR Project)

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Background:
Anti-PD-1/PD-L1 antibodies including pembrolizumab, nivolumab and atezolizumab have entered clinical practice in the management of metastatic NSCLC as monotherapy and immunotherapy-based combinations. We have established a real-world prospective Advanced (Stage IV) Non-small Cell Cancer Holistic Registry (ANCHoR project). The goal is to determine the treatment choice and treatment sequence by PD-L1 status in the various histo-molecular categories of NSCLC. Additionally, we also seek to understand the impact of such treatment choice on treatment results (response rates, progression-free survival (PFS), and overall survival (OS)) and patient reported outcomes (PROs).

Methods:
Patients with a metastatic NSCLC diagnosis who are treated at MD Anderson Cancer Center between January 1, 2017 and December 31, 2020 are enrolled for the study project. The study period will end on June 30, 2021 to allow a minimum of six months of follow-up. Patient’s demographic, diagnostic, clinical, molecular (biomarker and PD-L1), treatment (regimens utilized in sequence and reason for discontinuation), response and survival (including PFS and OS), health care resource utilization, and PROs are collected and integrated in a comprehensive database. PRO is measured longitudinally by EQ-5D-5L and MDASI-LC instrument.

Results:
Seventy six patients with median age of 63 years (40 males) have been enrolled within two months. Fifty four are current or former smokers while 22 were never
smokers. Majority (N=61) had adenocarcinoma, 10 squamous cell carcinoma, four non-small cell carcinoma NOS, and one large cell neuro endocrine carcinoma. Sixty one patients had stage IV disease as an initial diagnosis. 71 % (N=54) patient with 0 or 1 ECOG PS at the time of consent. A total of 82.9% (63/76) patients were tested for PD-L1, 13.1% (10/76) were not tested (7 due to absence of test order by the treating physician and 3 due to lack of enough tissue), and 3.9% (3/76) had an unknown testing status. PD-L1 TPS was <1% in 34.9%, 1-49% in 39.7%, and ≥50% in 25.4% patients. PD-L1 testing rate was 93.9% in male smokers and 76.2% in female smokers (p=0.017).

**Conclusions:**
The ANCHoR is a first of its kind, prospective database that integrates demographic, clinical, molecular, treatment, response and survival, and patient reported outcomes data. This database is scalable to other institutions. Machine learning algorithms can be used to make complex data analyses possible in the future. In an early and preliminary analyses of this data set we find that there is statistically significant tendency to test males more than females.