TCR A/B, TCR G/D, cytotoxic markers, EMA, Ki-67 proliferation index. The induction chemotherapy and response rate in patients with SC/LH ALK+ ALCL were similar to patients with non-SC/LH ALK+ ALCL. After a median follow-up of 30.5 months (range, 0.3–224 months), there was no significant difference in OS between patients with SC/LH versus non-SC/LH ALK+ ALCL ($p = 0.88$).

Conclusions In adults with ALK+ALCL, the SC/LH morphologic pattern is associated with a CD8+ T cell immunophenotype and retention of expression of T cell markers (CD2, CD3, and CD7). The trend of decreased PD-L1 expression in SC/LH ALCL suggests that these patients may not be ideal candidates for PD-L1 immunotherapy. The SC/LH patterns of ALK+ ALCL have no impact on the prognosis of adult patients which is in contrast to the reported association of the SC/LH patterns with poorer outcome in children with ALK+ ALCL.

Ethics Approval The study was approved by the Institutional Review Board at MD Anderson Cancer Center, Approval number: PA16-0897

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ADVANCED T LYMPHOCYTE ANALYSIS SYSTEM (ATLAS) FOR IN-DEPTH IMMUNOLOGICAL INTERROGATION IN REAL-WORLD CONDITIONS, A METHODOLOGICAL STRATEGY

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Background Humans are genetically diverse and possess a rich immunological history. It is logical to consider that these factors may lead to differences in individual immunological responses to therapy when diagnosed with cancer. The successful implementation of immune-based therapies against cancer has brought the need to develop strategies to create meaningful profiles that faithfully depict the patient's immunological status. We report an in-depth immunological interrogation methodology, termed ATLAS. This system was designed to generate an accurate representation of the patient's immunological landscape that can be used during various time points during immune-checkpoint inhibitor (ICI) therapy.

Methods We selected data from our prospective registry trial at Loyola University Medical Center to design individual immunological profiles of patients diagnosed with locally advanced or metastatic solid tumors planning to receive ICI. Only metastatic melanoma patients samples pre-ICI therapy are included in this first analysis. Twenty mL of peripheral blood were collected. Giving consideration to scientific rigor and limited sample availability, the assays were designed in miniaturized forms. ATLAS includes classical peripheral blood mononuclear cells (PBMCs) composition and T cell phenotypic and transcriptional analysis. To depict T cell functionality, we examined multiple parameters such as T cell receptor (TCR) signaling threshold, cell proliferation and NF- κ B activation, at

steady-state and in response to cell activation. To obtain both a broad and T cell-specific view, we quantified circulating chemokines and cytokines in plasma and from activated T cells.

Results For this first methodologic demonstration, patient characteristics are depicted in table 1. Data from different ATLAS assays were used to create individual immunological profiles presented as a dashboard for each patient. Distributional plots and measures of center (mean, median) and spread (range, variance) were used to eliminate low-information parameters from the figures. Data visualizations compared individual patients to the sample median for continuous parameters and

Abstract 52 Table 1 Patient characteristics

Table 1: Patient characteristics	Overall, n=11
Age, mean (SD)	56.5 (13.2)
Female, n (%)	5 (45.5)
Comorbidities and medical history, n (%)	
Diabetes	1 (9.1)
Hypertension	4 (36.4)
Hyperlipidemia	1 (9.1)
Autoimmune	1 (9.1)
BPH	1 (9.1)
Multinodular Goiter	1 (9.1)
Breast Cancer	1 (9.1)
Arthritis	1 (9.1)
Tobacco use	4 (36.4)
Alcohol use	2 (18.2)
Lab values, mean (SD)	
Hemoglobin	13.2 (1.6)
Platelets	279 (116)
Neutrophils	5.4 (2.5)
LDH	354 (376)
BUN	15.7 (5.5)
Creatinine	0.88 (0.24)
Calcium	9.4 (0.4)
Bilirubin	0.91 (0.34)
Started ICI, n (%)	9 (81.8)
No chemotherapy before ICI, n (%)	3 (27.3)
Metastases location, n (%)	
Brain	3 (27.3)
Lung	7 (63.6)
Cer. Lymph Nodes	1 (9.1)
Tho. Lymph Nodes	3 (27.3)
Med. Lymph Nodes	3 (27.3)
Abd. Lymph Nodes	2 (18.2)
Pel. Lymph Nodes	2 (18.2)
Liver	1 (9.1)
Bone	3 (27.3)
Other	3 (27.3)
ECOG Status Pre-ICI, n (%)	
0	5 (45.5)
1	4 (36.4)
2	2 (18.2)

Abstract 52 Figure 1 Patient 011 dashboard

Abstract 52 Figure 2 Patient 021 dashboard

compared patients' percentages to sample average relative abundance. Two patients, P011 shown in figure 1 and P021 shown in figure 2, are depicted using this approach.

Conclusions ATLAS can be used in real-world conditions to generate comprehensive immunological profiles of cancer patients. Individual profiles indicate that immunological constitution is heterogeneous among patients, even with the same tumor type. We propose that the addition of ATLAS to our clinical and immunological toolbox may help stratify patients to articulate truly personalized oncologic therapies.

Ethics Approval The study was approved by Loyola University Medical Center and Loyola University Chicago Ethics Board and Institutional Review Board, approval number 209364.

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PREDICTORS OF RESPONSE TO IMMUNE CHECKPOINT INHIBITOR THERAPY IN METASTATIC SOLID TUMORS: REAL WORLD EVIDENCE

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Background Immune checkpoint inhibitor (ICI) therapy is increasingly being used in oncology and novel predictive biomarker for efficacy and side effects are an unmet need.^{1,2} The study aims to do a comprehensive analysis of factors affecting outcome from ICI therapy with real-world data and identify potential predictive biomarkers in diverse populations. **Methods** We performed a retrospective analysis of patients with metastatic solid tumors who received ICI and underwent molecular profiling with FoundationOne® CDx panel between 2016 and 2020 at Markey Cancer Center, Lexington KY. Progression-free survival (PFS), radiological response, and autoimmune side effects were analyzed and compared with various molecular biomarkers (figure 1). Logistic regression, Fisher's exact test, Kaplan-Meier method, log-rank test, and Cox regression were used to analyze clinical features and efficacy outcomes.

Results 69 patients were included in the study (tables 1 and 2). A statistically significant improvement in PFS was observed in the PIK3 mutated cohort (median 123 vs. 23 weeks. HR=2.51. 95%CI 1.23, 5.14; table 3 and figure 2). This was independent of tumor mutational burden (TMB) status or PDL1 expression status (HR 3.24, p=0.016). PIK3 mutants had a higher overall response rate (ORR) than the wild type

(69.6% vs. 43.5%, OR 0.34; p=0.045; tables 3 and 4). PIK3 mutants had a higher risk of developing immune-related adverse events (IRAEs) (73.9% vs. 37%, p=0.004). PIK3 mutation did not associate with TMB, PDL1 expression or microsatellite stability status. Median PFS was higher in the high TMB cohort compared to the low-intermediate group and reached statistical significance (median not reached vs. 26

Abstract 53 Figure 1 Mutational analysis of patients receiving immunotherapy grouped based on radiologic response, in the order of mutational load and frequency of mutations

Abstract 53 Table 1 Baseline characteristics of the study population

Characteristics	Total (%)
Age group	
18-64	40 (58)
65-74	19 (27.5)
≥ 75	10 (14.5)
Male: Female	36 (52.2): 33 (47.8)
Race	
Caucasian	63 (91.3)
African American	4 (5.8)
Hispanic	1 (1.4)
Asian	1 (1.4)
Cancer Site	
NSCLC	26 (37.7)
SCC Head & Neck	8 (11.6)
Melanoma	7 (10.1)
Gastrointestinal	7 (10.1)
Kidney/Bladder	6 (8.6)
Small Cell lung Cancer	5 (7.2)
Hepatobiliary	2 (2.9)
Breast	2 (2.9)
Ovary and uterus	2 (2.9)
Thyroid	2 (2.9)
Merkel Cell	1 (1.4)
Unknown primary	1 (1.4)
Tobacco use	
Current/previous use	54 (78.3)
Never used	15 (21.7)
NSCLC: Non-small cell lung cancer, SCC: Squamous cell carcinoma	