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39P OLIMPIA dataset: Radiomics to predict outcomes in EGFR-mutant non-small cell lung cancerG. Pérez¹, J.N. Minatta², M. Aineseder³, C. Mosquera¹, S.E. Benitez¹¹Health Informatics Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina; ²Oncology Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina; ³Radiology Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina**Background:** Non-small cell lung cancer (NSCLC) with a detectable EGFR mutation represents up to 50% of cases depending on the geographic area. There are currently 5 approved tyrosine kinase inhibitors (TKI), including first, second, and third generations. Although osimertinib is currently the standard of care, cost-effectiveness could be improved by identifying patients who will present longer progression-free survival with more accessible treatments. We propose a non-invasive approach to identify risk of progression based on imaging biomarkers (radiomics) from the pre-treatment CT scan.**Methods:** We included 60 histologically proven cases of NSCLC with confirmed EGFR mutations. We evaluated progression at 12-months after starting TKI therapy: 32 patients showed disease progression and 28 did not. We manually segmented lesions in pre-treatment CT scans and extracted radiomic features. We applied machine learning techniques for dimensionality reduction and classification of patient outcomes. We compared the predictive power of this radiomics model to a logistic regression model trained solely on clinical data: gender, age, and smoking status. We used cross validation to calculate diagnostic metrics, reported as mean \pm std.**Results:** The final radiomics model is an ensemble of 12 classifiers trained with 20 features from principal component analysis. For the prediction of disease progression, the radiomics model showed a sensitivity of 0.84 ± 0.12 , specificity 0.70 ± 0.41 , positive predictive value 0.79 ± 0.23 and negative predictive value 0.67 ± 0.39 . Comparing radiomics to the regression with clinical data, they showed respectively an area under the ROC curve of 0.82 ± 0.15 vs. 0.39 ± 0.11 , and an area under the precision-recall curve of 0.82 ± 0.18 vs. 0.52 ± 0.13 . This suggests that the radiomics model has stronger predictive power than basic clinical data.**Conclusions:** Up to date, there is no publicly available dataset to target this issue. No previous work has addressed this problem in Latin American populations. Our results are presented as a baseline and we plan to release publicly the current dataset to motivate further studies on this topic. These results suggest that radiomics is a promising approach to predict progression in patients treated with TKI therapy.**Clinical trial identification:** Hospital Italiano de Buenos Aires IRB approval N°5647. Date: June 1st 2020.**Legal entity responsible for the study:** Hospital Italiano de Buenos Aires.**Funding:** Has not received any funding.**Disclosure:** All authors have declared no conflicts of interest.<https://doi.org/10.1016/j.annonc.2022.01.048>**40P** Real-world clinical genomic analysis of patients with BRAF mutated cancers identifies BRAF class II and III as a population of unmet medical needP. Severson¹, W. Kellner², A. Franovic¹, N. Miller¹, E. Murphy¹, E.S. Martin¹, R. Williams³¹Translational Medicine, Kinnate Biopharma, San Diego, CA, USA; ²Translational Science, Tempus Labs, Chicago, IL, USA; ³Clinical Development & Translational Medicine, Kinnate Biopharma, San Diego, CA, USA**Background:** Oncogenic BRAF mutations can be categorized into three classes (I, II and III) based on their distinct structural and signaling properties. BRAF inhibitors are approved in select cancer types for patients with Class I mutations. However, there are no approved targeted therapies for patients whose tumors bear BRAF Class II or III mutations. This research utilizes a clinico-genomic database to explore the real-world occurrence, characteristics, and outcomes of patients with oncogenic BRAF mutations by distinct classes across solid tumors.**Methods:** Analyses utilized a de-identified database containing genomic data from over 55,000 cancer patients whose tumors were profiled using the Tempus xT assay; a 648 gene DNA panel coupled with RNA sequencing. Clinical data was also available for a subset of the patients. Time to treatment discontinuation (TTD) was used as a real-world measure of treatment benefit.**Results:** More than 3,000 patients with oncogenic BRAF mutations were identified. Class II and III mutations were present in approximately 2% of all patients tested. Melanoma and NSCLC patients with BRAF Class II or III were commonly treated with immune checkpoint inhibitors (ICI) or chemotherapy +/- ICI. At least 70% of patients with BRAF mutations had stage IV disease, and stage distribution was similar across BRAF classes. Compared to Class I, BRAF Class II and III mutations were more likely to co-occur with other mutations in the MAPK pathway and were associated with higher tumor mutation burden (TMB). In NSCLC, patients with Class II or III mutations experienced shorter times to treatment discontinuation in first line (II vs I; $p=0.04$, III vs I; $p=0.009$) and second line (II vs I; $p=0.079$, III vs I; $p=0.039$) of therapy.**Conclusions:** The analysis of this large real-world dataset identified a substantial number of cancer patients with BRAF Class II and III mutations. BRAF Class II and III mutations were associated with unique tumor characteristics, including higher TMB and more frequent co-occurrence with other MAPK pathway alterations. Relative to NSCLC patients with BRAF Class I, NSCLC patients with Class II or III mutations had inferior outcomes when treated with available therapies.**Legal entity responsible for the study:** Kinnate Biopharma Inc.**Funding:** Kinnate Biopharma Inc.**Disclosure:** P. Severson, A. Franovic, N. Miller: Financial Interests, Institutional, Full or part-time Employment: Kinnate Biopharma; Financial Interests, Institutional, Stocks/Shares: Kinnate Biopharma. W. Kellner: Financial Interests, Institutional, Full or part-time Employment: Tempus Labs. E. Murphy: Financial Interests, Personal and Institutional, Advisory Board: Kinnate Biopharma; Financial Interests, Personal, Stocks/Shares: Kinnate Biopharma. E.S. Martin: Financial Interests, Personal, Stocks/Shares: Kinnate Biopharma. R. Williams: Financial Interests, Institutional, Full or part-time Employment: Kinnate Biopharma; Financial Interests, Institutional, Stocks/Shares: Kinnate Biopharma.<https://doi.org/10.1016/j.annonc.2022.01.049>**41P** The SARS-CoV-2 vaccine and enrollment of patients with cancer in phase I trials: The experience at Institute Gustave RoussyL. Belcaid¹, C. Baldini², A. Laparra²¹Department of Medical Oncology, Rigshospitalet, Copenhagen, Denmark; ²Drug Development Department, Institut Gustave Roussy, Villejuif, France**Background:** The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been associated with a disruption of all components of cancer care from screening, diagnosis, surveillance, treatment and clinical trial enrollment. Patients with cancer are considered a priority for SARS-CoV-2 vaccination. However, no data are available regarding patients with cancer enrolled in phase I trials and vaccination status.**Methods:** We conducted a retrospective chart review, single-center study, to observe the relationship between patients enrolled in a phase I trial and SARS-CoV-2 vaccination. Between January and June 2021, 178 patients with cancer were enrolled in a phase I trial at Institute Gustave Roussy.**Results:** Out of the 178 patients, vaccine status was available for 143 patients (100%). Among them 107 patients (75%) were vaccinated, and 7 patients (5%) did not want to be vaccinated. Out of the 107 patients (100%) who were SARS-CoV-2 vaccinated, 70 patients (65%) were treated by immunotherapy and 23 patients (22%) were in trials with a risk of developing cytokine release syndrome (CRS). Of the 107 patients, 18 patients (17%) had been vaccinated by SARS-CoV-2 from 21 days before and up to cycle 1 day 1 (C1D1) of their investigational medicinal product (IMP), and 9 patients (8%) had been vaccinated up to 21 days after C1D1. Out of the 9 patients, two patients vaccinated with Pfizer-BioNTech developed a pulmonary embolism detected by imaging 48 and 51 days after initiation of the patients' trial IMP. The pulmonary embolisms were not considered to be related to the Pfizer-BioNTech vaccine according to the safety data on the Pfizer-BioNTech vaccine. Among the 23 patients receiving their IMP at risk of CRS, 9 patients were SARS-CoV-2 vaccinated after C1D1. None of the 9 patients experienced any severe infusion related reaction after the vaccination.**Conclusions:** These findings demonstrate SARS-CoV-2 vaccine enthusiasm in patients enrolled in phase I oncological trials. Our study illustrates that the patients vaccinated up to 21 days after the initiation of their IMP did not experience any additional adverse events. Therefore, we suggest that phase I trials should not delay the SARS-CoV-2 vaccination in this specific population.**Legal entity responsible for the study:** The authors.**Funding:** Has not received any funding.**Disclosure:** All authors have declared no conflicts of interest.<https://doi.org/10.1016/j.annonc.2022.01.050>**42P** BAL0891: A novel, small molecule, dual TTK/PLK1 mitotic checkpoint inhibitor (MCI) with potent single agent activityH.A. Lane¹, E. Zanini¹, N. Forster-Gross¹, K. Litherland², F. Bachmann¹, L. Bury¹, N. Willemsem-Seegers³, J. De Man³, D. Vu-Pham³, W. Van Riel³, G. Zaman³, R. Buijsman³, A. Groner¹, M. Roceri¹, K. Burger¹, P. McSheehy¹, L. Kellenberger¹¹Research, Basilea Pharmaceutica, Basel, Switzerland; ²Development, Basilea Pharmaceutica, Basel, Switzerland; ³Research, Netherlands Translational Research Center B.V., Oss, Netherlands**Background:** BAL0891 is a dual inhibitor of threonine tyrosine kinase (TTK) and polo-like kinase 1 (PLK1). These kinases collaborate in activating the mitotic spindle assembly checkpoint (SAC) at the kinetochore (KT) ensuring correct chromosomal segregation. Here the dual activity of BAL0891 on TTK and PLK1 in tumor cells was linked to profound effects on SAC integrity, rapid induction of aberrant mitosis and