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**Introduction:** TIM-3 and PD-1 are markers of T-cell exhaustion co-expressed on tumor-infiltrating T cells (CD4+, CD8+) and antigen presenting cells in lung cancer. TIM-3 expression has also been associated with poor overall survival (OS) outcomes in NSCLC. In the Phase 1 AMBER study (NCT02817633), cobolimab (GSK4069889, a TIM-3 inhibitor) plus dostarlimab (a PD-1 inhibitor) showed clinical responses with an acceptable safety profile in patients with heavily pretreated, PD-1/PD-L1 relapsed/refractory, advanced or metastatic NSCLC. COSTAR Lung (NCT04655976) aims to compare the efficacy and safety of cobolimab plus dostarlimab and standard of care chemotherapy (CT, docetaxel; Arm A) to dostarlimab plus docetaxel (Arm B) to docetaxel alone (Arm C) in patients with PD-1/PD-L1 relapsed/refractory NSCLC. **Methods:** This is an ongoing global, multicenter, parallel-group treatment, randomized, Phase 2, open-label, 3-arm study, with the potential for a Phase 3 expansion. Eligible patients will be  $\geq 18$  years old, with pathologically confirmed advanced/metastatic NSCLC (squamous or non-squamous) who have received  $\leq 2$  prior lines of therapy that include an anti-PD-1/PD-L1 therapy plus platinum-based CT only. Additional inclusion criteria are documented radiological disease progression on prior therapy, confirmed PD-L1 status, absence of sensitizing *EGFR*, *ALK*, or *ROS-1* mutations, and ECOG PS 0-1. Patients will be randomized 2:2:1 to Arm A, Arm B, or Arm C. Patients will receive cobolimab (300 mg IV), dostarlimab (500 mg IV), and/or docetaxel (75 mg/m<sup>2</sup> IV) Q3W. Cobolimab and dostarlimab treatment will continue until disease progression, unacceptable toxicity, patient withdrawal, investigator's decision, or death. Docetaxel treatment will continue for  $\geq 4$  cycles or until unacceptable toxicity or disease progression. The primary endpoint is OS for Arms A or B vs C. Secondary endpoints include OS for Arm A vs B and investigator-assessed confirmed objective response rate (ORR); progression-free survival (PFS) and duration of response (RECIST v1.1); quality of life assessments; safety; and tolerability. Exploratory endpoints include investigator-assessed confirmed ORR and PFS (iRECIST), pharmacokinetics, biomarkers of response, and patient-reported efficacy and tolerability. Approximately 250 patients will be randomized to the Phase 2 portion with an interim analysis planned after at least 18 weeks of follow-up. An additional 500 patients (n=200 each in Arms A-B and n=100 in Arm C) may be included in the Phase 3 portion. **Funding:** GSK (213410). Editorial support provided by Fishawack Indicia Ltd., UK, part of Fishawack Health, and funded by GSK.

### P1.11-02

#### Combined Regimen of Anlotinib and Trametinib for NSCLC Patients Harboring Pan-KRAS Mutation without KRASG12C



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**Introduction:** KRAS mutation accounts the one of the most frequent alterations in non-small cell lung cancer (NSCLC). For 40 years, the KRAS mutations had been considered undruggable until the advent of inhibitors targeting KRAS<sup>G12C</sup>, but it just covered about 13% of NSCLC. The strategy of approximately 20% of NSCLC harboring other KRAS mutation types including KRAS<sup>G12F</sup>, KRAS<sup>G12D</sup>, KRAS<sup>Q61H</sup>, KRAS<sup>G12V</sup> and KRAS<sup>G12A</sup> is still considered elusive. **Methods:** Here we evaluated a novelty combination strategy of MEK inhibitor-trametinib and multi-targeted TKI-anlotinib for pan-KRAS mutant NSCLC harboring KRAS<sup>G12F</sup>, KRAS<sup>G12D</sup>, KRAS<sup>Q61H</sup>, KRAS<sup>G12V</sup> and KRAS<sup>G12A</sup>, as well as KRAS<sup>G12C</sup>. A series of *in vitro* and *in vivo* experiments were performed to examine the synergistic effect of the combined regime of trametinib plus anlotinib. Furthermore, a phase I clinical trial

(NCT04967079) was performed to explore the potential clinical value of the combined regimen for the NSCLC patients harbouring pan-KRAS mutation without KRAS<sup>G12C</sup>. **Results:** In preclinical, co-blocking of MEK pathway and anlotinib-covered targets via the combination strategy demonstrated its clinical translational potential for the pan-KRAS mutant NSCLC. Clinically, our results of clinical trial provided the primary results that 6 of 10 NSCLC (harboring the mutation of KRAS<sup>G12F</sup>, KRAS<sup>G12D</sup>, KRAS<sup>Q61H</sup>, KRAS<sup>G12V</sup>, KRAS<sup>G12A</sup>, respectively) had remarkably responses after receiving at least 1 cycle of combination treatment. **Conclusions:** Collectively, this study indicated the potential of the novelty combination of anlotinib and trametinib a strategy against the NSCLC patients harbouring pan-KRAS mutation without KRAS<sup>G12C</sup>. **Keywords:** Targeted Therapy and Immunotherapy Combination, Immunogenic Cell Death, Tumour Microenvironment Remodeling

## P1.12 MANAGEMENT OF LUNG CANCER IN THE ERA OF COVID-19, SUNDAY, AUGUST 7, 2022 - 17:00 - 19:00

### P1.12-01

#### Lung Cancer Screening in the COVID-19 Era: Understanding Program-Level Impact



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**Introduction:** Lung Cancer Screening (LCS) via Low Dose Computed Tomography (LDCT) reduces lung cancer mortality, yet utilization has remained low even before the onset of the COVID-19 pandemic and the resulting disruption to screening (Aberle et al., 2011; de Koning et al., 2020; Jemal, 2017). The impact of COVID-19 on specific LCS program components and how this has led to differences in LCS uptake is unknown. Understanding program-level barriers experienced in the context of COVID-19 will help guide resource allocation and inform optimization of LCS in the future. **Methods:** The GO2 Foundation for Lung Cancer conducts an annual, retrospective survey of United States (US) LCS programs meeting comprehensive screening standards designated as Screening Centers of Excellence in Lung Cancer Screening (SCOE). Our academic lung center partnered with the GO2 Foundation to add additional questions related to delivering LCS in the context of COVID-19. We conducted descriptive statistical analysis of survey results from 2021, reflecting the 2020 screening year, to understand LCS program demographics and self-reported perception of LCS program components most affected by COVID-19. **Results:** Ninety-nine programs completed the survey with 61% representing multi-site centers. Programs represented a broad US sample with the Southern, Northern, Midwestern, and Western regions representing 33%, 28%, 25%, and 13% of respondents, respectively. Together, community hospital-affiliated programs including both teaching and non-teaching sites, represented 67% of respondents while academic medical centers represented 10% of respondents. Programs reported a median of 868 patients (Range 0 - 7,930; SD 1267) screened in 2020. Components most commonly cited as being somewhat or significantly compromised by the COVID-19 pandemic were patient recruitment (85%), in-person consultation (79%), patient education (71%), access to radiology services (67%), and smoking cessation (60%). Coordination of care and timely reporting of results were felt to be unaffected by COVID-19 by 71% and 85% of respondents. Sixty-two percent of respondents felt the use of telemedicine had been improved somewhat or significantly. **Conclusions:** Our findings suggest some of the most critical components of screening, those associated with recruitment, maintaining optimal patient communication,

access to CT services, and smoking cessation efforts, were most vulnerable to compromise. Our findings also suggest that once patients had completed the LDCT scan, screening workflows were relatively unaffected. These findings underscore the role telemedicine can play in the delivery of LCS within the context of COVID-19 when in-person visits are placed on hiatus. More research is needed to fully understand and optimize the use of telehealth visits to conduct patient recruitment, education, and smoking cessation efforts. The importance of the ongoing participation in this survey effort cannot be overstated as it establishes a longitudinal understanding of real-world LCS challenges, particularly in the context of COVID-19, and helps guide targeted solutions to optimize the future of LCS. **Keywords:** Lung Cancer Screening, Covid-19, Patient Education

## P1.12-02

### The Impact of COVID-19 on Quality of Care for Lung Cancer - Analyses of Prospective Clinical Data from The EnRICH Cohort



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**Introduction:** The COVID-19 pandemic has impacted healthcare systems worldwide, causing substantial changes to routine healthcare delivery such as a shift to virtual-health consultations, and postponed or cancelled planned-procedures. Simultaneously, patients have changed their healthcare-seeking behaviours. In New South Wales (NSW), Australia's most populous State, there were sizeable declines in a wide range of healthcare activities from March-June 2020 compared with the same period in 2019, prior to the emergence of COVID-19. Of note, were decreases of 22.1% in primary care face-to-face consultations, 13.9% in emergency department visits, and 32.6% in public-hospital planned surgical activity. There is a need to understand how these changes in healthcare delivery have affected quality-of-care and outcomes for lung cancer. The EnRICH program, a prospective clinical cohort of over 2000 consecutive patients diagnosed with lung cancer between 2016 and 2021 in regional and metropolitan hospitals across the State, is ideally placed to examine the impact of COVID-19 on quality-of-care for lung cancer in NSW. The EnRICH dataset includes comprehensive patient, diagnostic, treatment, and outcome data, mapped against evidence-based clinical-quality-indicators (QIs). **Methods:** Sample: Pre-COVID cohort, n=1144 patients diagnosed 8 September 2016 to 10 March 2020; post-COVID cohort, n=849 patients diagnosed 11 March 2020 (date COVID-19 declared global pandemic by World Health Organisation) to 29 October 2021. Data collection: Clinical data are extracted from medical records longitudinally. This analysis reports data collected to 12-months post-diagnosis. Statistical methods: Patient characteristics and performance against QIs were compared between pre- and post-COVID-19 cohorts using Wilcoxon rank sum and chi-square tests. One-year survival was compared using Kaplan-Meier estimates. **Results:** Patient and disease characteristics were similar in the pre- versus post-COVID-19 cohorts (median age 70; 55% v53% male; 88%v80% NSCLC, 42%v40% stage IV). Fewer patients received a diagnosis within 28-days of presentation with symptoms in the post-COVID-19 cohort (80%v75%; p=0.01) (Table1). The proportion of stage III patients discussed by a multidisciplinary team (MDT) and the proportion of those with advanced disease promptly referred to palliative care improved post-COVID-19. There was no significant difference in the proportion of patients commencing treatment within 28-days of diagnosis. One-year survival did not differ (70%v71%; p~0.54).

**Table 1. Performance against quality indicators pre- and post-COVID-19**

ALL PATIENTS	Pre-COVID-19 N=1144 <sup>1</sup>	Post-COVID-19 N=849 <sup>1</sup>	p value <sup>2</sup>
<b>Diagnostic Quality Indicators</b>			
Proportion diagnosed within 28 days of first presentation	910 (80%)	582 (75%)	0.01
Proportion with a pathological diagnosis within 28 days of first presentation	668 (61%)	419 (56%)	0.078
Proportion of Stage III patients reviewed by MDT	341 (54%)	277 (60%)	0.037
Proportion of Stage IV patients with molecular testing	343 (96%)	220 (97%)	0.4
<b>Treatment Quality Indicators</b>			
Proportion of Stage I-III patients commencing curative treatment with 28 days of diagnosis	129 (24%)	101 (27%)	0.2
Proportion of Stage IV patients commencing systemic treatment with 28 days of diagnosis	87 (21%)	75 (26%)	0.14
Proportion of Stage IV patients referred to palliative care within 8 weeks of diagnosis	146 (48%)	108 (60%)	0.014
<b>Outcome Quality Indicators</b>			
1-year survival <sup>3</sup>	70% (67, 73) <sup>4</sup>	71% (68, 75) <sup>5</sup>	~0.54

<sup>1</sup>n (%) <sup>2</sup>Pearson's Chi-squared test <sup>3</sup>Kaplan Meier estimates (95% CI) <sup>4</sup> Median follow-up 3.1 years <sup>5</sup> Median follow-up 1.2 years

**Conclusions:** After the emergence of COVID-19, performance changed against several QIs. Of concern, fewer patients received a lung cancer diagnosis within 28-days, however, to date, there has been no impact on survival. Whether the observed variations are due to changes in routine healthcare delivery or changes in patient healthcare-seeking behaviour requires further investigation. **Keywords:** Quality of care, Impact of COVID-19

## P1.12-03

### Computed Tomography-based Artificial Intelligence System in the Diagnosis of COVID-19



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**Introduction:** Thorax computed tomography (CT) is the main imaging method in the diagnosis of Coronavirus disease 2019 (COVID-19) which requires an experienced radiologist, workforce and time for the interpretation of radiologic findings. In this study, it was aimed to evaluate the results of the computed tomography-based artificial intelligence (AI) system in the diagnosis of COVID-19. **Methods:** Ten thousand cases of pneumonia (COVID-19/non-COVID-19 pneumonia) or non-pneumonic lung pathologies were detected with CT. After completing machine learning with these patients' images, an AI diagnosis platform was provided by a medical technology company originating from the People's Republic of China (*Dr.Turing AI-assisted diagnosis platform Huiying Medical Technology Co., Ltd.*). Thorax CT of 30 patients (Test set 1) who were operated for lung adenocarcinoma with subsolid radiological appearance and 32 COVID-19 positive patients (Test set 2) in our center between 2011-2020 was uploaded to the platform and the diagnostic success of the platform was tested. **Results:** Automatic contour marking (automatic segmentation) of the images of the test sets was successfully achieved [Dice score=0.9 (0-1)] by the platform (Figure 1: Lung window sections of thorax CT of a