1430 DEVELOPMENT OF ICTIS: A NOVEL SCORING SYSTEM FOR THE INCLUSIVITY OF ADVANCED NON-SMALL-CELL LUNG CANCER IMMUNOTHERAPY CLINICAL TRIALS

[1]Ashley Wei*, [2]Nagashree Seetharamu, [3]Wint Yan Aung, [4]Kira Nguyen. [1]*Great Neck South High School, Great Neck, NY, USA*; [2]*Northwell Health, Lake Success, NY, USA*; [3]*Northwell Health, Manhasset, NY, USA*; [4]*Northwell Health and Feinstein Institute for Medical Research, Great Neck, NY, USA*

Background Immunotherapy has transformed lung cancer care and tremendously improved outcomes over the last decade. However, the majority of many immunotherapy trials contain overly restrictive criteria, excluding many patients and resulting in limited applicability to the general population. We propose a novel scoring system, the Immunotherapy Clinical Trial Inclusivity Scale (ICTIS), to measure the inclusivity of immunotherapy clinical trials based on publicly available eligibility criteria.

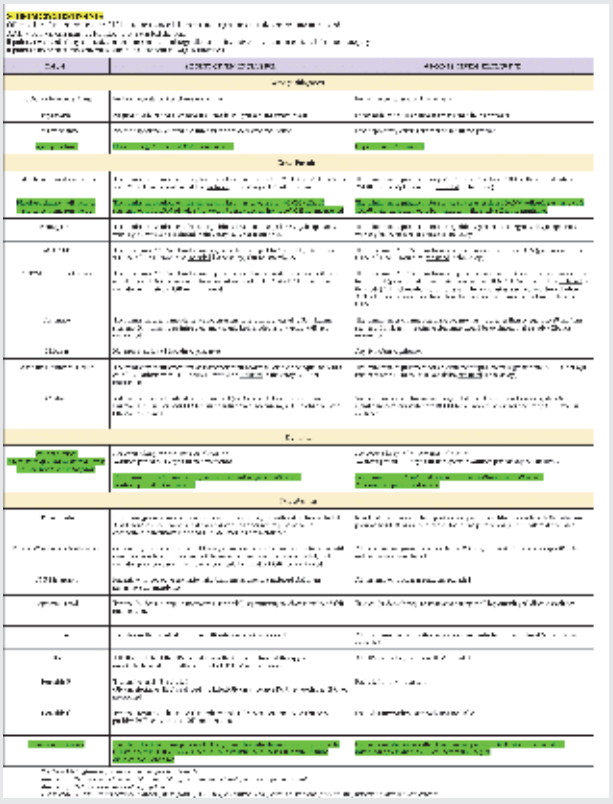
Methods National guidelines from various organizations-the FDA, ASCO, FOCR, and LUNGevity-informed the development of ICTIS. Additionally, 4 novel recommendations were created specific to lung cancer and immunotherapy. To validate the scoring system, 50 metastatic non-small-cell lung cancer (NSCLC) immunotherapy clinical trials were scored independently based on publicly available eligibility criteria to calculate Cohen's Kappa Coefficient for interrater reliability.

Results ICTIS is a 22-point summative scale based on a binary system awarding 1 point for the usage of each inclusive criterion (table 1). The points are divided across subcategories covering demographic, organ function, and comorbidity criteria. A higher ICTIS score indicates higher inclusivity and increased access to immunotherapy. Each point covers a specific criterion; if the trial follows ICTIS recommendations, it gains 1 point, and if the trial does not follow ICTIS recommendations, it gains 0 points. ICTIS addresses 4 novel criteria: age upper limit, platelets between treatment types, washout period, and bilirubin requirements. Due to lung cancer's large geriatric population, eliminating upper limit of age in the inclusion criteria was considered important and added to the scoring scale. Similarly, having an overly rigid platelet count requirement for immunotherapy monotherapy irrespective of etiology was thought to be unnecessary; and a platelet count of 100,000/μL of blood for chemoimmunotherapy and 75,000/μL of blood for immunotherapy monotherapy was thought to be more appropriate. Stringent serum bilirubin requirements were similarly felt to be unnecessary. Having specific washout periods after prior therapies was also felt to be inappropriate since this is unlikely to provide any additional tolerability prediction over other personalized eligibility criteria such as performance status and organ function. Additionally, adverse events secondary to checkpoint inhibitors can happen at any time after initiation, further making washout period criterions irrelevant.

Conclusions Overall, we created a novel scoring system that assesses an advanced NSCLC immunotherapy clinical trial's inclusivity through its eligibility criteria. 4 novel recommendations were made to broaden eligibility criteria. Through ICTIS, we hope to help investigators design immunotherapy studies to improve patient access and generalizability of results.

Acknowledgements Thank you to my partner Kira Nguyen for dedicating so much time and effort across the last year with me to this project. After everything, we have a project we can be proud of. Thank you to Ms. Spinelli, Dr. Seetharamu, and Dr. Aung for guiding and teaching us throughout this project. We could've never done it without you.

Abstract 1430 Table 1 Abbreviated Immunotherapy Clinical Trail Inclusivity Scale (ICTIS)



http://dx.doi.org/10.1136/jitc-2023-SITC2023.1430