490 DIRECT COHORT: AN NCORP LONGITUDINAL OBSERVATIONAL TRIAL FOR DISPARITIES IN RESULTS OF IMMUNE CHECKPOINT INHIBITOR TREATMENT BETWEEN BLACK AND WHITE CANCER PATIENTS

[1]Song Yao*, [1]Christine B Ambrosone, [2]Lori Sakoda, [1]Igor PuzanovCI, [3]Eva Culakova, [3]Michelle Janelsins, [1]Warren Davis, [1]Thaer Khoury, [1]Elisa Rodriguez, [1]Shipra Gandhi, [3]Allison Magnuson, [4]Guilherme Cantuaria, [5]Jennifer M Suga, [6]Rajasree P Chowdry, [2]Lawrence H Kushi, [3]Karen Mustian, [3]Gary R Morrow, [3]Charles Kamen. *[1]Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA; [2]Kaiser Permanente Northern California, Oakland, CA, USA; [3]University of Rochester School of Medicine and Dentistry, Rochester, NY, USA; [4]Northside Hospital, Atlanta, GA, USA; [5]Kaiser Permanente, Oakland, CA, USA; [6]Louisiana State University, New Orleans, LA, USA*

Background Although immune checkpoint inhibitors (ICIs) have become a mainstay in cancer immunotherapy for superior efficacy and fewer toxicities, Black and other minoritized groups have been underrepresented in randomized clinical trials for ICIs in the US. Convincing evidence indicates that Black patients have pro-inflammatory immune responses and stronger but more exhausted immune infiltration in the tumor microenvironment,[1] suggesting possibly differential efficacy and risk of immune-related adverse events in response to ICIs. Thus, it is important to address use of ICIs in diverse populations.

Methods Following a biopsychosocial model for disparity research,[2] we established the first longitudinal observational trial (ClinicalTrials.gov: NCT05364086) for disparities in ICI treatment outcomes by leveraging the NCI Community Oncology Research Program (NCORP) infrastructure to recruit patients from community oncology practices. Patients diagnosed with any cancer other than melanoma and scheduled to start anti-PD(L)-1 ICI immunotherapy according to FDA labels or NCCN guidelines as standard of care treatment alone or in combination with co-treatments, are eligible. Peripheral blood samples and clinical, laboratory and patient-reported outcome (PRO) data are collected before and after first ICI infusion, at 6 months, and annually. Saliva and archived tumor tissues are also procured. The accrual goal is 600 Black and 1,200 White patients.

Results The study was activated in 02/2022 with the 1stpatient recruited in 04/2022. As of 06/2023, 168 Black and 570 White patients have been registered; >90% participants have complete clinical and PRO data and blood at baseline. The median age at diagnosis was 62 (range: 31–85) years for Black and 66 (24–93) years for White patients. Lung cancer was the most common cancer diagnosis (34% in Blacks, 40% in Whites). A higher proportion of enrolled Black than White patients had breast cancer (30% vs. 15%), possibly due to their higher rates of triple-negative breast cancer; and a higher proportion of White patients had genitourinary cancer (16% vs. 7%). Other common cancer types include gastrointestinal, gynecological, liver cancer, and head and neck cancer. Most patients receiving ICI had stage IV disease (54% in Blacks, 60% in Whites), 3% of patients had stage I, and 15–18% stage II cancer.

Conclusions The NCORP Network provides a robust and effective infrastructure for recruiting minoritized racial and ethnic patients for cancer immunotherapy studies. When the enrollment goal is reached in 2025, the DiRECT Cohort will offer valuable resources of data and biospecimens to advance our understanding of health disparities in cancer immunotherapy.

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Trial Registration ClinicalTrials.gov Identifier: NCT05364086

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Ethics Approval For human subject protection, the study was reviewed and approved by Central IRB (URCC-21038).

Consent Written informed consent was obtained from the patient for publication of this abstract and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

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