FAST FACTS

URCC 21038 - Disparities in REsults of Immune Checkpoint Inhibitor Treatment (DiRECT):

A Prospective Cohort Study of Cancer Survivors Treated with anti-PD-1/antiPD-L1 Immunotherapy in a Community Oncology Setting

Eligibility criteria

Inclusion Criteria

- 1. Be 18 years of age or older
- 2. Self-identify as African/African American/Black (AA), or European American/Caucasian/white (EA)
 - Patients may identify a Hispanic/Latino ethnicity in combination with an AA or EA racial identity
- 3. Have a current diagnosis of invasive cancer at stage I-IV
 - Patients may have a history of previous cancer diagnosis and cancer treatment not involving immunotherapy
- 4. Be scheduled to receive anti-PD-1/-L1 ICI-containing therapy according to FDA labels or NCCN guidelines at Category 1 or 2A as standard of care treatment alone or in combination with co-treatments (including alternative ICIs)
- 5. Be able to speak and read English or Spanish
- 6. Be able to provide written or remote informed consent

Exclusion Criteria

- 1. Identify as Asian, Pacific Islander, or American Indian/Alaskan Native
- 2. Be diagnosed with melanoma (because melanoma is very rare in AAs)
- 3. Currently participate or plan to participate in any other cancer treatment trials
- 4. Have received prior immunotherapy for cancer, including checkpoint inhibitors, CAR-T therapy, and/or cytokine therapy

STUDY SCHEMA

Screen patients scheduled to receive an FDA approved anti-PD-1/-L1 immune checkpoint inhibitor (ICI) for the first time, alone or in combination with co-treatments Register and consent patients prior to the first infusion of ICIs Baseline (A1): up to two weeks before the patient's first ICI infusion, collect: - Clinical record and laboratory data - Patient Reported Outcomes (PROs) Peripheral blood samples Saliva sample Tumor samples (if available) During Treatment (A2): up to a week before the patient's second ICI infusion (usually 2-3 weeks after A1), collect: Clinical record and laboratory data Patient Reported Outcomes (PROs) Peripheral blood samples Saliva sample At each infusion while the patient is on 6 Month Follow Up (A3): 6 months ± 1 month after the first ICI infusion, ICI treatment. collect: collect Clinical record and laboratory data Cancer Patient Reported Outcomes (PROs) Treatment. Peripheral blood samples Toxicity and Response data Annual Follow Up (A4+): 1 year ± 3 months after the first ICI infusion, and yearly thereafter until patient death or study end, collect: Clinical record and laboratory data Patient Reported Outcomes (PROs) Peripheral blood samples