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
- 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 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 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 in any trials of a cancer therapeutic nature; participation in non-interventional trial, or trials of symptom control or supportive nature is allowed; participation in future cancer therapeutic trials after completing the A2 assessment (e.g. after the second infusion of ICIs) is also allowed.
- 4. Have received prior immunotherapy for cancer, including checkpoint inhibitors, CAR-T therapy, cytokine therapy, and/or Bacillus Calmette-Guerin (BCG) for bladder cancer

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 or at the patient's first ICI infusion, collect: - Clinical record and laboratory data Patient Reported Outcomes (PROs) Peripheral blood samples Saliva sample Stool sample (optional) Tumor samples (if available) On Treatment (A2): up to a week before or at the patient's second ICI infusion, collect: While the Clinical record and laboratory data patient is on Patient Reported Outcomes (PROs) treatment. Peripheral blood samples collect Cancer Saliva sample Treatment. Stool sample (optional) Toxicity and Response data Participant Qualitative Interview (optional) (at each infusion or every 3 month after the A3 6 Month Follow Up (A3): 6 months ± 1 month after the infirst ICI infusion, collect: - Clinical record and laboratory data Patient Reported Outcomes (PROs) Also collect Toxicity form Peripheral blood samples and blood sample at time of grade 3-4 Annual Follow Up (A4+): 1 year ± 3 months after the first ICI infusion, and toxicity yearly thereafter until patient death or study end, collect: Clinical record and laboratory data Patient Reported Outcomes (PROs) Peripheral blood samples