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 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 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:

- Clinical record and laboratory data
- Patient Reported Outcomes (PROs)
- Peripheral blood samples
- Saliva sample
- Stool sample (optional)

6 Month Follow Up (A3): 6 months ± 1 month after the first ICI infusion, collect:

- Clinical record and laboratory data
 - Patient Reported Outcomes (PROs)
 - Peripheral blood samples

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

patient is on ICI treatment, collect Cancer Treatment. Toxicity and Response data (at each infusion for the first 6 months, then every 3 months thereafter); Also collect Toxicity form and blood sample at time of grade 3-4

toxicity

While the