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/anti-PD-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

**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

**At each infusion** while the patient is on ICI treatment, collect Cancer Treatment, Toxicity and Response data