KCRC Kidney Cancer RESEARCH CONSORTIUM

Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer

NOW ENROLLING
150 patients

at

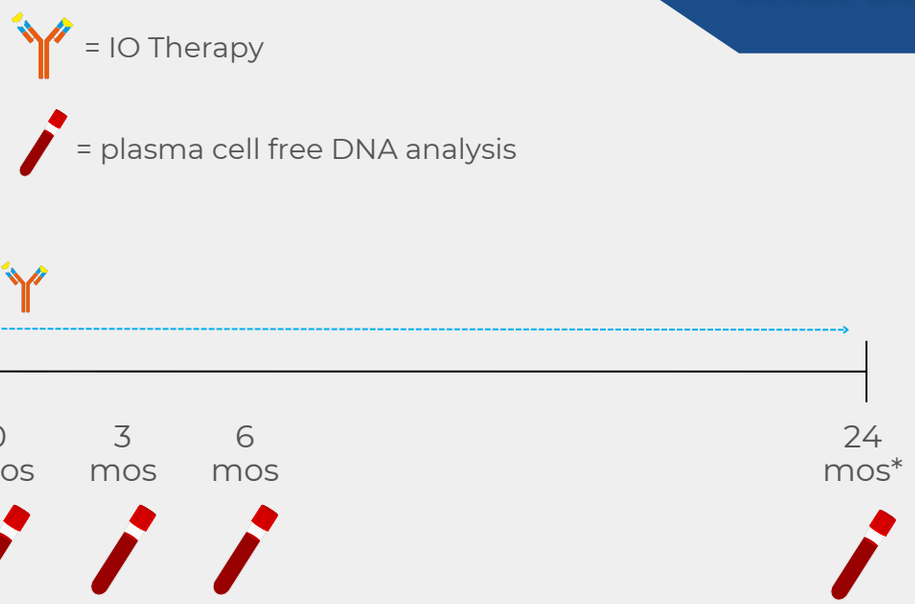
5 KCRC SITES:
Vanderbilt University
University of Michigan
University of Pennsylvania
UT Southwestern
MD Anderson Cancer Center

Initiating Site:
Dr. Scott Haake, Vanderbilt University

Summary: The study's goal is to determine if DNA released by kidney cancer can be used as a tool to check patient response to immunotherapy.

This study will evaluate tumor cell free DNA (cfDNA) as a dynamic marker of response to immuno-oncology (IO) therapy. It will also collect data on somatic mutations in cfDNA to gain insight into the biology of IO-responders and non-responders. The patient will not benefit from this study. There is potential for future patients to benefit from the information learned in this study.

Trial Schema



Primary Clinical Endpoint: 50% decrease in cfDNA tumor fraction at 6 months in IO-responders vs. non-responders.

Key Criteria

- Clear Cell Renal Cell Carcinoma
- Stage IV Metastatic Disease
- Receiving Immunotherapy-Containing Treatment Regimen
- Measurable Disease per RECIST 1.1
- > 18 Years Old
- Adequate Organ Function

Costs: There is no cost to the patient to participate in this study.

Clinic Visit Frequency: Initial visit, 3-month visit, 6-month visit, 2-year visit to complete blood draws.