Collection of Research Data and Samples From Patients Treated With Immunotherapy to Study Its Side Effects

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age:
Healthy Volunteers: This study is NOT accepting healthy volunteers

- PRE-REGISTRATION ELIGIBILITY CRITERIA: Planning to receive a regimen containing one or more IO therapeutics
- PRE-REGISTRATION ELIGIBILITY CRITERIA: Has not previously been treated with CTLA-4, PD-1 or PD-L1 inhibitors
- PRE-REGISTRATION ELIGIBILITY CRITERIA: Willing and able to provide baseline blood and stool samples
- REGISTRATION ELIGIBILITY CRITERIA: Received a regimen containing one or more immuno-oncology therapeutics
    - Must have received one or more IO therapeutics
    - In addition to one or more IO therapeutics, patients may also have received other therapeutics such as chemotherapy, hormonal or targeted therapy, as long as these are reported
- REGISTRATION ELIGIBILITY CRITERIA: Must have experienced one or more of the following:
    - One or more serious (grade 3-54) AEs that are likely immune-related. AEs included in Common Terminology Criteria for Adverse Events (CTCAE) version (v.) 5.0 that may be immune-related

  ** Patients who experience only hematologic cytopenia(s) who have received cytotoxic therapies, e.g., chemotherapy, within 60 days prior to registration should be excluded
  * One or more grade 2 dermatologic, endocrine (except diabetes/hyperglycemia) or rheumatologic AEs that are likely immune-related. AEs included in CTCAE v. 5.0 that may be immune-related
  * Diagnosis of a rare infection, e.g., fungal or mycobacterial, after starting IO treatment

  ** Note: Diagnosis of SARS-CoV-2 (COVID-19) is excluded
  * Hyperprogression. Image submission for patients experiencing hyperprogression is required. For assistance in determining hyperprogression for purposes of eligibility, institutions may contact the study chair and submit images for central review
- REGISTRATION ELIGIBILITY CRITERIA: Has not previously been registered to this study * The same patient cannot be enrolled more than once to this study due to development of subsequent irAEs

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, OTHER: Medical Chart Review
Conditions:
Hematopoietic and Lymphoid Cell Neoplasm, Immune System Disorder, Malignant Solid Neoplasm

More Information

Description:
This study collects research data and samples from patients who experience immunotherapy side effects to store for use in future research studies. Studying research data and samples from patients who experience immunotherapy side effects may help researchers better understand how to predict, prevent, and treat these side effects.

Contact(s): - cancer@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase:
IRB Number:
System ID: NCT04242095