CAR-T Long Term Follow Up (LTFU) Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 0 years to 100 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- All patients who have received a CAR-T therapy and completed or discontinued early from a Novartis sponsored treatment protocol that utilized CAR-T cells or from any CAR-T trial sponsored by the University of Pennsylvania with which Novartis has a contractual agreement to co-develop the CAR technology.
- Patients who have provided informed consent for the long term follow up study prior to their study participation .

Exclusion Criteria:

- There are no specific exclusion criteria for this study.

Conditions & Interventions

Interventions:
GENETIC: Previously treated CAR-T patients
Conditions:
Long Term Safety of Patients Receiving CAR-T in an Eligible Clinical Trial or Managed Access Program

More Information

Description:
Per Health Authorities guidelines for gene therapy medicinal products that utilize integrating vectors (e.g. lentiviral vectors), long term safety and efficacy follow up of treated patients is required. The purpose of this study is to monitor all patients exposed to CAR-T therapied for 15 years following their last CAR-T (e.g. CTL019) infusion to assess the risk of delayed adverse events (AEs), monitor for replication competent lentivirus (RCL) and assess long-term efficacy, including vector persistence.

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