ASCO® CENTRA
Center for Research & Analytics

TAPUR Study

Overview

The TAPUR study is a phase II, prospective, nonrandomized basket clinical trial that aims to describe the safety and efficacy of commercially available, targeted anti-cancer drugs prescribed for treatment of patients with advanced cancer that has a potentially actionable genomic variant. TAPUR uses a Simon two-stage design to study Food and Drug Administration (FDA)-approved targeted therapies that are contributed by collaborating pharmaceutical companies, catalogue the choice of molecular profiling test by clinical oncologists and develop hypotheses for additional clinical trials. More information can be found in the publications below and at the following website: https://clinicaltrials.gov/study/NCT02693535.

Data collected for the TAPUR Study include clinical and genomics data across non-randomized arms or cohorts. All patients who receive treatment with a drug available in the protocol are followed for standard toxicity and efficacy outcomes including tumor response, progression-free and overall survival as well as duration of treatment and high grade or serious adverse events. We plan to make available a subset of data from previously published cohorts and select data elements.

Key Publications

Mangat PK, Garrett-Mayer E, Perez JK, Schilsky RL. The Targeted Agent and Profiling Utilization Registry Study: A pragmatic clinical trial. Clinical Trials. 2023;20(6):699-707. doi:10.1177/17407745231182013

Mangat PK, Halabi S, Bruinooge SS, Garrett-Mayer E, Alva A, Janeway KA, Stella PJ, Voest E, Yost KJ, Perlmutter J, Pinto N, Kim ES, Schilsky RL. Rationale and Design of the Targeted Agent and Profiling Utilization Registry (TAPUR) Study. JCO Precis Oncol. 2018;2(2):1-14. doi: 10.1200/PO.18.00122

Types of Data Collected

- Screening (e.g., reason for screen fail)
- Demographics (e.g., age, race, ethnicity, sex)
- Clinical
    - Diagnosis/tumor type (e.g., ICD-10 diagnosis code, histology code)
    - Prior lines of therapy (e.g., systemic, radiation, surgery)
    - Physical exam (e.g., height, weight, smoking status)
    - ECOG performance status
    - Labs (e.g., metabolic panel, liver function)
    - RECIST tumor evaluations
- Participant level evaluability
    - Indicates whether participants are included in primary outcome analysis
- Genomics

    - Complete genomic profile performed prior to enrollment on TAPUR
- Outcomes
    - Tumor response
    - Progression free survival
    - Overall survival
    - Duration of treatment
    - High grade or serious adverse events