Protocol Title: An Observational Study Profiling Biospecimens from Cancer Patients to Screen for Molecular Alterations Related to Treatment Selection (STRATA)

Target Population: Subjects with advanced (metastatic or unresectable) histologically-documented solid tumors and lymphomas that have surplus FFPE tumor tissue (e.g. biopsy, fine needle aspiration, fluid cytology, surgical resection) available will be eligible for the Strata trial.

Summary: Many patients are treated for advanced cancer without knowledge of underlying molecular features that might indicate FDA approved therapies or potential eligibility for biomarker-selected clinical trials. Strata Oncology is initiating the Strata Trial (STR-001-001) with the primary goal of understanding the proportion of subjects available for clinical trials and approved targeted therapies in advanced cancer while assessing the feasibility of using a large-scale NGS screening program to match subjects for eligibility assessments in clinical trials and/or for approved targeted therapies. The Strata Trial does not require additional procedures but rather uses surplus, or leftover tumor specimens for molecular profiling.

Key Inclusion Criteria:
- Subjects must be ≥ 18 years of age.
- Subjects must have histologically documented solid tumors or lymphoma.
- Specific criteria for individual tumor types are as follow:
  - Subjects with Glioblastoma or Pancreatic Cancer are eligible at any stage of disease.
  - Subjects with Lung Cancer are eligible at Stage IIIB and Stage IV, or with metastatic disease.
  - Subjects with rare tumors (i.e. cancer started in an unusual place in the body, it is unusual type and requires special treatment) are eligible at Stages II-IV.
  - Subjects with Lymphoma must have advanced disease refractory to standard curative therapy or have contraindication to standard therapy.
  - Subjects with other solid tumors must have metastatic or incurable disease.
- Subjects must have an adequate formalin-fixed paraffin-embedded tumor specimen for genomic sequencing.

Contacts:
Principal Investigator: Marc Matrana, MD
Clinical Research Associate (CRA): Christina Robinson (chrrobinson@ochsner.org, ext. 23798)

For additional information: https://clinicaltrials.gov/ct2/show/NCT03061305