Cancer Research Consortium of West Michigan
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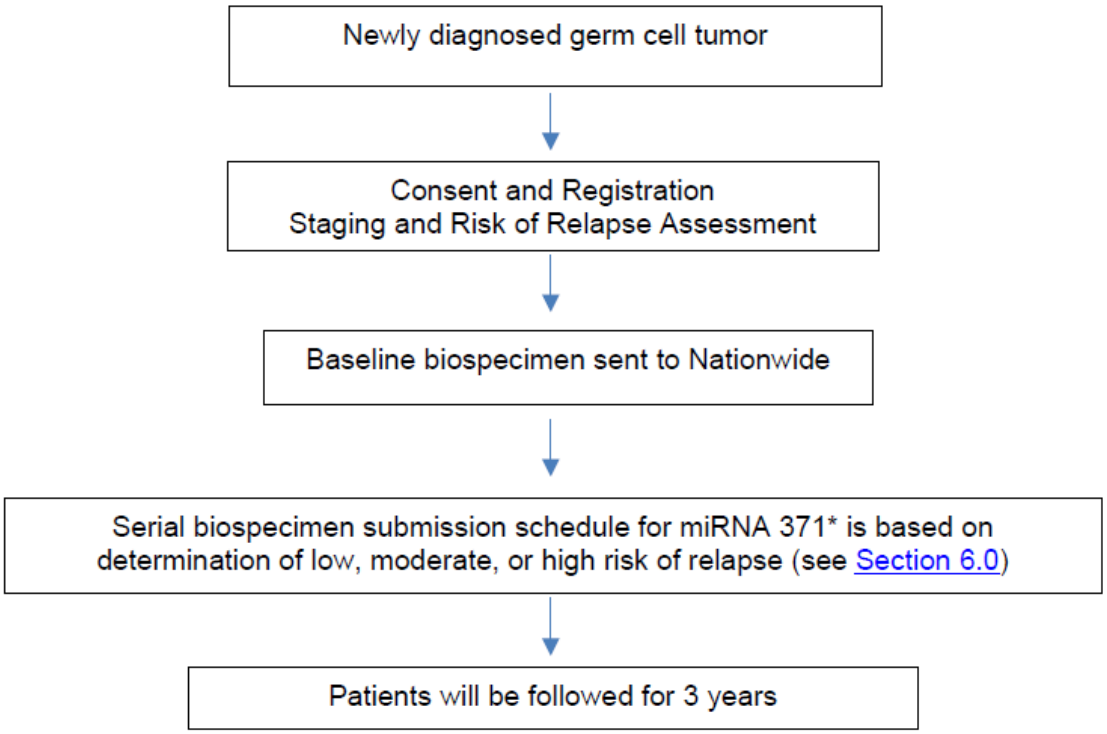
FAST FACTS

S1823 - A PROSPECTIVE OBSERVATIONAL COHORT STUDY TO ASSESS miRNA 371 FOR OUTCOME PREDICTION IN PATIENTS WITH NEWLY DIAGNOSED GERM CELL TUMORS

ELIGIBILITY CRITERIA

1. Disease Related Criteria
    a. Patients must have a new diagnosis of a germ cell tumor confirmed pathologically or serologically (diagnostic elevation of HCG/AFP). All primary sites, stages, histological subtypes as defined in Section 4.0 of germ cell tumor are eligible. Metachronous second primary germ cell tumors are eligible.
    b. If surgery is planned, male patients with Clinical Stage I (see Section 4.0) testicular cancer must have orchiectomy completed within 42 days prior to registration.
2. Prior/Concurrent Therapy Criteria
    a. Patients must be registered within 42 days after diagnosis and prior to initiation of a management plan or treatment for the disease.
3. Clinical/Laboratory Criteria
    a. Patients must be ≥ 18 years of age. NOTE: patients less than 18 years of age should be considered for direct enrollment in COG AGCT 1531.
    b. Patients must have initial imaging, laboratory and other clinical evaluations (see below) performed within 42 days prior to registration. Imaging reports, pathology reports and performance status will be collected.
    c. Patients must have beta-human chorionic gonadotropin (beta-HCG), alpha-fetoprotein (AFP), and lactate dehydrogenase (LDH) assessments within 42 days prior to registration.
        NOTE: If the patient had an orchiectomy prior to registration, report tumor marker values before and after surgery on the Baseline Tumor Marker form.
    d. Patients must have risk of relapse assessment determined by the local investigator prior to registration. (See Section 6.0).
4. Specimen Submission Criteria
    a. Patients must agree to submit required specimens for defined translational medicine studies as outlined in Section 15.1. These specimens are drawn at the same time as standard laboratory evaluations (beta-HCG, AFP, and LDH).
        NOTE: Ideally, patients should be willing to return to their center performing surveillance (registering site) for the duration of the study to ensure that specimens are timed to standard clinical observations (the registering site's surveillance schedule).
    b. Patients must be offered participation in specimen banking for future research. With patient's consent, specimens must be submitted as outlined in Section 15.1 and Section 15.2.

SCHEMA



Patients and providers will not have knowledge of the results of the miRNA 371 analysis.