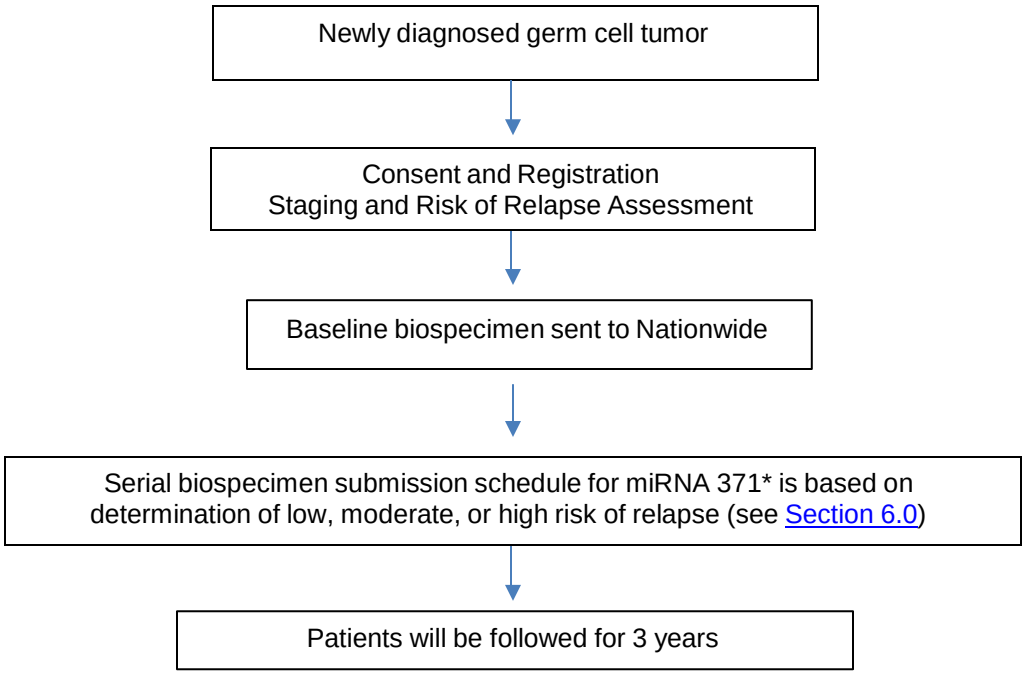
SCHEMA



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

5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration in OPEN. Section 5 may be printed and used to by the site, but is not to be uploaded in RAVE (unless specially stated). For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see Section 14.0). Any potential eligibility issues should be addressed to the SWOG Statistics and Data Management Center at 206/652-2267 or cancercontrolquestion@crab.org prior to registration. NCI policy does not allow for waiver of or deviation within any eligibility criterion (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).

In calculating days of tests and measurements, the day of registration is Day 0. Therefore, if the day of registration is on a Monday, the Monday 4 weeks later would be considered Day 28.

5.1 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.

5.2 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.

5.3 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).

5.4 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.

5.5 Regulatory Criteria

a. Patients ***must*** be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

b. As a part of the OPEN registration process (see Section 13.3 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

6.1 STRATIFICATION FACTORS

Patients will be stratified by the following factors:

a. Histology: testicular seminoma vs. testicular nonseminoma (including mixed germ cell tumors) vs. other germ cell tumors (ovarian germ cell tumors, and testicular non-germ cell histology).

b. Risk of relapse: low risk vs. moderate risk vs. high risk.

Patients will be assigned one of three risk group cohorts as determined by the local investigator. The risk designation is based on the composite clinical picture in the post-diagnosis/pre-registration window as follows: