Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

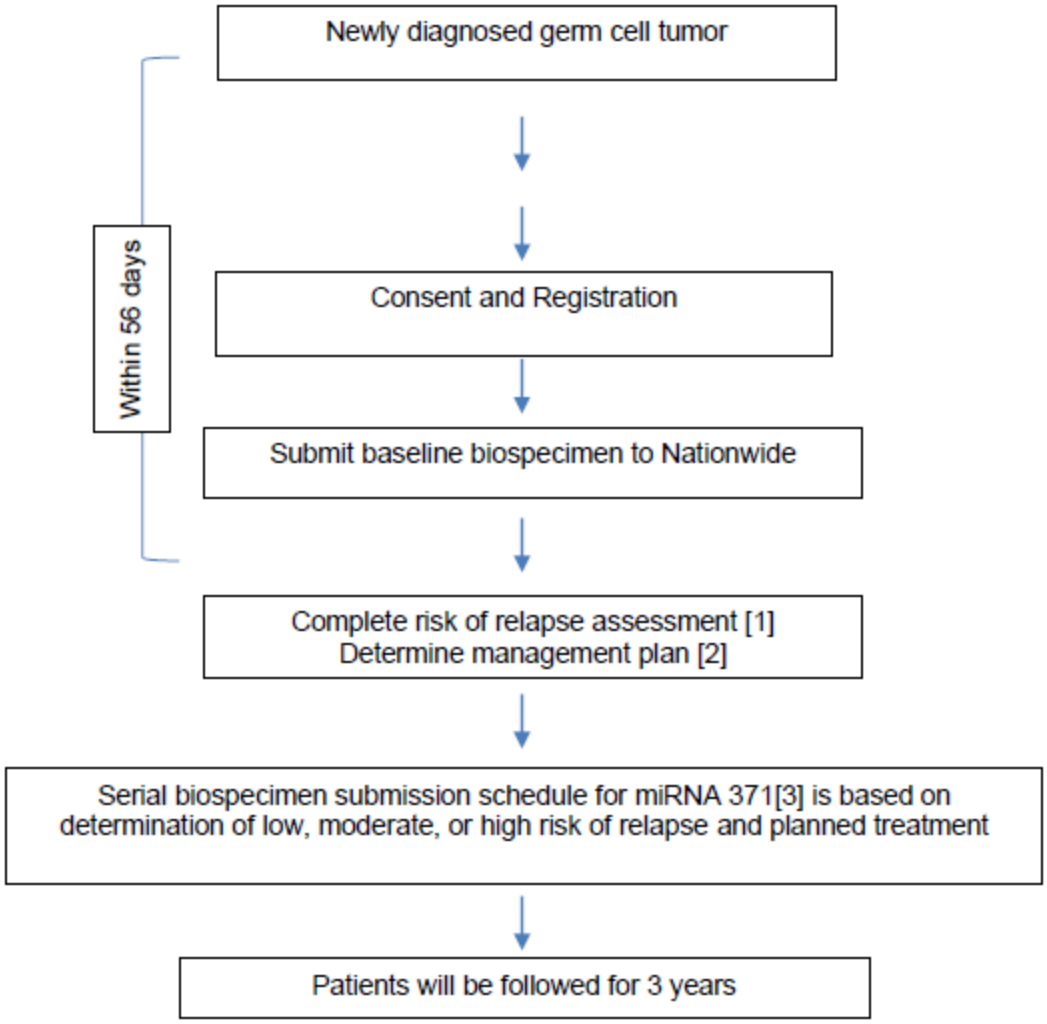
FAST FACTS

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 with definitive elevation of β-HCG or AFP in male patients. All primary sites andhistological subtypes of germ cell tumor, as defined in Section 4.0, are eligible. Metachronous second primary germ cell tumors are eligible. Testicular non-germ cell tumors such as Leydig cell tumors, lymphoma, Sertoli cell tumors, sarcomas, and mesothelioma are not eligible for the study.
   b. Patients must have Stage I, IA, IB or IIA disease. Testicular nonseminoma Stage IS disease is eligible.
   NOTE: Effective April 15, 2022, S1823 closed to the high risk of relapse group (except for nonseminoma Stage IS). With Revision #2, these patients are no longer eligible as new enrollments.
   c. Male patients with testicular cancer must have orchiectomy completed within 56 days prior to registration if surgical removal of the primary tumor is planned.
2. Prior/Concurrent Therapy Criteria
   a. Patients must be registered within 56 days after diagnosis and prior to initiation of a management plan and/or active interventional treatment for the disease. Management includes active surveillance (with imaging studies and classic markers) or active treatment (chemotherapy, retroperitoneal surgery, or therapeutic radiation therapy). Adjuvant treatments (chemotherapy, RT, or primaryRPLND) are allowed.
   Note: The "management plan" referred to here is the post-diagnosis managementplan. In most cases of Clinical Stage I and Clinical Stage II testicular cancer, the diagnosis is made with the orchiectomy. After the orchiectomy, every patient is managed with surveillance, chemotherapy, more surgery or radiation orcombinations thereof.
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.
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 may be drawn at the same time as standard of care clinical blood draws in order to minimize blooddraws in the participant.
   NOTE: Patients should be willing to return to their registering site, that is, the center performing surveillance for the duration of the study to ensure that specimens aretimed to the registering site's surveillance schedule. Telehealth visits are allowed for this study. See Section 7.1.
   b. Patients must be offered participation in specimen banking for future research.With patient's consent, specimens must be submitted as outlined in Section 15.2.

SCHEMA



[1] See Section 6.0.
[2] See Section 7.0.
[3] Patients and providers will not have knowledge of the results of the miRNA 371 analysis.