

“A PROSPECTIVE OBSERVATIONAL COHORT STUDY TO ASSESS MIRNA 371 FOR OUTCOME PREDICTION IN PATIENTS WITH NEWLY DIAGNOSED GERM CELL TUMORS.”

REVISION #2 UPDATES (PROTOCOL DATE 12/7/2022)

Key updates include:

- reduction in the number of biospecimen submissions for new and previously enrolled patients
- increasing the window between diagnosis and registration from 42 days to 56 days
- clarification of the eligibility criteria with regard to serum tumor marker labs and risk of relapse assessment
- clarifications surrounding imaging requirements
- allowance of remote consent and telehealth for clinic visits.

The purpose of reducing the number of specimen submission time points is to alleviate site burden while still being able to meet study endpoints.

COMMON QUESTIONS:

Why is the date of last contact incorrect on the Follow-up form?

*The date of last contact is automatically populated from the last submitted Vital Status form. You must submit a new Vital Status form to update the date of last contact before submission of an **S1823** Follow-up form.*

Can a Data Coordinator fix it if I forget to submit a Vital Status form?

No, the date is locked once the Follow-up form is submitted. Sorry!

Why do I keep finding queries in Rave asking for provider notes? Isn't this study focused on specimens?

Yes, S1823 is focused on collecting specimens for miRNA 371 analysis, but we also need source documents and provider notes to help us better understand the details of potential relapses/progressions. Think of it as a connect-the-dots picture. We can capture a lot more detail of what we're drawing if we have 100 dots vs. 10 dots.

The study calendar in Section 9 says that patients need to come in at XX month for exams. Why do I have to submit **S1823 Follow-up forms if the patient isn't required to come in every three months per Section 7.2?**

The study calendar is a good tool for a quick look at the study, but you should review the relevant sections of the protocol for data and specimen requirements. Section 7.2 does state that this observational protocol is intended to work alongside your SOC, but we do require a data “check-in” every three months per Section 14.4 with the Vital Status and Follow-up forms. We designed the Follow-up forms to act as collection “buckets” for follow-up data generated during whatever follow-up schedule your patient is on. You are required to give us that bucket no matter how much or how little data is in it. If there's data, then you can submit the Follow-up form normally. If there isn't any data, then you can just answer the first question on the form (“Was follow-up information obtained during this follow-up reporting period?”) with “no” and submit the form; no additional questions need to be answered!

Is there any way to make Rave stop asking for the patient’s weight?

Unfortunately, there isn’t. You have to keep telling us that it wasn’t done because the visit was virtual, and we’ll keep having to close out the automatic Rave query.

Our patient isn’t responding to our phone calls/emails/letters/carrier pigeons. Can we stop following them?

Nope, per SWOG Policy 30 you need to follow the patient for the full 36 months of the study unless the patient either a) meets criteria in Section 7.8, or b) meets all of the criteria for Lost to Follow-up. You can find the LTF criteria in Policy 30 or Chapter 10 of the ORP Manual. As a reminder, the Date of Last Contact is obtained either by direct contact with the patient or via physician records, family members, or other patient caretakers.

I’m not sure how to determine the patient’s Risk of Relapse. What should I do?

The patient’s Risk of Relapse should be determined by your local investigator or the treating physician based on the composite clinical picture in the post-diagnosis pre-registration window. Section 6 acts as a guide but ultimately the risk determination is up to your investigator. SWOG is relying on sites to determine the risk level because you have all of the information. The study chairs, Dr. Lucia Nappi and Dr. Craig Nichols, are more than happy to help your investigator with determining risk.

Why is the overdue clock icon showing up in Rave? None of my forms are overdue.

Sometimes a form will show up as overdue in Rave, but it won’t show up as overdue on your expectation report. Surprise! You found a programming bug we haven’t been able to fix. We’re reviewing the affected patients and working on a solution, but until then we’re relying on you to notify us when it happens to your patients.

Do I need to re consent patients with Revision #2 (12/7/2022)?

From SWOG’s point of view, we only need to notify patients when there is increased risk during study participation. Fewer blood sample collections would not increase risk for the patient, therefore it was deemed that patients do not need to be informed.

Who do I contact if I have a question about eligibility and data submission? Or specimen submissions? Weather delays? Overdue expectations?

Reach out to your data coordinator at the SWOG SDMC at cancercontrolquestion@crab.org. We usually have the answers and we also triage your questions to the rest of the study team.

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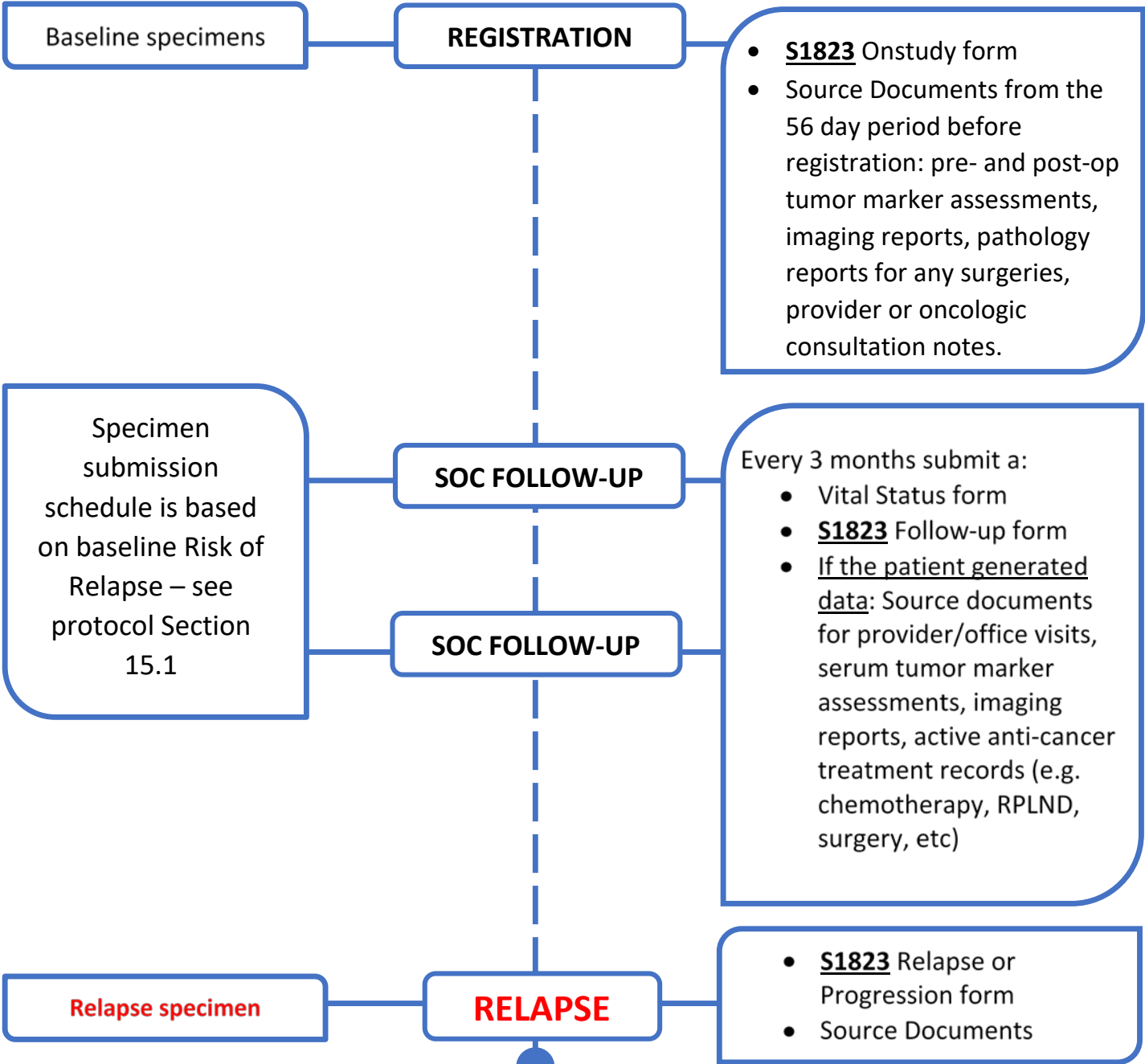
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SPECIMEN SUBMISSION	PATIENT CARE EVENTS	STUDY FOLLOW-UP
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- The **S1823** Follow-up Tumor Markers, **S1823** Follow-up Imaging, **S1823** Relapse or Progression, and **S1823** Anti-Cancer Therapy forms are generated based on your completion of the **S1823** Follow-up form.
- Please review the questions on the **S1823** Follow-up form carefully.
- Be sure that you have reported all events that occurred during the period between a previously submitted **S1823** Follow-up form and the current **S1823** Follow-up form.
- Due dates for the **S1823** Follow-up form are calculated from the date of registration.