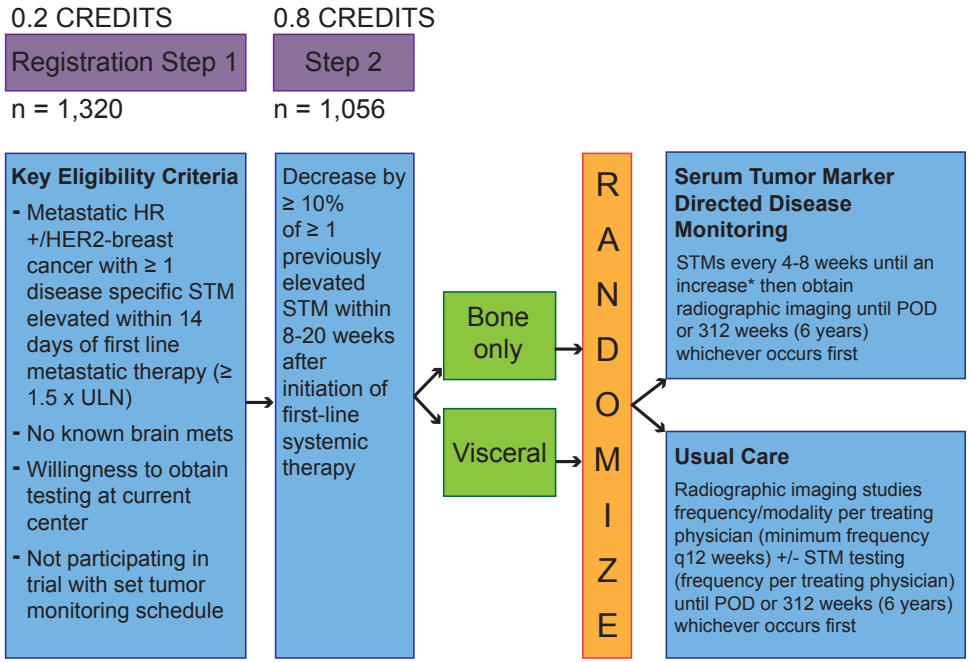
S1703 Schema



Primary Endpoint | overall survival

Secondary Endpoint | direct healthcare costs, anxiety (STAI-S), QOL (PROMIS-29)

Other Evaluations | patterns of disease monitoring in the usual care cohort, patient and physician preferences and attitudes regarding disease monitoring testing (baseline only)

Increase defined as *a) if STM is ≥ 1.5 x IULN and this STM has not previously been measured at ≥ 1.5 x IULN; b) STM is > the IULN and increased in value by at least 25% since the last STM measurement; c) increase on 3 consecutive assessments.*

For eligibility or data submission questions contact:

cancercontrolquestion@crab.org

(206) 652-2267

This brochure is intended for staff education and is not to be used for patient recruitment.

Version 28 APR 2021

SWOG STUDY S1703

Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring Versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer

STUDY CHAIR | Melissa Accordino, MD, MS

A Clinical Trial Investigating Serum Tumor Marker Directed Disease Monitoring

SWOG Cancer Care Delivery Committee

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

About S1703

S1703, the first disease monitoring study in SWOG, is a randomized noninferiority trial to assess whether patients with HR+, HER2- MBC who are monitored with serum tumor marker directed disease monitoring (STMDDM) have non-inferior overall survival compared to patients monitored with usual care.

Cumulative direct health care costs and patient reported outcomes of anxiety and quality of life among patients monitored with STMDDM intervention vs. usual care will be compared.

The STMDDM intervention arm consists of serum tumor marker (STM) (CEA and either CA 15-3 or CA 27.29) evaluation every 4-8 weeks without imaging until an elevation of at least one STM.

In the usual care arm, patients have imaging studies (alone or with STMs) until disease progression; frequency and imaging modality is determined by the treating physician.

Why is S1703 important?

We hypothesize that STMDDM will not alter survival outcomes and may lower healthcare costs and improve quality of life. The results of this study will allow cost-comparison of the different disease monitoring strategies and possibly lead to practice-altering changes in how cancer care is delivered and reduce expensive imaging testing.

Who qualifies? This study has a 2-step registration process:

Patients eligible for Step 1:

- ER+ and/or PR+, HER-2- metastatic breast cancer, who have ≥1 STM (CEA and either CA 15-3 or CA 27.29) that is ≥1.5 x the institutional upper limit of normal.
- No known history of brain or leptomeningeal metastases, cirrhosis, untreated B12 deficiency, thalassemia, sickle cell anemia.
- Except for breast cancer (and previous history of breast cancer), no other prior malignancy is allowed with the following exceptions: adequately treated basal (or squamous cell) skin cancer, any cancer from which the patient has been disease-free for 5 years, or prior Stage 0 or pre-cancerous lesions that have been removed with clear margins.
- Must have systemic radiographic imaging prior to initiation of systemic therapy or within 30 days after intitiation of systemic therapy.
- Patients cannot enroll or plan to enroll on a first-line treatment trial with a defined monitoring schedule.

Patients eligible for Step 2:

- Must have at least a 10% decrease of ≥1 STM, that was previously elevated, within 56-140 days after initiation of first line therapy and no evidence of disease progression since registration to Step 1.

What if my patient on the STMDDM arm develops a new symptom, but the STMs have remained stable?

If a patient develops new signs or symptoms concerning for disease progression, imaging may be performed at any time regardless of STM trend.

How will progression be determined?

Progression will be determined based on the clinical judgement of the treating physician.

Can a patient enroll if only one STM is elevated?

Yes, a patient can enroll if at least one of the tested breast cancer STMs (CEA, CA 15-3 or CA 27.29) is elevated +/- 14 days of initiation of first-line systemic therapy. For step 2 registration, there must be a decrease in value of an elevated STM by at least 10%.

Do I need to test all 3 tumor markers (CEA, CA 15-3, and CA 27.29) at each time point?

Testing all three STMs is encouraged, but only two are required. (CEA must be tested). In our clinical experience, these 3 markers are routinely covered by insurance.

How do I talk to patients about this trial?

It is important to monitor patients who are receiving systemic therapy, but we don't know the "right" way to do this. Currently, we use imaging tests at varying frequencies and sometimes combine them with blood tests called tumor markers. There is no evidence that frequent disease monitoring with either imaging tests or tumor markers is associated with longer survival. However, frequent disease monitoring may be linked to higher levels of anxiety and higher costs of care. Anxiety around scans (or "scanxiety") can be overwhelming for cancer patients. The goal of this study is to see if a different monitoring approach, called serum tumor marker directed disease monitoring, using the trend of patient tumor marker values to decide when to do imaging tests, is as effective as usual care and associated with less anxiety, better quality of life, and lower costs of care.

Please contact Dr. Accordino if your site is interested in participating or has any questions.

Study Chair | Melissa Accordino, MD, MS
Columbia University Irving Medical Center
mkg2134@cumc.columbia.edu | (212) 305-1945