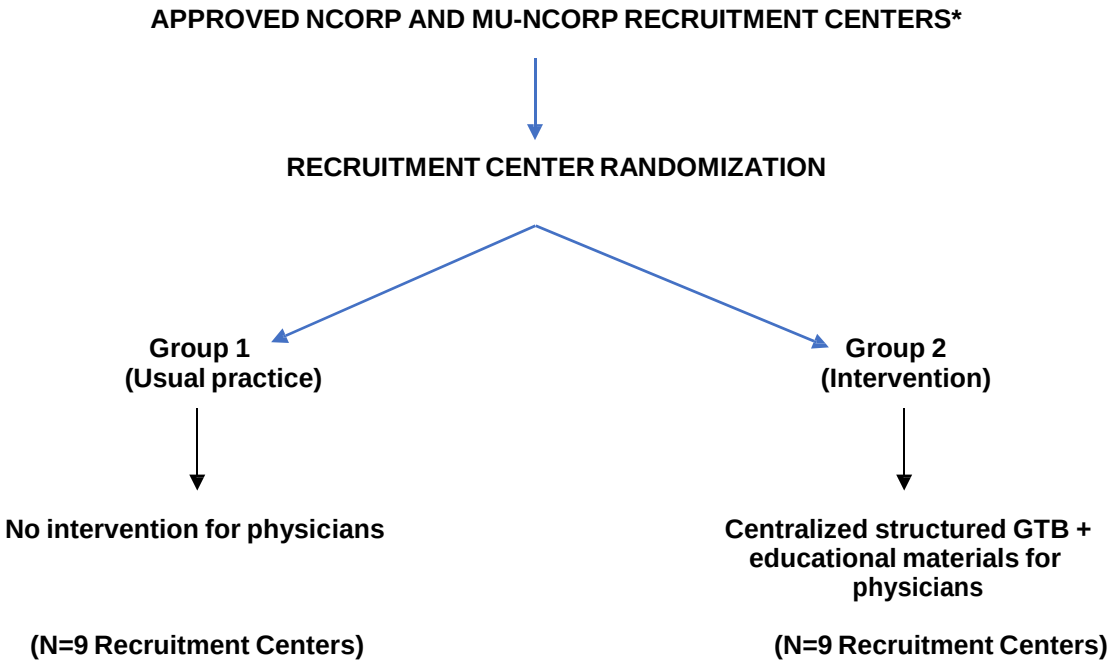
SCHEMA



* A Recruitment Center is defined as an outpatient clinic, or group of clinics, belonging to the same NCORP or MU-NCORP, that will be contributing physician and patient participants to the study. Each clinic within the Recruitment Center must have a CTEP Site ID. All Recruitment Centers must have completed a **S2108CD** Recruitment Center Application and received approval for participation.

5.0 RECRUITMENT CENTER, PHYSICIAN AND PATIENT ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a Recruitment Center, physician participant and patient participant to be considered eligible for registration in OPEN. Section 5 may be printed and used by the Recruitment Center 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 SDMC in Seattle at 206/652-2267 or cancercontrolquestion@crab.org prior to registration. **NCI policy does not allow for waiver of any eligibility criterion** (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).

In calculating days of tests and measurements, the day a test is ordered is considered Day 0. Therefore, as an example, if a test is done on a Monday, the Monday 1 week later would be considered Day 7. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 7 falls on a weekend or holiday, the limit may be extended to the next working day.**

5.1 Recruitment Center Definition and Eligibility Criteria

Recruitment Centers must have completed the **S2108CD** Recruitment Center Application and be approved for participation in the study. Eighteen Recruitment Centers will be selected to participate in the study based on the eligibility criteria listed below.

a. A Recruitment Center is defined as an outpatient clinic, or group of clinics, belonging to the same NCORP or MU-NCORP, that will be contributing physicians and patient participants to the study.

b. Participating Recruitment Centers must meet the following requirements:

1. Recruitment Centers must be part of an NCORP or MU-NCORP site with CCDR funding. Each clinic included in the Recruitment Center must be associated with CTEP site ID.

2. Recruitment Centers must order large panel next generation sequencing genomic tests on at least 10 unique patients per month.

3. Recruitment Centers must have at least 4 practicing oncologists (including medical, gynecologic, or neuro-oncologists) at the site willing to participate in the study and register within three months of study activation.

4. Recruitment Centers must be willing to register a total of 66 patients (over 2 years) to the study.

5. Recruitment Centers must be able to send at least one member of the clinical team to attend the Recruitment Center's cases presented to the **S2108CD** Genomic Tumor Board, should the Recruitment Center be randomized to the intervention arm.

6. Recruitment Centers must be willing and able to document the number of unique patients for whom GTT were ordered at the Recruitment Center and submit this monthly via Rave®.

7. Recruitment Centers must not have an existing Genomic Tumor Board. For the purposes of this study, a Genomic Tumor Board is defined as an interdisciplinary team of clinicians and scientists that reviews genomic testing results and provides guidance on treatment options based primarily on genomic data to the treating physician. The existence of a general

multidisciplinary tumor board that addresses all aspects of patient care and treatment is not considered an exclusion criterion. A general multidisciplinary tumor board is defined as an interdisciplinary team of clinicians that primarily discusses all aspects of cancer care, including diagnostic aspects (pathology and radiology), therapeutic options (surgical, radiation and medical) as well as palliative and psychosocial support options.

5.2 Physician Participant Criteria

a. Physician participant must be a registering investigator of the Recruitment Center that is participating in the study. If the physician is a registering investigator at more than one Recruitment Center, he/she must choose one Recruitment Center to identify with and enroll patients from.

b. Physician participants must be board-eligible or board-certified in Medical Oncology, Gynecologic Oncology, or Neurology with certification or eligible for certification in Neuro-oncology.

c. Physician participants must be willing to offer participation in the study to all eligible patients under their care for the duration of the study. A single physician may enroll multiple patients on the study.

d. Physician participants must be willing to complete all study questionnaires and, as part of the implementation objective, participate in interviews if invited.

e. Physician participants must complete all baseline questionnaires prior to registration.

f. Physician participants at a Recruitment Center randomized to the intervention arm must be willing to participate in the educationally enhanced GTB (EGTB).

5.3 Patient Participant Criteria

a. Disease Related

1. Patient participants must have a solid tumor malignancy that is either recurrent, relapsed, refractory, metastatic, or newly diagnosed Stage III or Stage IV.

2. Patient participants must be under the care of a physician enrolled on the study.

3. Patient participants must not be going on hospice care at the time of registration.

b. Prior/Concurrent Therapy Criteria

1. Patient participants may have started anti-cancer treatment for the current diagnosis.

2. The treating physician anticipates that the patient will start a new anti-cancer treatment (either first or subsequent lines) within 6 months after registration.

3. Patient participants are allowed to be co-enrolled on other clinical trials including non-treatment studies and studies that include investigational drugs. Patients may be enrolled on genome-informed therapeutic trials, such as LungMAP, MATCH, or TAPUR.

c. Clinical/Laboratory Criteria

1. Patient participant must have a genomic tumor test (GTT) ordered prior to registration with results pending. The genomic testing may be a commercially available panel (such as FoundationOne, Caris, or Tempus) or a non-commercial tumor panel performed at an academic medical center.

NOTE: Qualifying GTTs are defined as a genomic test conducted on the tumor tissue, tumor cells, or cellfree DNA (cfDNA). They must be CLIA-certified NGS tissue or liquid biopsy panels, including hotspot, whole gene, or DNA and RNA (including expression data) panels. Fluorescence-in-situ hybridization (FISH) and immunohistochemistry test results assessing cancer-relevant proteins (e.g. Her2/neu, ALK, MET) and immune parameters (e.g. PD-L1 tests) are also permissible if performed in the context of a larger panel that includes NGS or expression profiling. These tests can come from any commercial or academic laboratory within the US and they should be ordered with the intent to influence genome-informed treatment decision. Oncotype DX and other panels used for making treatment decisions based on a prognostic read-out (e.g. liquid biopsy minimal residual disease (MRD)) are not permitted.

2. Patient participants must be at least 18 years of age.

3. Patient participants must have a Zubrod performance status of 0-2.

4. Patient participants with tests assessing cancer-risk defining germline variants only (“germline test”) are not eligible.

5.4 Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 13.5 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.

a. Participants (patients and physicians) must sign and give written informed consent in accordance with institutional and federal guidelines.

For patient participants with impaired decision-making capabilities, legally authorized representative may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and CIRB regulations. Documentation of informed consent via remote consent is permissible, as indicated in Section 18.7.