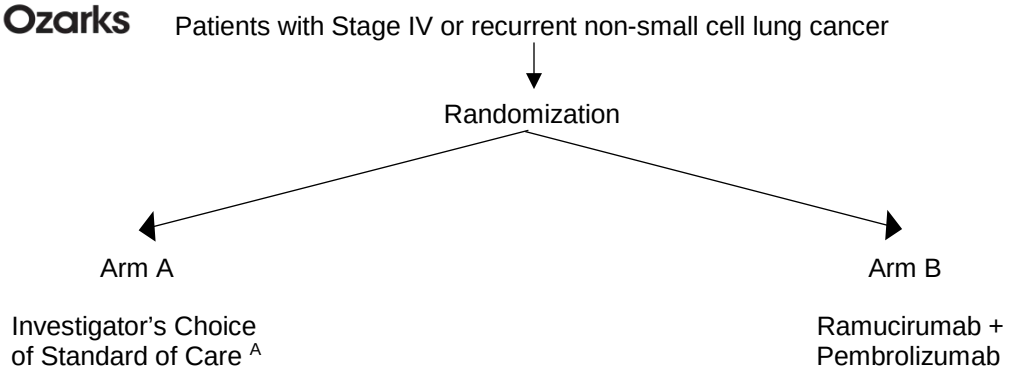
SWOG S2302
SCHEMA



A For guidance on Investigator's Choice of Standard of Care, see Section 7.2.

5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following sections must be met in order for a participant 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. 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 Lungquestion@crab.org prior to registration. **NCI policy does not allow for waiver of any eligibility criterion (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).**

5.1. Disease Related Criteria

a. Participants must have histologically or cytologically confirmed non-small cell lung cancer (NSCLC) which is Stage IV or recurrent.

5.2. Prior/Concurrent Therapy Criteria

a. Participants must have received at least one line of anti-PD-1 or anti-PD-L1 therapy for any stage of NSCLC. Anti-PD-1 or anti-PD-L1 may have been given alone or in combination with other therapy.

b. Participants must not have received more than one line of anti-PD-1 or anti-PD-L1 for Stage IV or recurrent disease.

c. Participants must have experienced disease progression (in the opinion of the treating physician) more than (>) 84 days following initiation (Cycle 1 Day 1) of their most recent anti-PD-1 or PD-L1 therapy.

d. Participants who received anti-PD-1 or anti-PD-L1 therapy for Stage IV or recurrent disease, must have had a best response on anti-PD-1 or anti-PD-L1 therapy of stable, partial response or complete response (in the opinion of the treating physician).

e. Participants who received neoadjuvant, adjuvant, and/or consolidation anti-PD-1 or anti-PD-L1 therapy as their only line of anti-PD-1 or anti-PD-L1 therapy must have experienced disease progression within (<=) 365 days from initiation (Cycle 1 Day 1) of anti-PD-1 or PD-L1 therapy.

f. Participants must have received platinum-based chemotherapy and experienced disease progression (in the opinion of the treating physician) during or after this regimen.

g. Participants with a known sensitizing mutation for which an FDA-approved targeted therapy for NSCLC exists (e.g., EGFR, ALK, ROS1, BRAF, RET, NTRK, KRAS, HER2 and MET sensitizing mutations), must have previously received at least one of the approved therapy(s). Prior targeted therapy for participants with targetable alterations is allowed if all other eligibility criteria are also met.

h. Participants must not be receiving or planning to receive another investigational therapy during study participation.

5.3. Clinical/Laboratory Criteria

a. Participants must be ≥ 18 years old.

b. Participants must be able to safely receive the investigational drug combination and the investigator's choice of standard of care regimens described in Section 7.2, per the current FDA-approved package insert(s), treating investigator's discretion, and institutional guidelines.

c. Participants must have Zubrod Performance Status of 0-2 (see Section 10.3).

5.4. Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 18.4e 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 ***must*** be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines. Documentation of informed consent via remote consent is allowed, as indicated in Section 18.9.

For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and CIRB regulations.