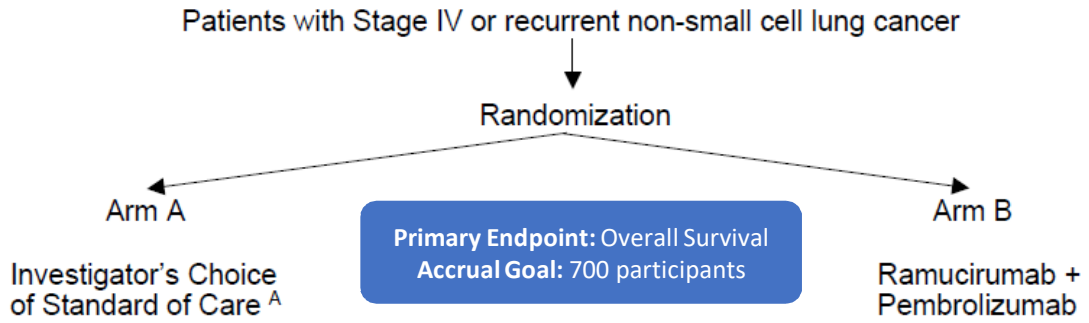
SWOG CANCER RESEARCH NETWORK | NCI National Clinical Trials Network | NCI Community Oncology Research Program

S2302 PRAGMATICA-LUNG

A PROSPECTIVE RANDOMIZED STUDY OF RAMUCIRUMAB (LY3009806; NSC 749128) PLUS PEMBROLIZUMAB (MK-3475; NSC 776864) VERSUS STANDARD OF CARE FOR PARTICIPANTS PREVIOUSLY TREATED WITH IMMUNOTHERAPY FOR STAGE IV OR RECURRENT NON-SMALL CELL LUNG CANCER

ACTIVATION DATE: 06-MAR-2023

SCHEMA



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

Treatment assignment will be determined by block randomization with equal probability within block. Stratification factors are:

(1) Most recent line of therapy for NSCLC included anti-PD-1 or anti-PD-L1 therapy (yes versus no), and

(2) Performance status (0 or 1 versus 2).

ARM A Investigator's Choice of Standard of Care

- The specific treatment is to be determined by the treating investigator and participant.
- Recommended that the choice of SoC drug(s) is based on NCCN guidelines for a "systemic therapy for advanced or metastatic disease-subsequent."
- Dosing administration should be based on participant's previous therapy and disease.
- Drug(s) should be administered according to the current FDA-approved package insert(s).

ARM B Ramucirumab + Pembrolizumab

PLAN TO INITIATE TREATMENT NO MORE THAN **10 DAYS** AFTER RANDOMIZATION

AGENT	DOSE	ROUTE	DAY	SCHEDULE
Ramucirumab	10 mg/kg	IV (over 30-60 minutes)	Day 1	Q 21 days
Pembrolizumab	200 mg	IV over 30 minutes	Day 1	Q 21 days up to 35 cycles

FOR QUESTIONS REGARDING ELIGIBILITY, DATA SUBMISSION & GENERAL INQUIRIES, CONTACT: LungQuestion@crab.org

FOR MEDICAL OR TREATMENT-RELATED S2302 QUESTIONS, CONTACT: S2302Chairs@swog.org

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PRAGMATIC DESIGN CONSIDERATIONS

The goals of **S2302** include:

- Empowerment of investigators to treat patients as would be done in real world practice.
- To decrease barriers to enrollment, and
- To minimize the data collection burden.

This means:

- No protocol-required disease assessments (CT, imaging). Instead, imaging should be done per institution standard. Tumor measurements and images are not collected in the Rave EDC.
- No protocol-required lab tests. Labs should be done per institutional standard and FDA-approved package inserts(s) and are not collected in the Rave EDC.
- No specimen collection.
- No Patient Reported Outcome instruments.
- Only report Grade 5 and unexpected treatment-related serious Grade 3 and Grade 4 Adverse Events. In other words, only AEs requiring expedited reporting via CTEP-AERS are required to be entered in the Rave EDC.
- No cycle-based Treatment Forms. Treatment information will be captured once at initiation and once at discontinuation of protocol treatment.
- No detailed Follow-up Form, only Vital Status (alive or not).

RESOURCES AND MATERIALS

All available on protocol page on www.CTSU.org:

- Link to site initiation training in CLASS – recorded presentation and slides available
- Funding Sheet & Coverage Analysis: Note additional $500 per participant payment
- EMR template to assist with EMR implementation
- Coming soon: Patient-friendly plain language trial summary

ADDITIONAL CONTACT INFORMATION (SEE PROTOCOL SECTION 18.1):

Regulatory, Protocol & Informed Consent Questions:	protocols@swog.org, phone: (210) 614-8808
Patient Advocate:	judyjohnson.519@gmail.com
Access to iMedidata Rave, Delegation Task Log (DTL) Issues, OPEN:	ctsucontact@westat.com, phone: (888) 823-5923
Serious Adverse Event (SAE) Reporting Questions:	adr@swog.org

FOR QUESTIONS REGARDING ELIGIBILITY, DATA SUBMISSION & GENERAL INQUIRIES, CONTACT: LungQuestion@crab.org

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