



# Pragmatica-Lung

A real-world clinical trial for patients whose non-small cell lung cancer has returned after chemo- and immuno-therapy

## Pragmatica-Lung Success: Messages from High-Enrolling Sites

“ The clinical research team at Lahey Hospital and Medical Center has fully embraced S2302 with great enthusiasm. Its simplified eligibility criteria and data management requirements have greatly enhanced our patient recruitment efforts and more accurately reflect real-world clinical practice. ”

**Dr. Paul Hesketh**, Lahey Cancer Institute director and the first physician anywhere to enroll a patient to Pragmatica-Lung. He's shown here with some of the members of his Lahey team [L-R]: **Julie C. Roache, Donna Cossar, Amanda Tong, Dr. Paul Hesketh, Dr. Andrew Piper-Vallillo**




“ As you know, the eligibility criteria are not like any other lung cancer trial we have seen. The majority of our patients are excluded from clinical trials. I think we are used to looking for that 'perfect trial' patient. We realize now that we really can consider this trial for most of our patients who have relapsed. Our referring oncologists are also finding this to be a rewarding process so they are referring more patients. ” **Dr. Deborah Mulford**, University of Rochester


“ The striking ease with which physicians can assess eligibility, along with the user-friendly nature of the protocol, provide patients the opportunity to get two study drugs which have been shown to be better than chemotherapy in a phase II clinical trial. ” **Dr. Liza Villaruz**, UPMC Hillman Cancer Center


“ We love the trial! The pragmatic design makes it nearly effortless; a key consideration for busy clinicians. Based on my experience, I am optimistic that the combination of pembrolizumab and ramucirumab will be shown to offer an effective and well-tolerated alternative to cytotoxic chemotherapy for patients who would be eligible for S2302. ” **Dr. Bryan Faller**, Missouri Baptist Medical Center/Heartland NCORP




## S2302 Pragmatica-Lung Protocol Revision Ups Accrual Goal

 **The Pragmatica-Lung protocol** has been revised, primarily to increase the total enrollment goal from 700 patients to 800 patients.

 **This change will increase** the study's statistical power to detect the target improvement in the hazard ratio between the two arms. It will also allow our statistical team to compare overall survival in key subgroups – patients with squamous cell histology versus those with non-squamous cell histology.

 **The study's informed consent document** has also been updated to indicate each study group now will enroll 400 participants.

 **The revision will be posted** to the S2302 abstract page on [CTSU.org](https://www.ctsu.org).

---

## Tips from Our Data Coordinators

When patients are randomized to S2302, they are stratified based on the answers to these two questions:

### STRATIFICATION QUESTIONS

Did the most recent line of therapy for NSCLC include anti-PD1 or anti-PD-L1 therapy?

Yes  No

What was the participant's ECOG Performance Status?

0-1  2

Entering accurate data here when registering a patient will prevent an imbalance between treatment groups. Unfortunately, we have seen errors in responses to the question *Did the most recent line of therapy for NSCLC include anti-PD-1 or anti-PD-L1 therapy?*

Please carefully review the patient's treatment history before responding to this question. Anti-PD-1 or anti-PD-L1 therapies include

- nivolumab
- pembrolizumab
- atezolizumab
- durvalumab
- avelumab
- cemiplimab

If SWOG data coordinators see that a stratification question answer does not match the Onstudy Form, they will write a query requesting a hand-amended copy of the SWOG Registration Worksheet or OPEN registration form as documentation for a Data Change Request.

If you have questions, please email [LungQuestion@crab.org](mailto:LungQuestion@crab.org).



# Tools to Help You Enroll to S2302 Pragmatica-Lung: Now in Spanish!

CIRB-approved Spanish-language versions of Pragmatica-Lung patient materials are now posted to the S2302 page on CTSU.org, along with the English-language versions.

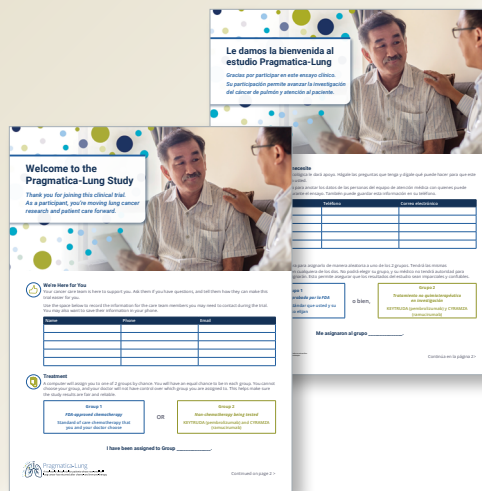
## PATIENT FLYER

Post in patient reception areas to raise awareness of the study and give patients a basis for a more detailed conversation with staff. Also look for alternative versions of patient flyers with content highlighting different communities.



## INFORMED CONSENT FLOWCHART

A companion tool to facilitate the informed consent discussion.



## PRE-ENROLLMENT FACTSHEET

Hand this to patients who are considering joining the study. It provides basic study information in a handy format they can also share with loved ones.

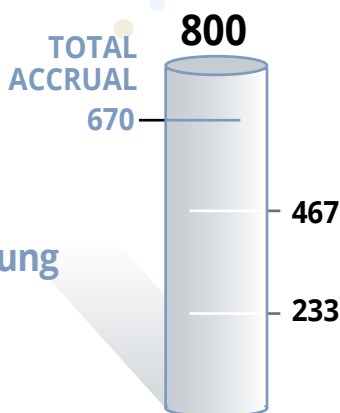
## PARTICIPATION GUIDE

For patients who have just enrolled, this offers details about study responsibilities, visit schedules, site contact information, and more.



## S2302 Pragmatica-Lung Enrollment

AS OF OCTOBER 1, 2024

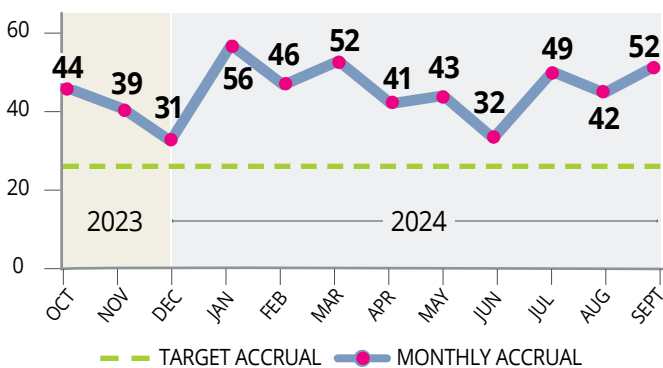


### TOP-ACCRUING SITES

35	Moffitt Cancer Center
15	Northwestern University
14	Medical University of South Carolina
13	University of Alabama at Birmingham Cancer Center
12	University of Rochester
11	U of California Davis Comprehensive Cancer Center
10	Dartmouth Hitchcock Med Cntr/ Dartmouth Cancer Center (ALLIANCE)
10	Lahey Hospital and Medical Center NCORP
9	Vanderbilt University/Ingram Cancer Institute
8	Cancer Care Center of O'Fallon
8	Carolinas Medical Center/Levine Cancer Institute
8	Monument Health Rapid City Hospital (ALLIANCE)
8	Saint Luke's Hospital of Kansas City

### Monthly Accrual (Last 12 Months)

OPEN TO ACCRUAL ON MARCH 6, 2023



## Top-Accruing Sites by Organization Type

AS OF OCTOBER 1, 2024

### TOP-ACCRUING LAPS

Washington University - Siteman Cancer Center LAPS	23
Northwestern University LAPS	17
CWRU Case Comprehensive Cancer Center LAPS	17
Mayo Clinic LAPS	17
Vanderbilt University - Ingram Cancer Center LAPS	16
Dartmouth College - Dartmouth Cancer Center LAPS	15
U Alabama-Birmingham/Deep South Res Consort LAPS	13
University of Rochester LAPS	13
Yale University - Yale Cancer Center LAPS	12
UC Davis Comprehensive Cancer Center LAPS	12
UPMC Hillman Cancer Center LAPS	10
University of Oklahoma Health Sciences Center LAPS	7
University of Wisconsin Carbone Cancer Center LAPS	7
U Michigan Comprehensive Cancer Center LAPS	6
Fred Hutchinson Cancer Research Center LAPS	6

### TOP-ACCRUING NCORPS

Heartland Cancer Research NCORP	46
Kaiser Permanente NCORP	22
Michigan Cancer Research Consortium NCORP	15
MUSC Minority Underserved NCORP	15
Georgia NCI Community Oncology Research Program	14
Baptist Mem HC/Mid-South MU NCORP	13
Carle Cancer Center NCORP	8
Columbus NCI Community Oncology Research Program	8
Hawaii Minority Underserved NCORP	6
Montefiore Minority Underserved NCORP	6
Southeast Clinical Oncology Research Consortium NCORP	6
Columbia University Minority Underserved NCORP	6
Gulf South Minority Underserved NCORP	6
Delaware/Christiana Care NCORP	6
Cancer Research of Wisconsin & N Michigan Consort	6

### TOP-ACCRUING MEMBER/AFFILIATES

Moffitt Cancer Center	38
University of Texas Health Science Center at San Antonio	19
Lahey Hospital and Medical Center	11
Rutgers Cancer Institute of New Jersey	11
Cedars-Sinai Medical Center	10
University of Arkansas for Medical Sciences	10
Mass. Veterans Epidem Research & Information Center	9
University of Kentucky/Markey Cancer Center	8
U Miami Miller School of Med-Sylvester CC	7
Sutter Cancer Research Consortium	6
Edwards Comprehensive Cancer Center	6
Miami Valley Hospital	5
Wake Forest University Health Sciences	5
University of Illinois	5