

# Project Pragmatica:

Exploring Ways to Promote Efficient, Patient-Centric  
Drug Development for Patients with Rare Cancers

**FDA Rare Disease Day 2024**

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# OCE's Project Pragmatica



**Problem:** Traditional clinical trials can sometimes be complex & burdensome



**Solution:** Explore appropriate use of pragmatic design elements in clinical trials for *approved* oncology medical products

# Current State



Complex and Restrictive



Resource Intensive



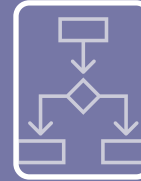
Highly Burdensome

- Patients
- Providers

# Future State



More streamlined and generalizable



Targeted Objective-focused Approaches



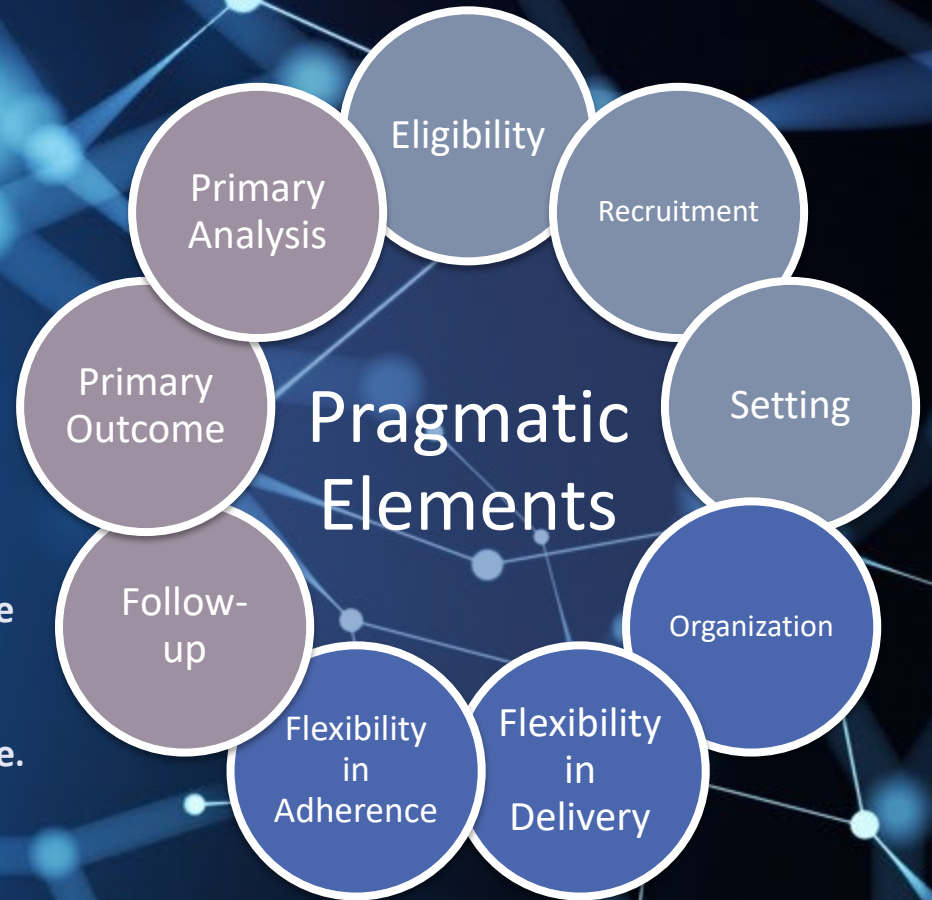
Closer to Routine Care

- Increased Access
- Appropriate Flexibilities

# OCE Project Pragmatics

## Objective

Advancing evidence generation for approved oncology medical products by exploring innovative trial design approaches that introduce functional efficiencies and patient centricity through integration with real-world routine clinical practice.

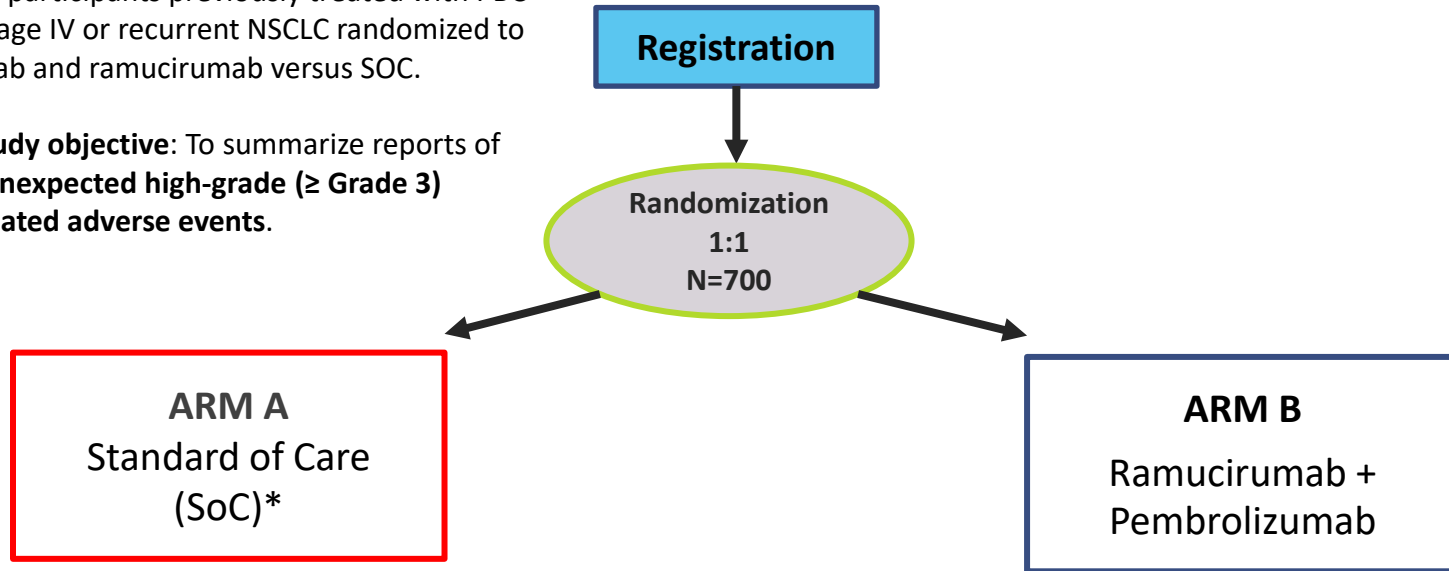


# PRAGMATICA LUNG TRIAL S2302 DESIGN



**Primary study objective:** To compare **overall survival (OS)** between participants previously treated with PBC and I/O for Stage IV or recurrent NSCLC randomized to pembrolizumab and ramucirumab versus SOC.

**Secondary study objective:** To summarize reports of **serious and unexpected high-grade ( $\geq$  Grade 3) treatment-related adverse events.**



\*SoC per Investigator.  
Recommended to be based on NCCN guidelines and should not be an investigational therapy.

# EXAMPLE: PRAGMATICA LUNG

tRCT

Fully PCT



**Pragmatic Domain**

**Pragmatic Element**

Recruitment:  
Patients and  
Investigators

Eligibility

Recruitment

Setting

Trial Intervention  
and Delivery

Organization

Flexibility in  
Delivery

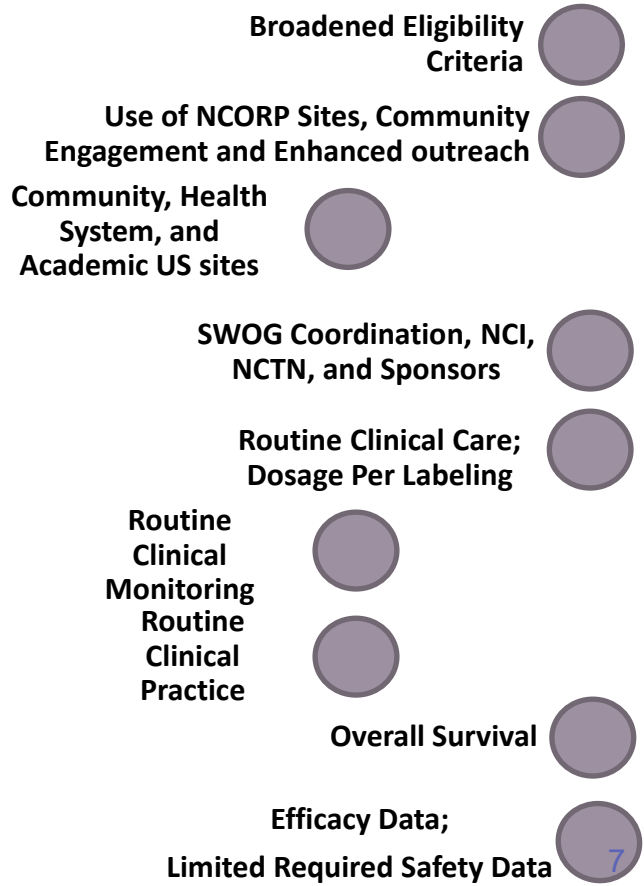
Flexibility in  
Adherence

Measurement

Follow up

Primary Outcome

Primary Analysis

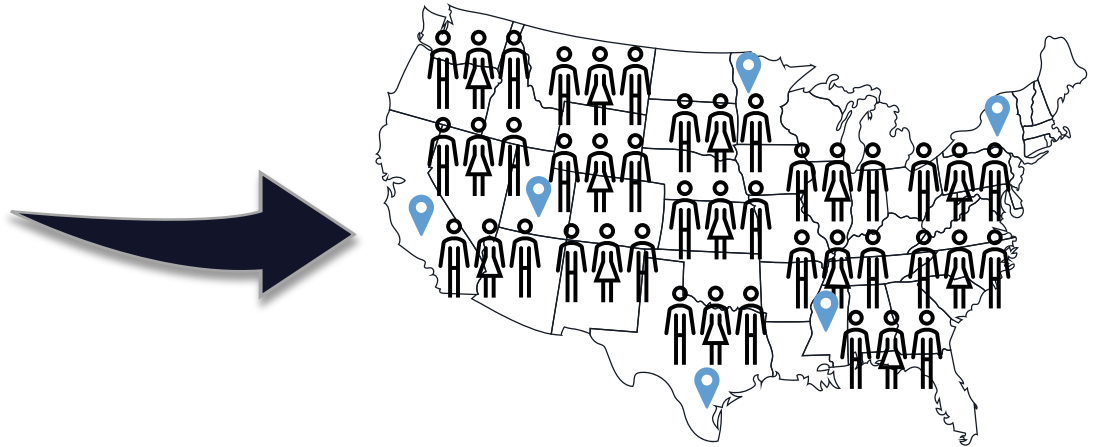


# ENHANCING GENERALIZABILITY

## Clinical Trials



## Real World US Population





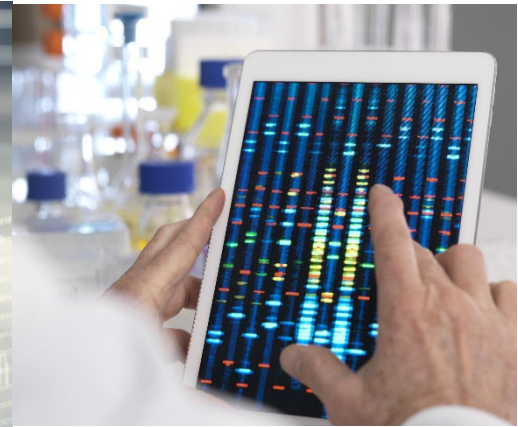
# Envision the Future



**Clinical  
Practice**



**Point of Care**



**Clinical  
Research**

# Acknowledgements

- OCE Leadership
  - Richard Pazdur
  - Paul Kluetz
  - Marc Theoret
  - Tamy Kim
  
- Project Pragmatica Leadership
  - Paul Kluetz
  - Donna Rivera
  - Harpreet Singh
  - Timil Patel



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**Thank you to patients, families, and caregivers for all you do to support development of new treatments for patients with cancer.**