U.S. FOOD & DRUG ADMINISTRATION

Oncology Center of Excellence

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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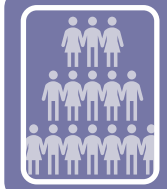
OCE's Project Pragmatica

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



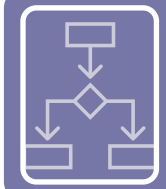
Resource Intensive

Highly Burdensome

- Patients
- Providers

Future State

More streamlined and generalizable



Targeted Objective-focused Approaches

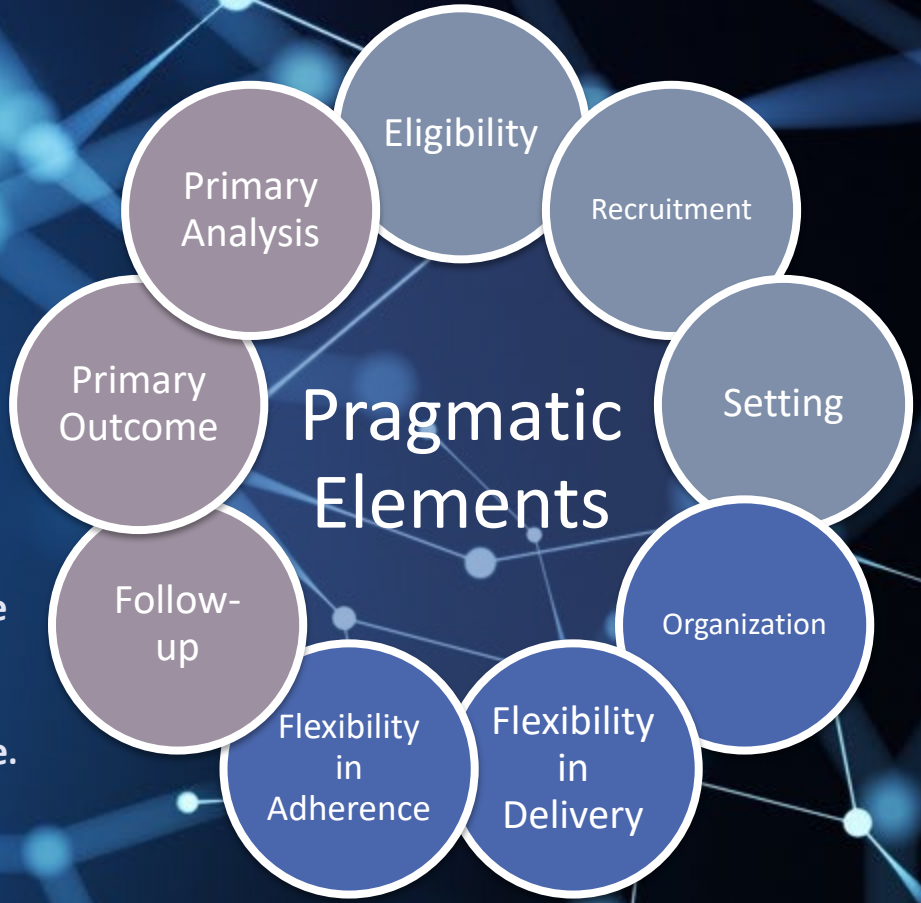
Closer to Routine Care

- Increased Access
- Appropriate Flexibilities

OCE Project Pragamatica

Objective

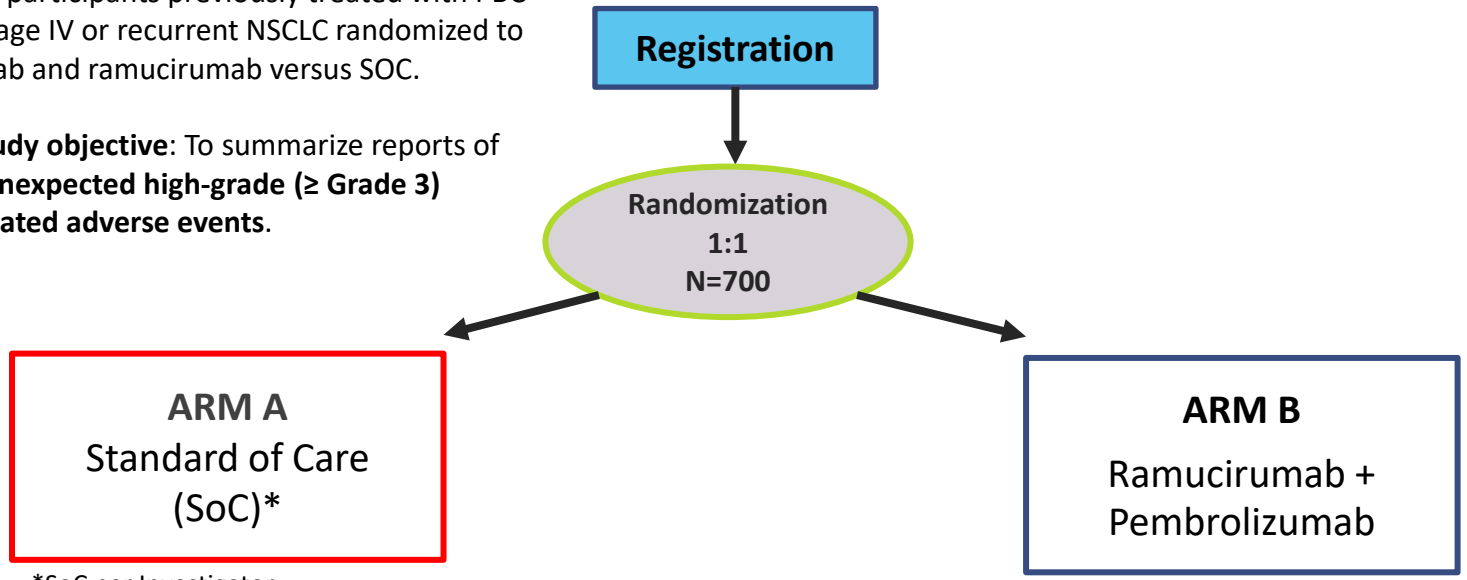
Advancing evidence generation for approved oncology medical products by exploring innovative trial design approaches that introduce functional efficiencies and patient centricity through integration with real-world routine clinical practice.



PRAGMATICA LUNG TRIAL S2302 DESIGN

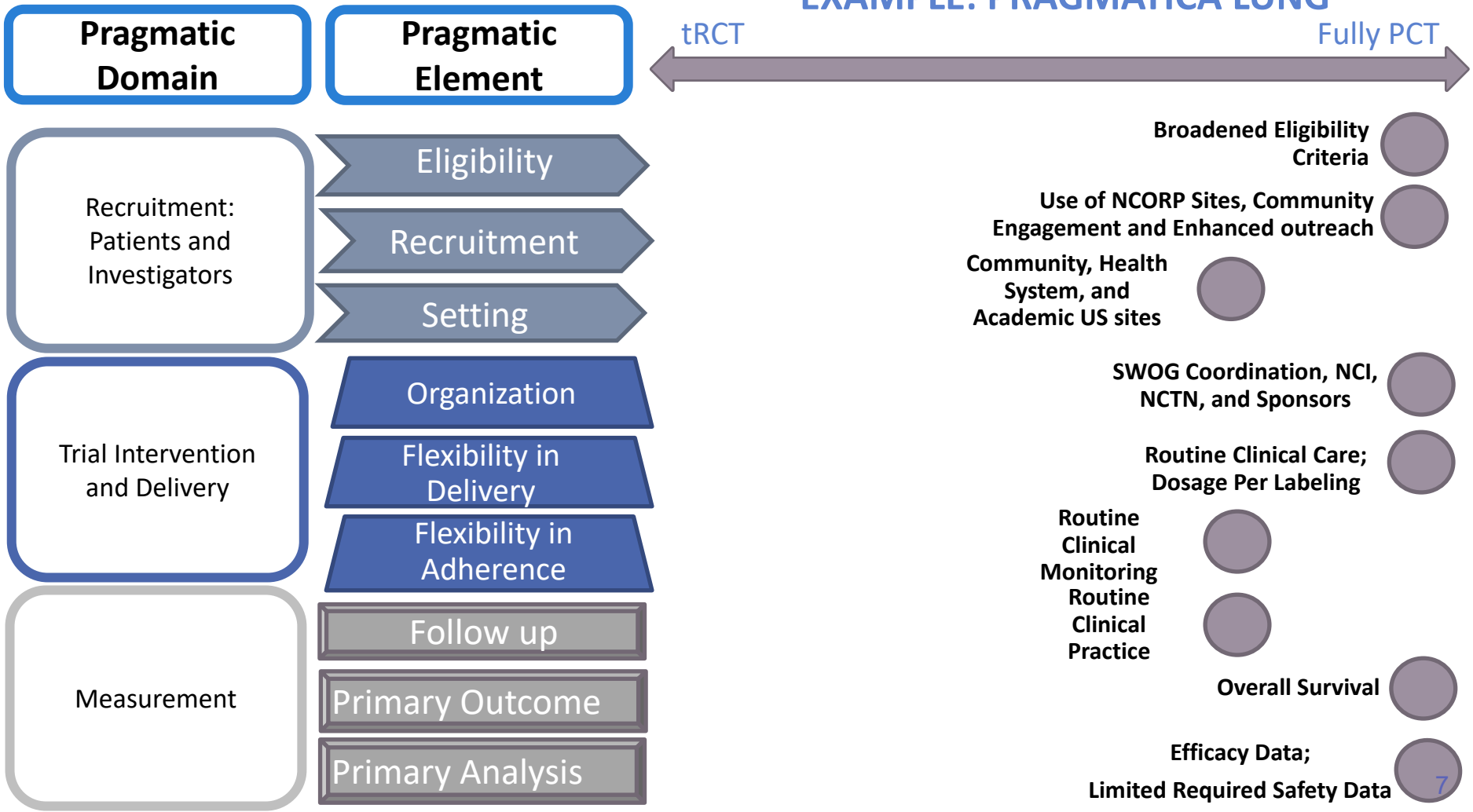
Primary study objective: To compare **overall survival (OS)** between participants previously treated with PBC and I/O for Stage IV or recurrent NSCLC randomized to pembrolizumab and ramucirumab versus SOC.

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



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

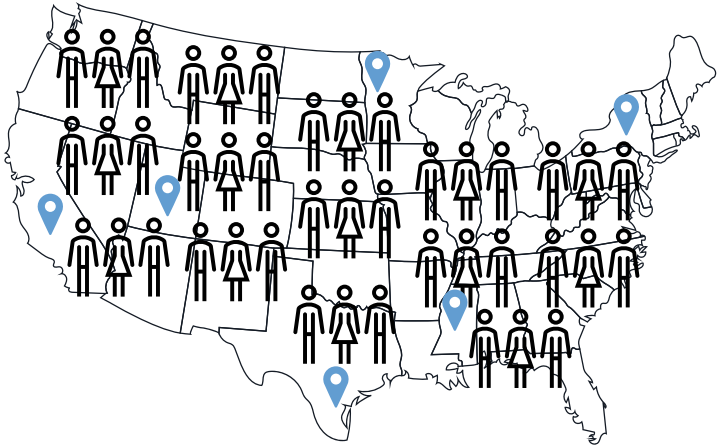
EXAMPLE: PRAGMATICA LUNG



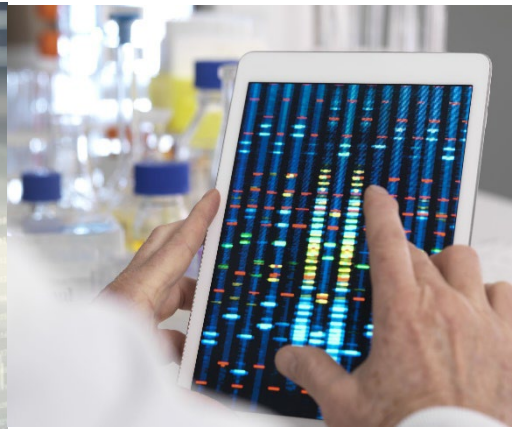
ENHANCING GENERALIZABILITY

Clinical Trials

Real World US Population



Envision the Future



Clinical Practice

Point of Care

Clinical Research

Acknowledgements

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  - Tamy Kim

- Project Pragmatica Leadership
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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.