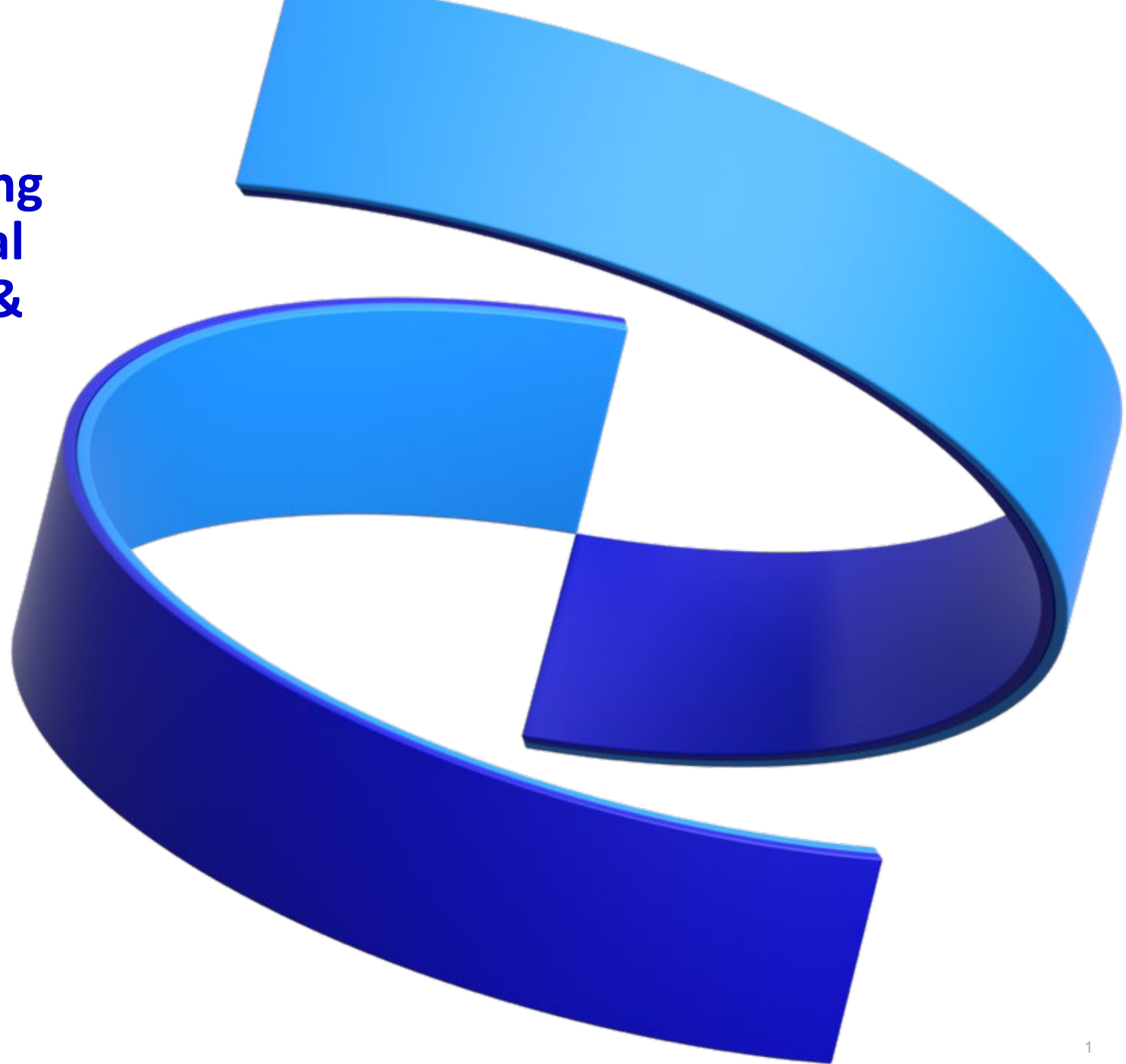

Building a Framework for Setting Enrollment Goals to Ensure Trial Participant Diversity: Insights & Challenges

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Global Medical Epidemiology
BIO Clinical Trial Diversity Roundtable
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Breakthroughs that change patients' lives



Situation: Pfizer needed a transparent and reproducible process for setting clinical trial diversity enrollment goals

Pfizer is committed to “racially and ethnically diverse participation in all of our trials.”



Contents lists available at [ScienceDirect](#)

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Demographic diversity of participants in Pfizer sponsored clinical trials in the United States

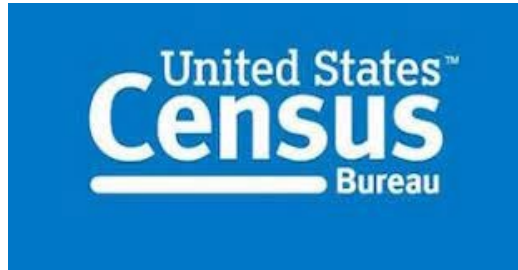
Melinda Rottas^{a,*}, Peter Thadeio^b, Rachel Simons^b, Raven Houck^b, David Gruben^b, David Keller^b, David Scholfield^c, Koshika Soma^b, Brian Corrigan^b, Annette Schettino^d, Patrick J. McCann III^b, Marie-Pierre Hellio^b, Kannan Natarajan^d, Rob Goodwin^b, Judy Sowards^e, Peter Honig^f, Rod MacKenzie^e



Needed to take the next step and base trial diversity goals on disease epidemiology.

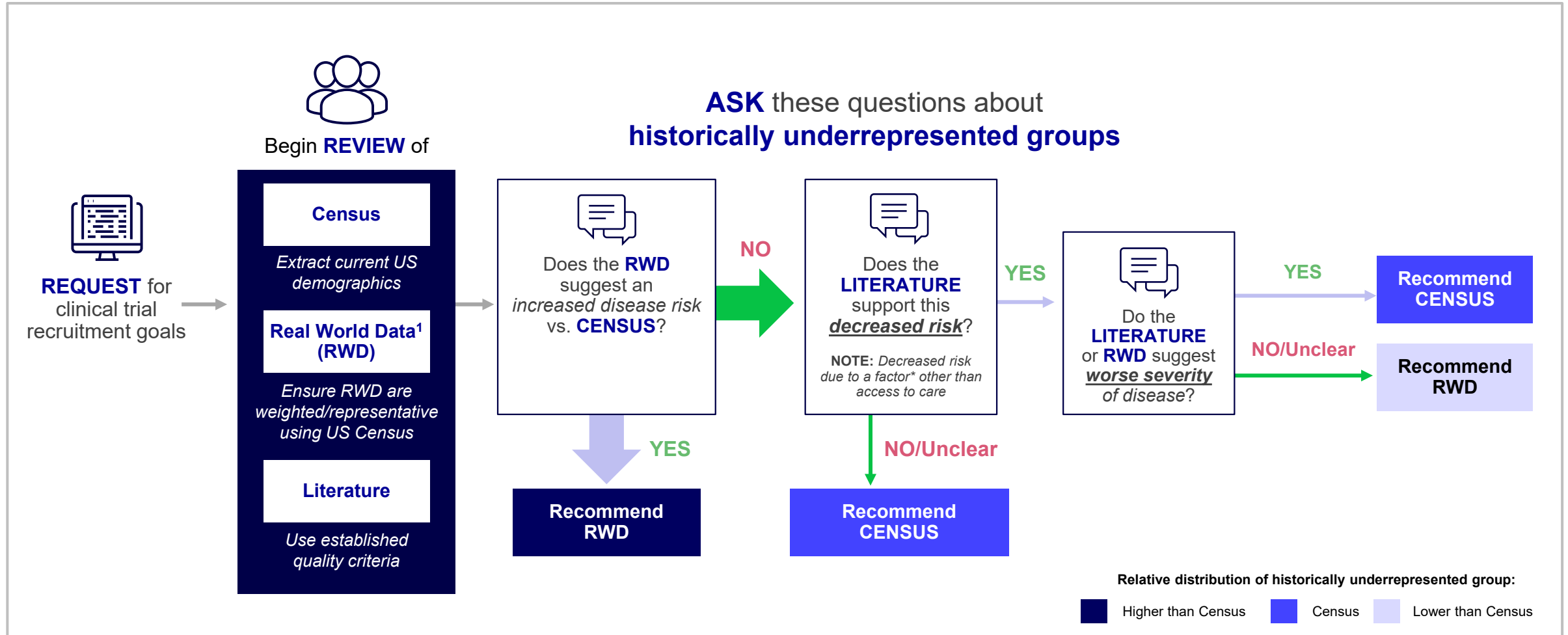
Action: Built a framework using epidemiologic expertise and convened Advisory Board to evaluate, strengthen, and endorse.

Data Sources



- Limitations considered and addressed.
- Designed to address underrepresentation of historically underserved groups.
- Considers access to care, severity of disease/outcome, and type of trial.
- Compares race and ethnicity distributions of diseases population to general population
- Based on decisions embedded in the framework, enrollment goals are selected.

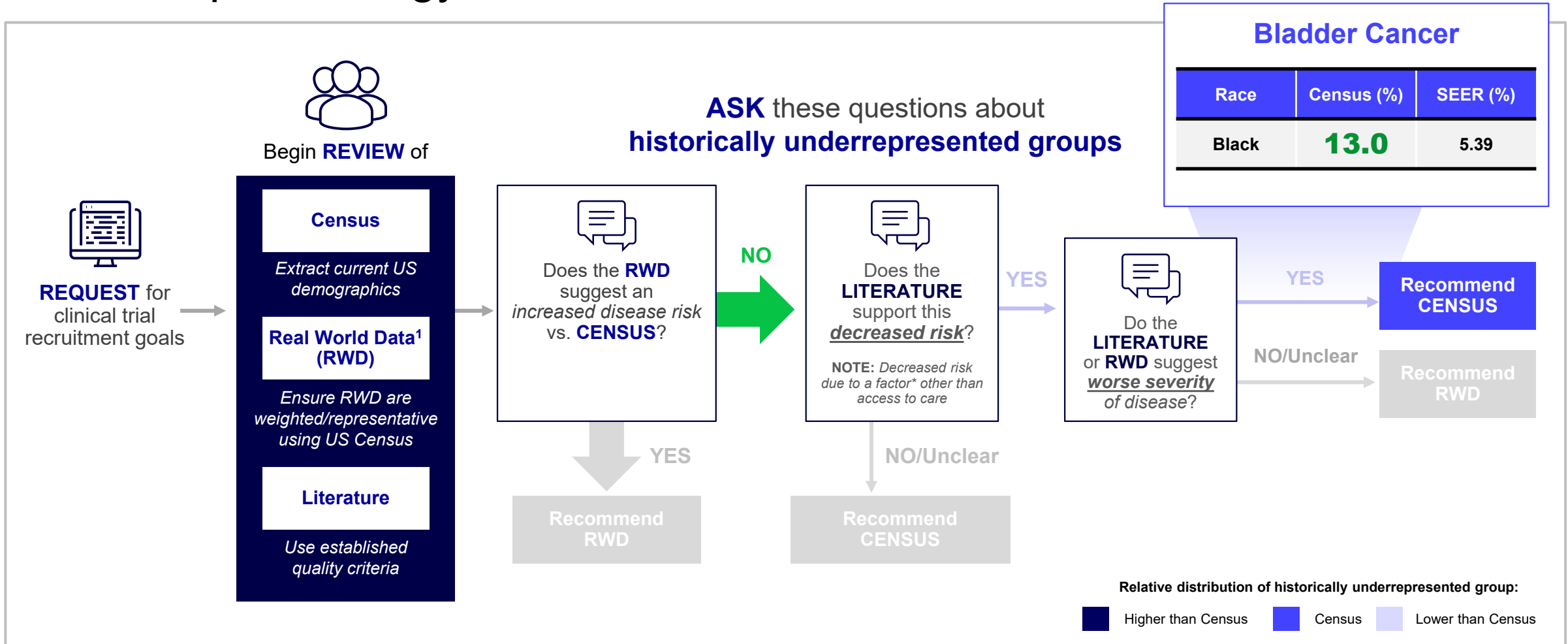
Result: A process that is scientifically rigorous, flexible, and based the disease epidemiology



* E.g., due to a biological factor.

1. Real world data refer to in-house, recent analyses of the demographic distribution of diseases targeted by Pfizer's medicines, from sources such as disease registries, surveys, electronic health records, and claims.

Result: A process that is scientifically rigorous, flexible, and based the disease epidemiology



* E.g., due to a biological factor. **SEER – Surveillance, Epidemiology, and End Results

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Lessons learned: What went well & what were the challenges ?



- Framework endorsed as methodologically sound and ethical.
- Weighting of RWD to improve representation of disease populations.
- Pfizer has solid foundation on which to build and enhance



- RWD sources vary in depth and reliability in capturing disease population.
- Missing values for race (11.9%) and ethnicity (12.5%) in RWD.
- Medical literature has potential biases that must be navigated.

Recommendations: What is needed to improve representation ?



- Broaden definition of diversity beyond race and ethnicity.
- Data providence and standardization for race and ethnicity variables.
- Recruitment and retention of historically underserved groups .
- Enrollment levels that facilitates meaningful sub-group analyses