



# Initiatives to Diversify Clinical Trials

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# National Minority Quality Forum (NMQF)

- Founded in 1998, NMQF is a non-profit Washington, D.C.-based, health care research and education organization whose mission is to reduce patient risk by assuring optimal care.

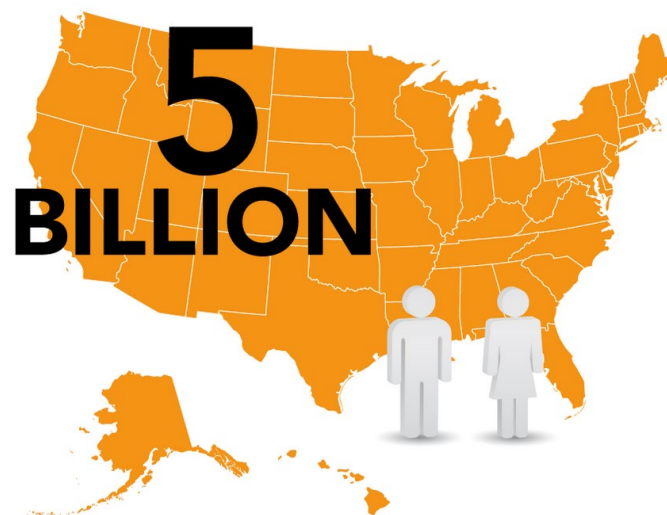


## Vision

- To have an American health services research, delivery and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life

# National Minority Quality Forum (NMQF)

- The Forum has developed a comprehensive database comprised of over **5 billion** patient records, which it uses to define disease prevalence, costs and outcomes for demographic subpopulations by geography (zip code, state, county, congressional and state legislative districts).





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# Objectives

- Define underrepresentation of racial and ethnic populations in clinical trials
- Describe initiatives taken by the National Minority Quality Forum to diversify clinical trials (NMQF)



# Challenges

- Increasing clinical trial diversity in an effective, sustainable, and scalable manner remains a challenge.
- Join together to support “the development and long-term sustainability of an infrastructure that unites clinical research with clinical care”
- “Many strategies have been developed to increase enrollment of diverse populations, but they have produced mixed results. One strategy that has not been scaled up in a sustainable way is engaging community clinicians in research”.

*J. Woodcock, R. Araojo, T. Thompson, G. Puckrein; 2021, Integrating Research into Community Practice — Toward Increased Diversity in Clinical Trials, NEJM DOI 10.1056/NEJMp210733*



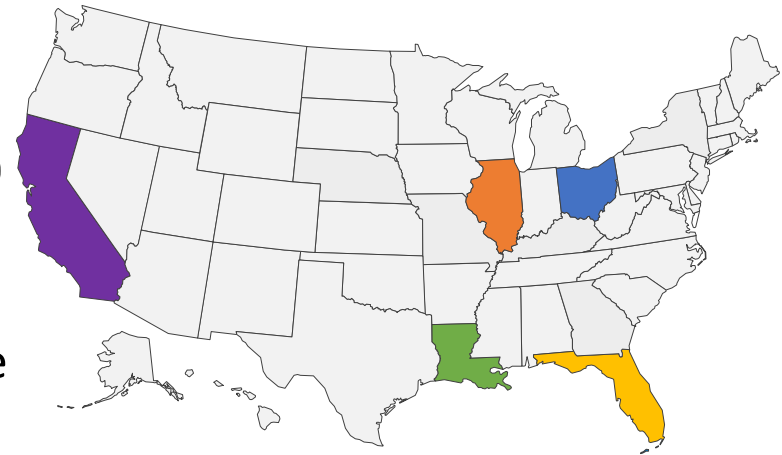
# Successful Strategies

- Recruit community and minority physicians
- Build trust with transparent communication
- Cultural sensitivity
- Raise health awareness in underserved populations
- Involve communities

# MCRIS Study Overview

## Methods and Design

- Prospective 5-year longitudinal study (target 5,000 participants)
- 5 community health centers in 5 states (FQHC)
- Participant inclusion based on convenience sample



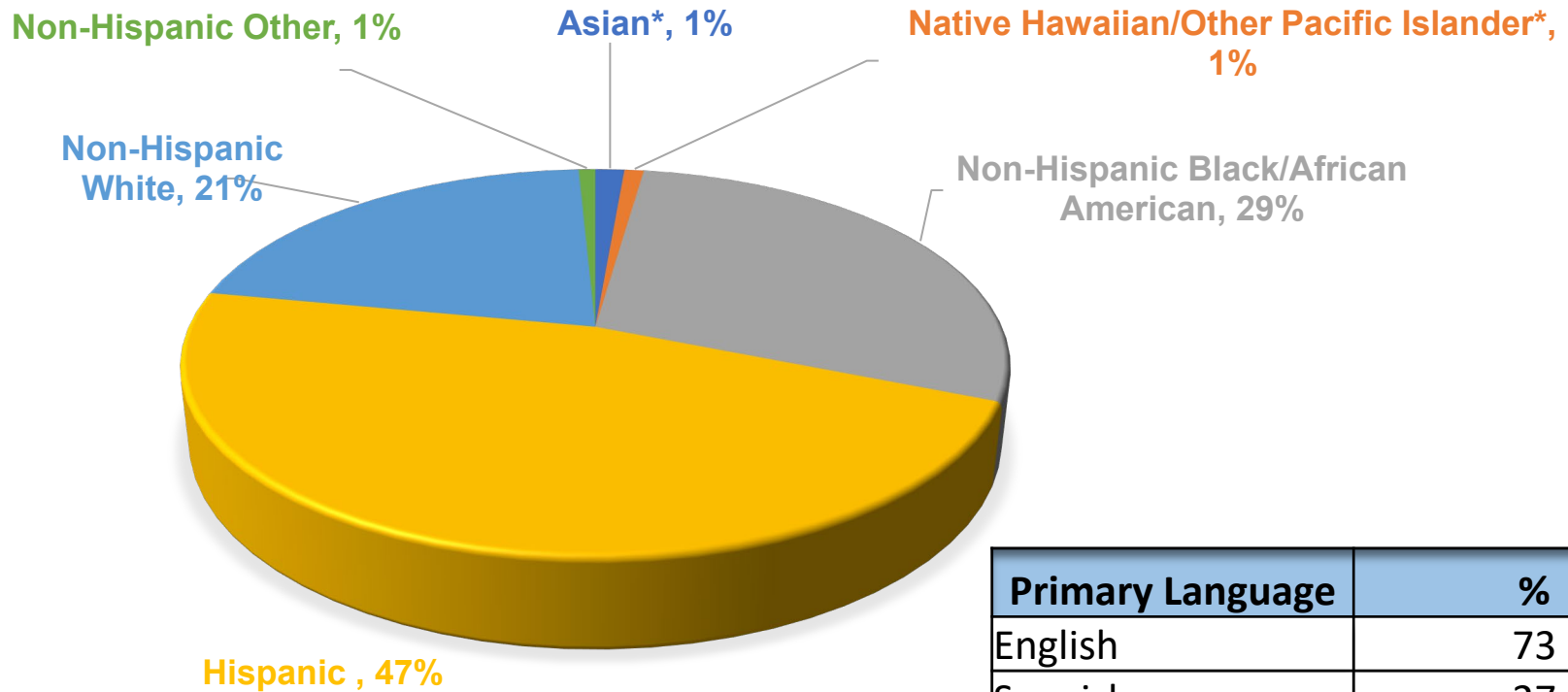
### ***All participants at baseline:***

- Informed consent for participation
- Pre-test survey (demographics, clinical and social determinants information)
- Viral (PCR) test and antibody test
- Other labs: CBC, CMP, HbA1C, CRP, Serum Vitamin D, and other labs



# Preliminary Results: Demographics

## RACE / ETHNICITY DISTRIBUTION



Primary Language	%
English	73
Spanish	27
Grand Total	100

# Alliance for Representative Clinical Trials (ARC)

*ARC is a multi-sponsor public/private program of community clinicians that are organized to diversify and bring clinical trials to communities of color and other communities that have been underrepresented in clinical trials.*



# Alliance for Representative Clinical Trials (ARC)

- To advance health equity in clinical trials, trials require a representative participant sample of the US population. This collaborative effort allows for a significant sample size of the minority population to be included in clinical trials by including community clinic participation, thus providing sufficient power for drawing meaningful conclusions that would otherwise exclude minorities and not account for their health outcomes.

# Support Provided by ARC

## I. PI Institute

- Community clinicians and their research team are invited to enroll in the PI Institute where they attend a thirteen-hour course conducted by a leading global contract research organization (CRO).
- Training includes a site feasibility survey to determine what, if any, upgrades (human and physical) are required to organize the clinician practice as a clinical research site.
- Upon successful completion a certificate that a community clinician (and the practice site) has met its standards to be a PI is issued.
- The institute will offer programs and recertification to ensure that its network of investigators remains in compliance with best clinical trial standards.

# Support Provided by ARC

## II. Research Coordinator

- Support the staffing of a research study coordinator into community practices
- Coordinators are essential and a center piece of the clinical research enterprise
- Coordinator improves:
  - Subject recruitment numbers
  - Enhances subject retention
  - Added efficiency

Davis, A. M., Hull, S. C., Grady, C., Wilfond, B. S., & Henderson, G. E. (2002). The invisible hand in clinical research: the study coordinator's critical role in human subjects protection. *Journal of Law, Medicine & Ethics*, 30(3), 411-419.

# Support Provided by ARC

## III. Clinical Investigative Site Network (CISN)

Upon completion of the PI Institute training course, investigators and the clinics in which they conduct business will be eligible to join the Under the umbrella of ARC, serving as a single entity representing the network sites, CISN liaises with sponsors, as well as streamlines and coordinates all clinical trial activities. Furthermore, CISN refines clinical trial processes to ensure optimally performed trials, using a centralized IRB, single contracting, budgeting, Informed Consent Form processing, and more, via a centralized study activation center.



# Bringing the Clinical Trial Ecosystem to Community

In 2020 \$245.1 billion in the U.S. was invested in medical and health research and development. Industry accounted for two-thirds of that investment (\$161.8 billion) while the federal government invested 25% (\$61.5 billion). Because of the absence of clinical research infrastructure, very little of those investment dollars are available in minority and poor communities. The absence of investment means that the professional, skilled and technical jobs associated with medical and health research and development are also not available in those communities.

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**THANK YOU!!**

