

Opportunities to Engage with the NCI Community Oncology Research Program (NCORP)

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A program of the National Cancer Institute
of the National Institutes of Health

Disclosures

- None.

Topics

1. *Context*
2. *NCI-Supported Trials Networks*
3. *NCI Community Oncology Research Program (NCORP)*
4. *Potential Opportunities*

Context: What is a “Clinical Trial”?

National Institutes of Health (NIH) defines a clinical trial as:

A research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Includes studies with:

Healthy participants

No comparison group

Behavioral interventions

<https://grants.nih.gov/policy/clinical-trials/definition.htm>

Context: What are the Phases of Clinical Trials?

- I
 - Test treatment/intervention in small group of people (20 to 80) for first time, to learn about safety and side effects
- II
 - Treatment/intervention given to larger group of people (100 to 300) to determine effectiveness and safety
- III
 - Treatment/intervention given to large groups of people (1,000 to 3,000) to confirm effectiveness, monitor side effects, and compare to standard/similar treatments
- IV
 - Use of approved drug tracked in general population to learn about optimal use

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>

Context: Funders & Governance (examples)

- Funders
 - Federal (NIH, NCI, AHRQ, CDC, HRSA)
 - Non-federal (pharmaceutical companies, PCORI, foundations)
 - Partnerships

- Governance
 - Funders – scientific and administrative/financial
 - Institutional Review Boards – protection of human subjects
 - FDA – scientific (approval requirements)

Context: NCI Role in Supporting Clinical Trials

“working to generate a seamless pipeline of biomarkers and therapeutics that runs the gamut from initial efforts in drug discovery through late-stage clinical trials”

<https://dctd.cancer.gov/DirectorsMessage/default.htm>

“supports many programs that could not be done without government funding...scientifically sound, high-risk research that may yield great benefits for patients with cancer, but are too difficult or risky for industry or academia to pursue”

<https://dctd.cancer.gov/About/default.htm>

Context: History of NCI Support of Phase II & III Treatment Trials

- 1937: National Cancer Institute Established
- 1950s: Cancer Cooperative Groups Formed
- 1971: National Cancer Act (aka “War on Cancer”)
- 1976: Cooperative Group Outreach Program Formed
- 1983: Community Cancer Outreach Programs (CCOP) Formed
- 1990: Minority-Based CCOP Formed
- 2007: NCI Community Cancer Centers Program Formed
- 2014: Current Networks Funded (refunded 2019)
 - National Clinical Trials Network (NCTN)
 - NCI Community Oncology Research Program (NCORP)

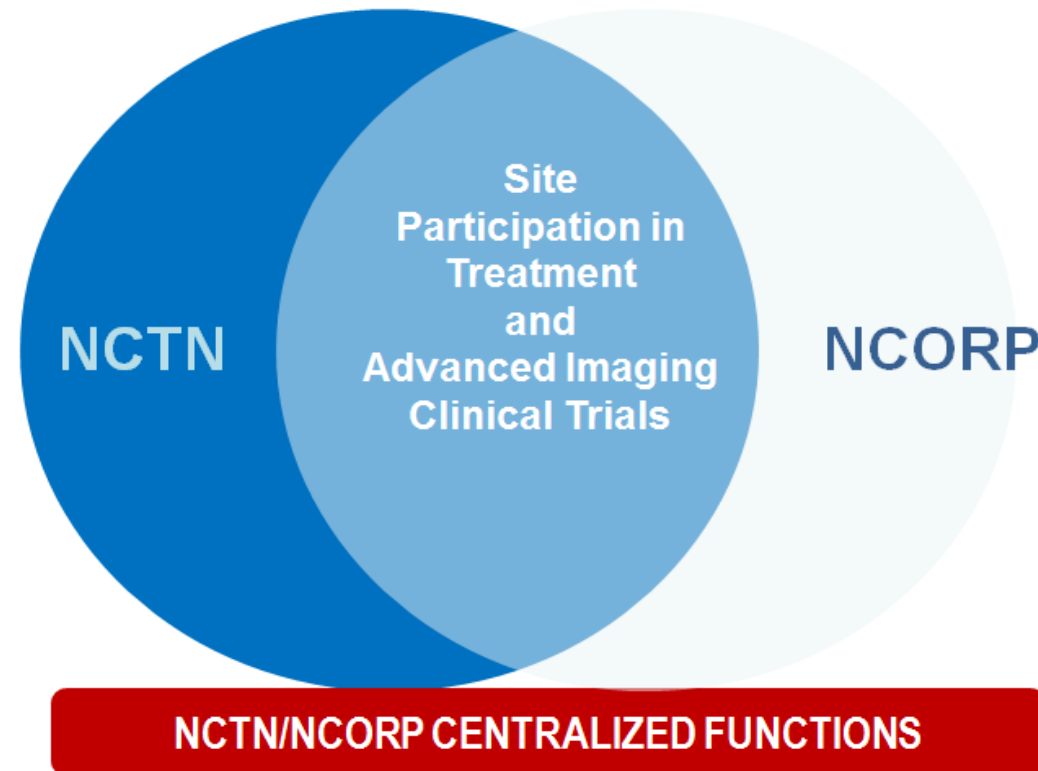
NCI-Supported Phase II & III Networks

NCTN Focus:

- Late-Phase Treatment Trials
- Advanced Imaging Trials

NCORP Focus:

- Cancer Prevention & Control Trials
- Cancer Care Delivery
- Comparative Effectiveness Research



National Clinical Trials Network (NCTN)

- Goal: “help to establish new standards of care, set the stage for approval of new therapies by the Food and Drug Administration, test new treatment approaches, and validate new biomarkers” [and imaging]

- Structure:
 - 5 Groups
 - 32 Lead Academic Participating Sites (LAPS)
 - NCI infrastructure

- Hundreds of disease treatment trials open:
https://ctep.cancer.gov/initiativesPrograms/docs/nctn_trials/NCTN_all_disease_diagrams.pdf

NCI Community Oncology Research Program: Goal (1)

- Bring cancer clinical research studies to individuals in their own communities
- Designs and conducts studies in cancer control, prevention, and care delivery
- Enhances patient and provider access to treatment and imaging trials conducted under the National Clinical Trials Network (NCTN)
- ~60 trials open (in addition to NCTN) (<https://ncorp.cancer.gov/find-a-study/>)

NCI Community Oncology Research Program: Goal (2)

- Cancer control
 - reduce the morbidities associated with cancer and its treatment, as well as improving the quality of life of individuals undergoing cancer treatment or with a history of cancer
- Cancer prevention
 - reduce cancer risk, incidence and mortality
- Cancer care delivery
 - improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence care delivery

<https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-015.html>

NCI Community Oncology Research Program: Goal (3)

- Incorporates the needs of diverse populations into studies and enhances participation of these groups including:
 - Pediatrics
 - Adolescents and young adults (AYAs)
 - Elderly

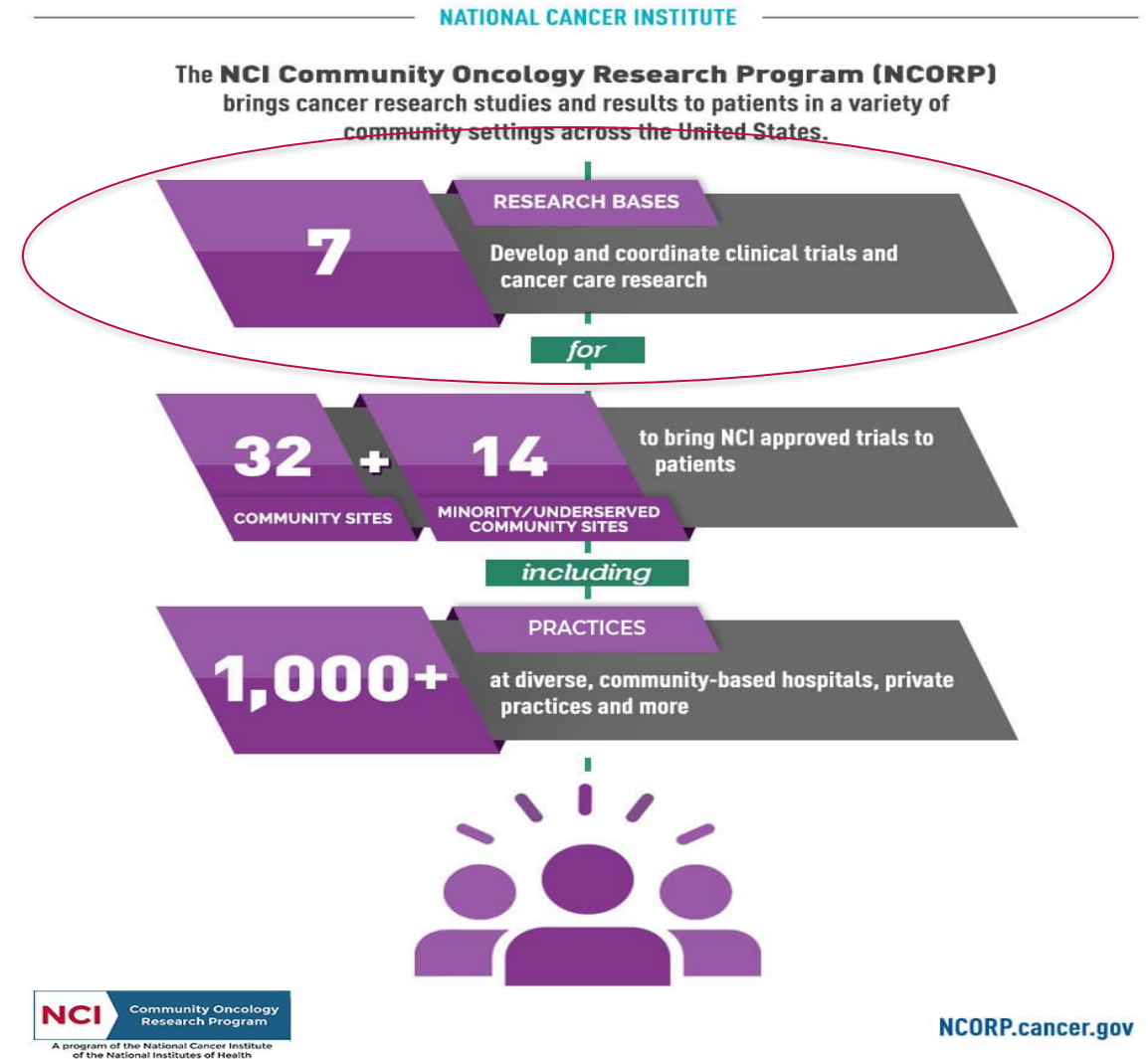
 - Racial and ethnic minorities
 - Rural
- Integrates cancer disparities research within the network.

NCORP Structure: Research Bases (n=7)

Research ideas developed by academic researchers who design and conduct studies.

Research Base provides infrastructure for all functions related to study conduct, including:

- Engagement with research staff at participating sites
- Protocol oversight
- Comprehensive data and statistical support
- Regulatory compliance (& auditing)
- Publication of study findings



NCORP Structure: Research Bases

- Alliance
- Children's Oncology Group
- ECOG-ACRIN
- NRG Oncology
- SWOG
- University of Rochester
- Wake Forest

<https://ncorp.cancer.gov/findasite/research-bases.php>

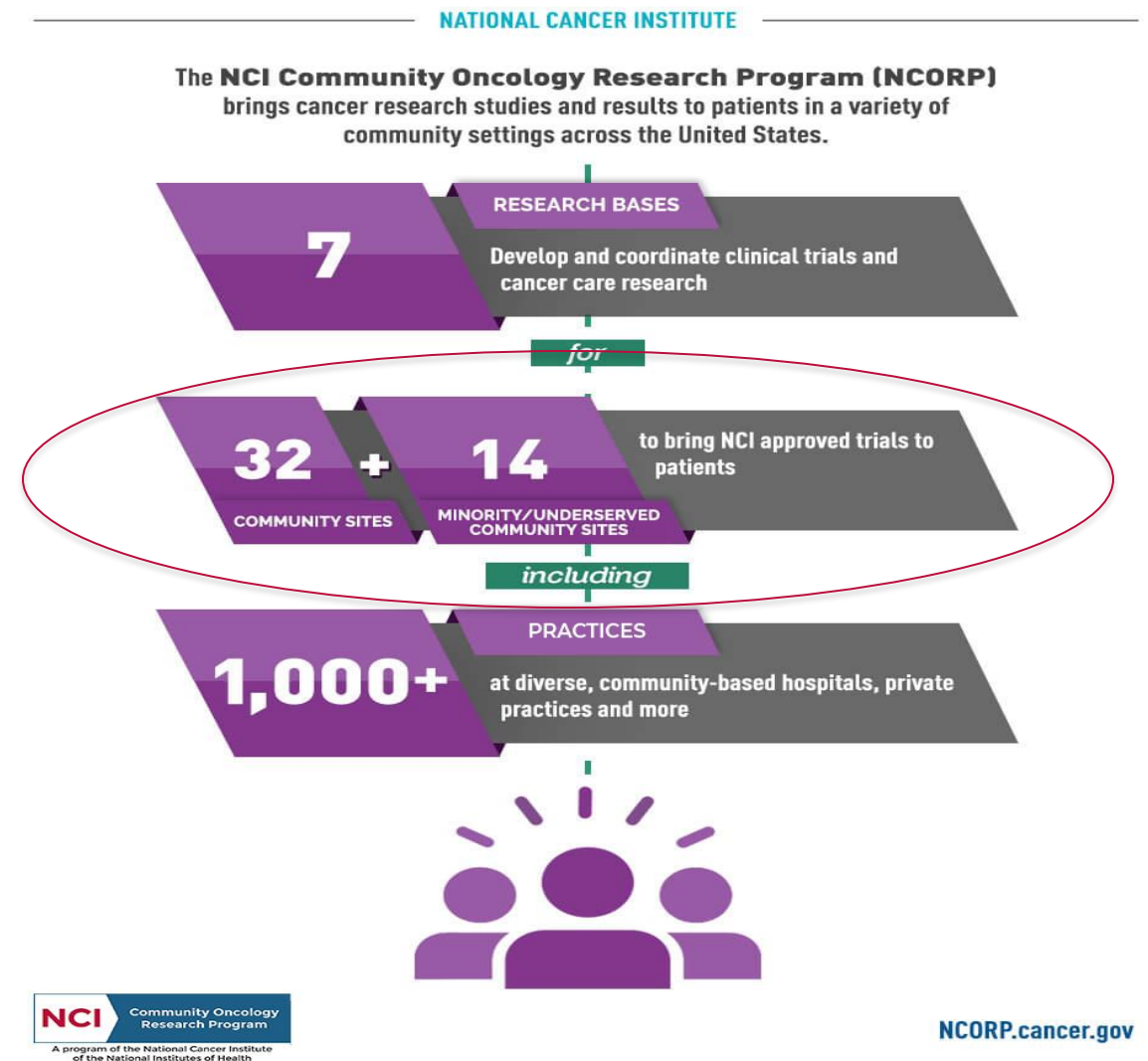
NCORP Structure: Community & Minority/Underserved Sites (n=46)

Site Principal Investigators and Administrators evaluate studies for feasibility, identify potential practice locations, and study champions.

Site study staff:

- Recruit study participants
- Administer intervention (as applicable)
- Collect data
- Participate in audits conducted by Research Bases
- Provide feedback to Research Base study team at beginning and throughout studies

List: <https://ncorp.cancer.gov/findasite/index.php>

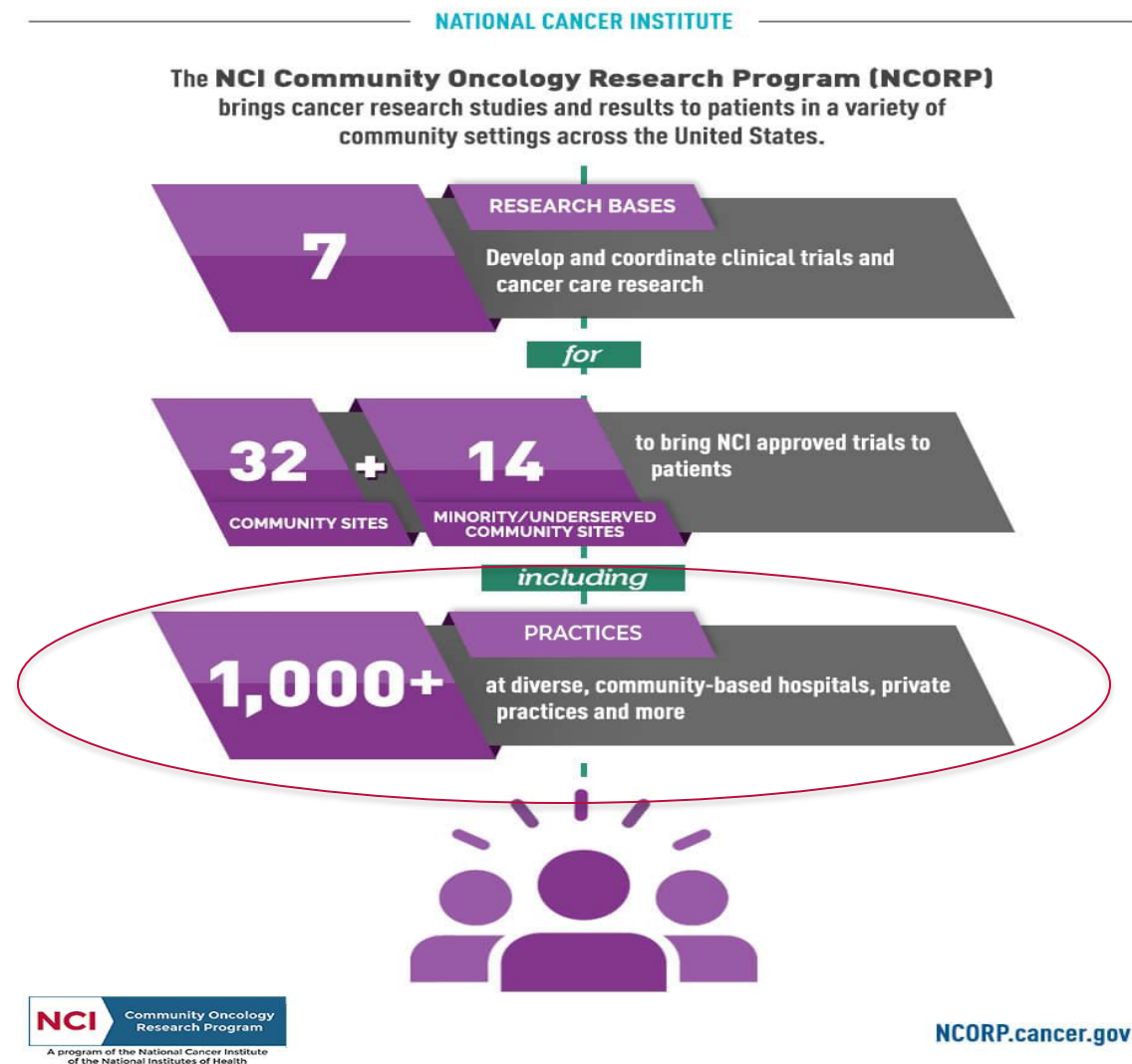


NCORP Structure: Practice Settings

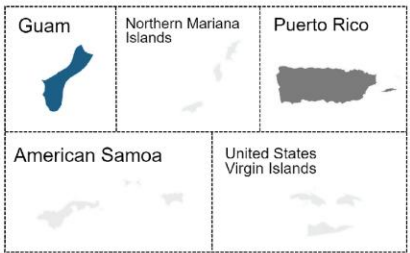
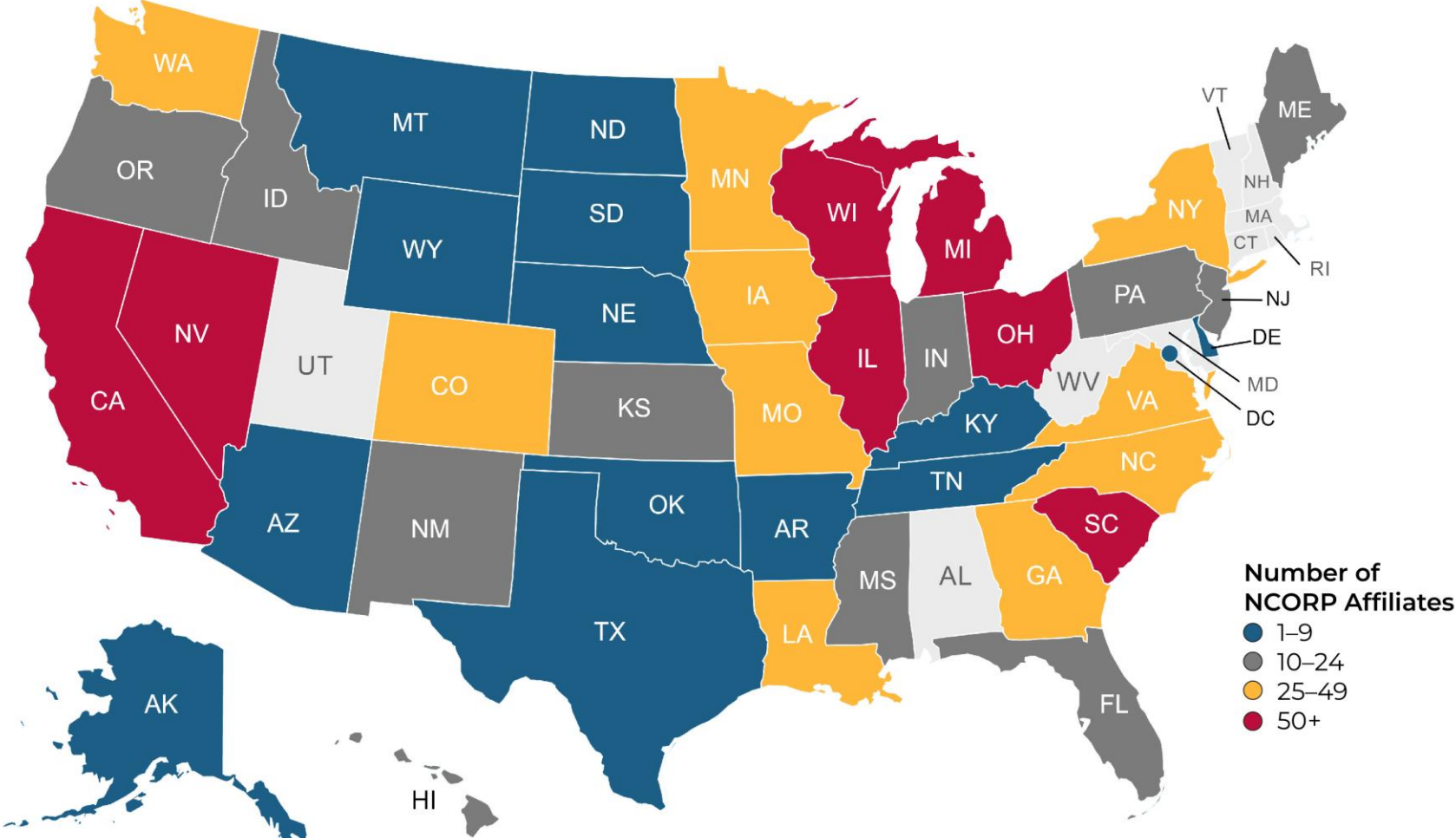
Each Site includes multiple practice settings that take various forms:

- Vertically integrated (aka, HMO)
- Horizontally integrated (aka, hospital-based systems)
- Hospital-based & private practices
- Safety net & federally qualified health centers

Sites may be single or multiple organizations in one or more geographic areas



NCORP affiliated practices span 41 states and 2 territories



Opportunities to Engage with NCORP (1)

- Applications for third round likely due late 2024
 - Sample requests for applications: <https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-016.html> and <https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-017.html>
 - Must document capacity to conduct research and regulatory infrastructure

Opportunities to Engage with NCORP (2)

- Assess interest (both physician/APP and practice)
 - Who has a passion for offering clinical trials to West Virginians in their local communities?
- Learn more about activities and requirements from existing grantees
 - Local states?
 - Similar organizational structure?
 - Minority/Underserved with rural focus?
- Explore affiliation with existing grantee
 - Small “proof of principle” effort?

Questions? Discussion?