

NCI Community Oncology Research Program (NCORP) Update

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Division of Cancer Prevention

NCORP Overview – Launched August 2014:

Merging of two community programs, Community Clinical Oncology Program (est. 1983) and NCI Community Cancer Centers Program (est. 2007), into one comprehensive community program, NCORP, with the following goals:

- Enroll patients in treatment and advanced imaging clinical trials that are developed in the NCI National Cancer Treatment Network (NCTN) through Division of Cancer Treatment and Diagnosis (DCTD)
- Support the inclusion of health-related quality of life (HR-QOL) correlative studies in NCTN treatment trials as follows
- Engage large and diverse patient populations receiving care in a variety of community oncology settings in studies focused on cancer control, prevention and care delivery.
- Goal to generate a broadly applicable evidence base that contributes to improved patient outcomes and reduction in cancer disparities.

Honoring Dr. McCaskill Stevens



Worta McCaskill-Stevens, M.D., M.S.

NCORP Director

PAR-24-153

New Funding Opportunity

NCI Worta McCaskill-Stevens
Career Development Award
for Community Oncology and
Prevention Research

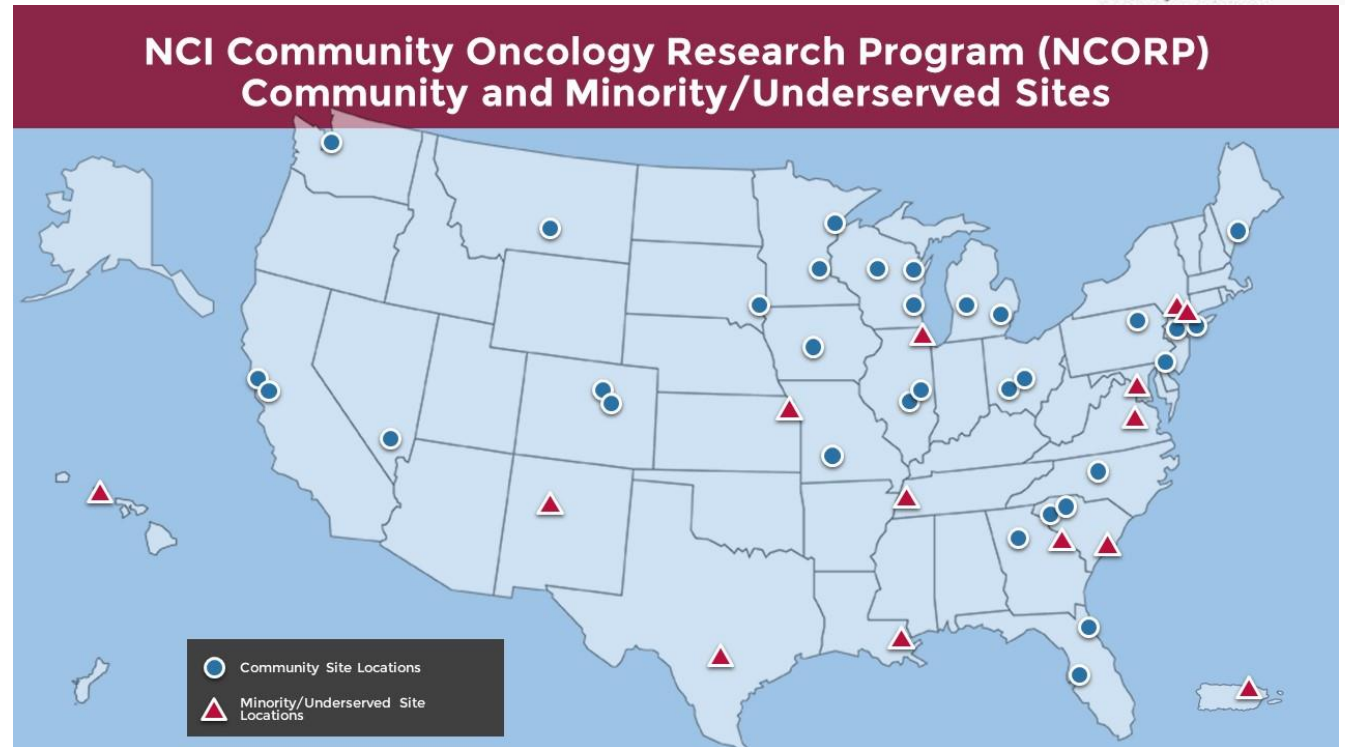
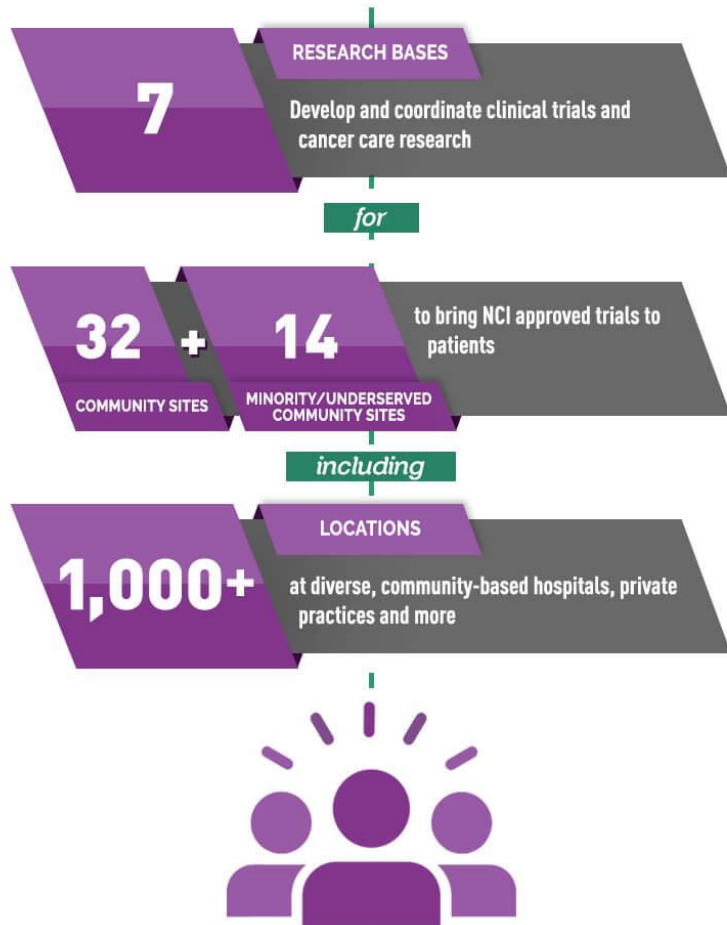
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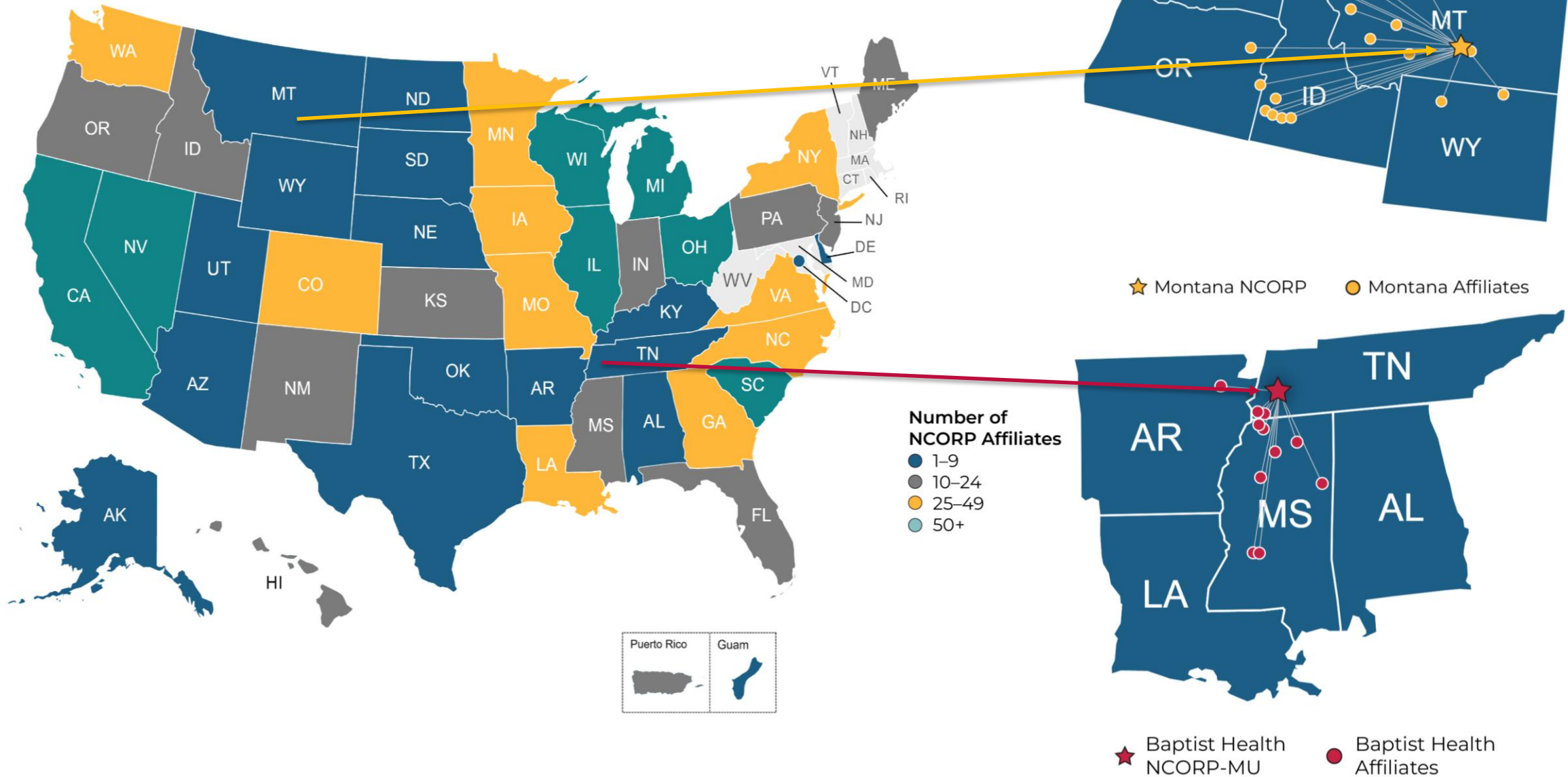
Brandy Heckman-Stoddard,
Ph.D., M.P.H.

NATIONAL CANCER INSTITUTE

The **NCI Community Oncology Research Program (NCORP)** brings cancer research studies and results to patients in a variety of community settings across the United States.



NCORP Coverage Map



NCORP Network Attributes

■ People:

- 4,274 Physician Investigators (active/accruing)
- 1,292 Non-Physician Investigators
- 4,791 Research Staff (Associate/Associate Plus)

■ 11 Health Care Systems:

- Advocate/Aurora, Baptist, CommonSpirit Health System (formerly Catholic Health Initiatives), Essentia, Geisinger, Kaiser Permanente, MaineHealth, Nemours, Northwell Health, Prisma (Greenville), Sanford

■ 6 Standalone (vs. within an institution):

- Columbus, Dayton, Montana, Nevada, Southeast Clinical Oncology Research Consortia, Western States

■ 1,019 Affiliates and Sub-Affiliates:

- 383 Community Affiliates
- 98 MU Affiliates
- 441 Community Sub-Affiliates
- 97 MU Sub-Affiliates

■ Type of Clinical Site:

- Non-Academic Hospitals – 346
- Academic Hospitals – 72
- Community Physician Practice – 264
- Academic Physician Practice - 18
- Free Standing Oncology Clinic – 146
- VA Hospital – 7
- Government Facility - 2
- Military – 3
- NCI Cancer Center – 3
- Administrative Clinical – 5
- Undesignated - 66

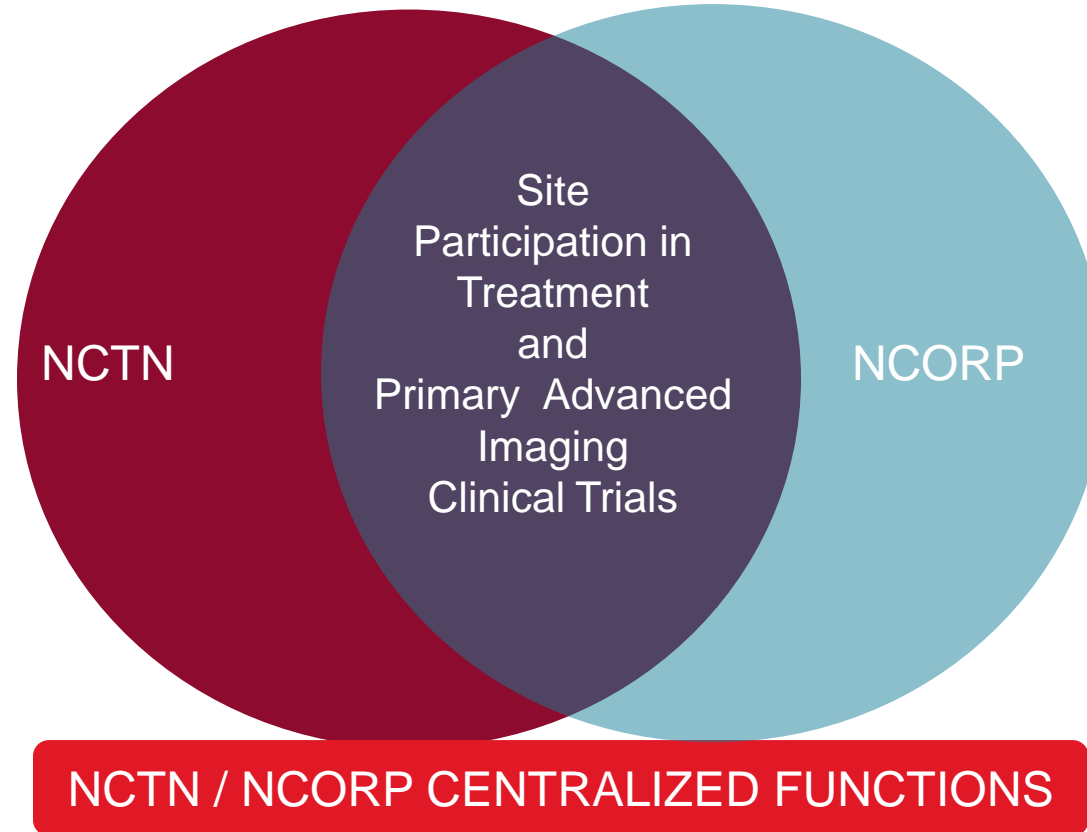
Relationship of NCTN and NCORP

NCTN Focus (DCTD):

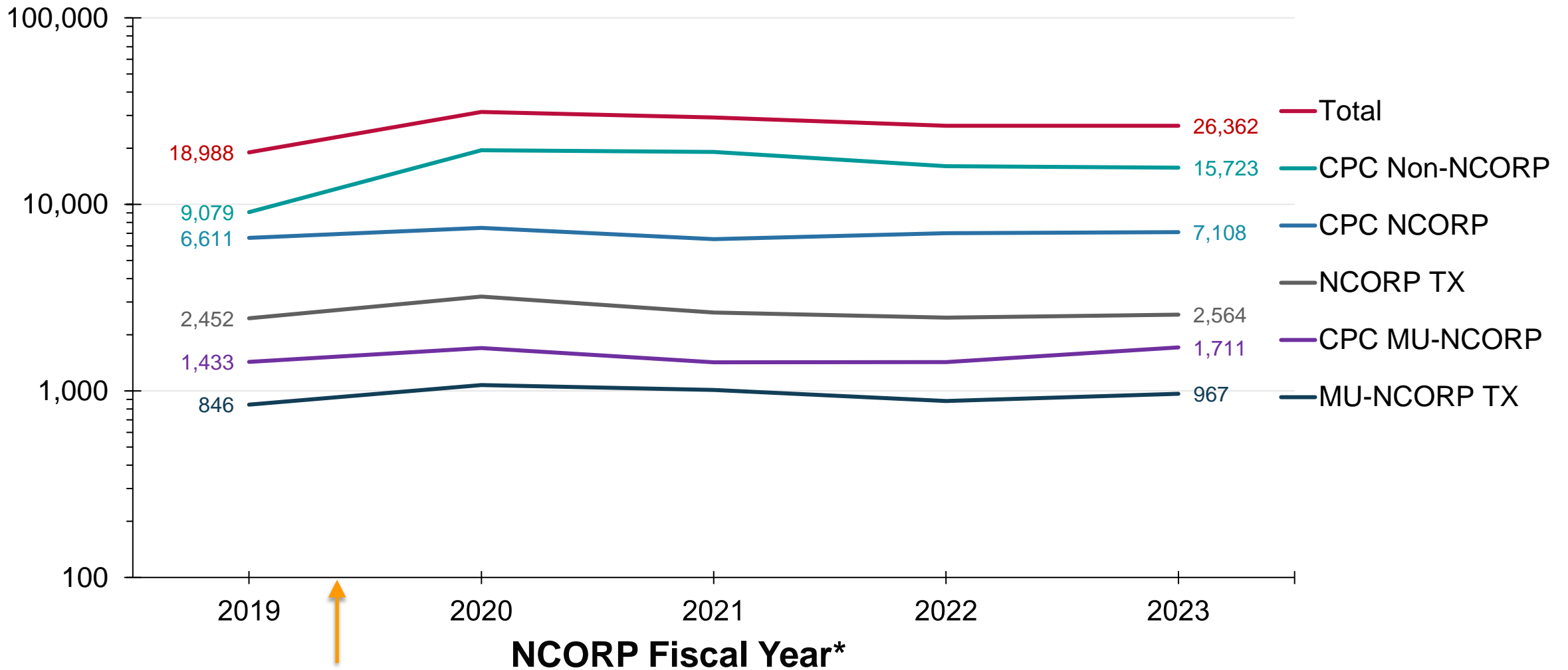
- Late-Phase Treatment Trials
- Primary Advanced Imaging Trials

NCORP Focus (DCP/DCCPS):

- Cancer Control (Symptom Management)
- Quality of Life
- Cancer Prevention and Screening Trials
- Cancer Care Delivery



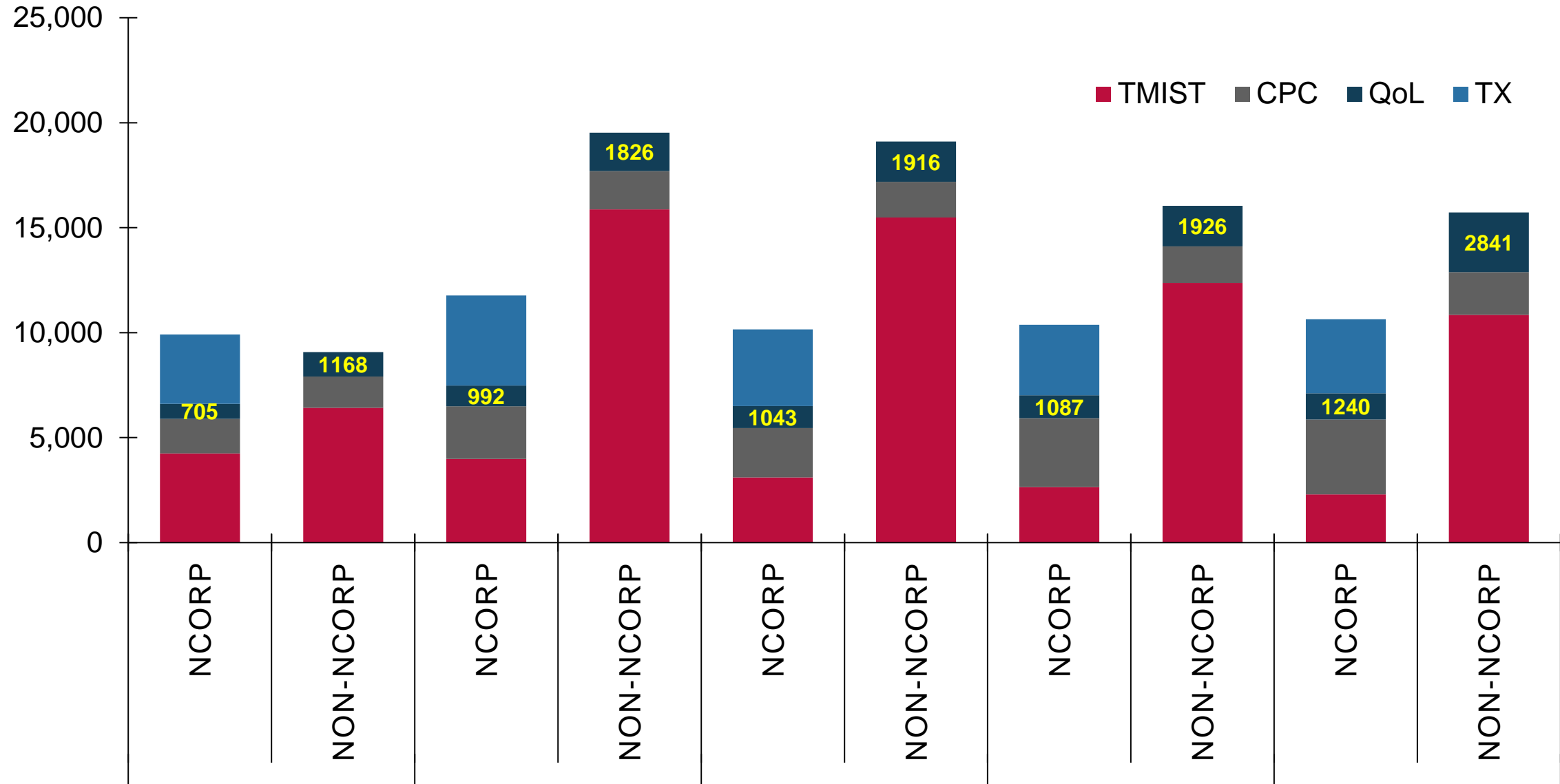
NCORP Program Accrual 2019 - 2024



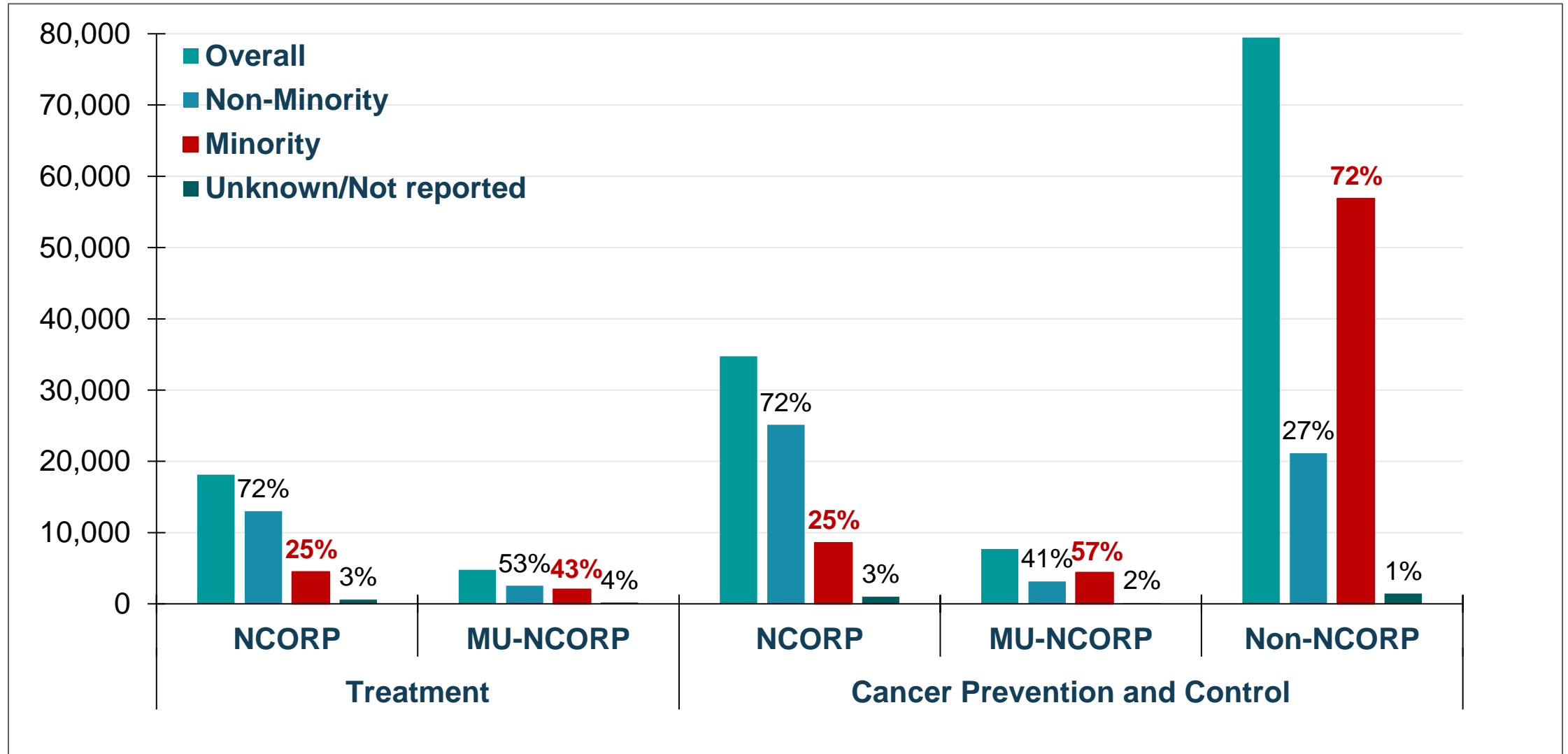
March 2020
Onset COVID-19
pandemic in US

*NCORP Fiscal Year starts in August e.g., 2019 begins in August of 2019

NCORP Accrual Credit by Type 2019-2023



Minority Accrual within the NCORP Program



Study Development in NCORP

Research Base Concept Development

- Investigators with the RB Working Groups develop a concept that is vetted by other researchers and community members
- RB approval
- Submitted for NCI review
- Reviewed by the Steering Committee
- If approved moves on to protocol development

Externally Funded Studies

- Investigators with the RB Working Groups develop a concept that is vetted by other researchers and community members
- Meet with RB to get support for grant submission
- Obtain NCI approval for grant submission
- If funded comes in as a protocol within 90 days of funding
- 25% of the NCORP portfolio

2015 Symptom Management and QoL Strategic Priorities

NCORP SxQOL First Tier High Priority Areas:

- 1) Cognitive Impairment
- 2) Neurotoxicity
- 3) Cardiovascular Toxicity
- 4) Fatigue
- 5) Cancer Specific Pain

NCORP SxQOL Second Tier High Priority Areas:

- 1) Sleep Disorders
- 2) Bone Health Toxicity
- 3) Metabolic Toxicity
- 4) Psychological Distress

Symptom Management Trials in NCORP

Cognitive Impairment

- NRG: A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy (WBRT) With or Without Hippocampal Avoidance (HA) in Patients With Brain Metastases – Memantine preserves **cognitive function** and reduce patient-reported symptoms, with no difference in intracranial PFS and OS
- COG: A Phase 3 Randomized, Placebo-Controlled Trial Evaluating Memantine for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors

Neuropathy

- URCC: Wireless Transcutaneous Electrical Nerve Stimulation (TENS) for **Chemotherapy-Induced Peripheral Neuropathy**: A Phase II Clinical Trial – Positive study , planning phase III
- Alliance: Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study

Cardiotoxicity

- COG: Pharmacologic Reversal of Ventricular Remodeling in **Childhood Cancer Survivors at Risk for Heart Failure** (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial – showed improvement in adverse cardiac remodeling parameters
- SWOG: Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III

NCORP Currently Active Large Screening Trials

Protocol	Actual Accrual (08/28/2024)/Planned Accrual
EA1151 (TMIST) - Randomized to 2D digital mammography versus 3D tomosynthesis mammography for 4 years; primary endpoint is reduction in advanced cancers	104,153/108,508
NRG-CC005 (FORTE)- Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) study will help to determine if certain people can wait for a follow-up colonoscopy after a routine screening colonoscopy	1,895/9,500

New DCP Screening Trial Requirements

Study Design/ Study Plan



- Sample size appropriately justified
- Accrual duration explicitly stated
- Eligibility criteria clearly defined

Recruitment Planning



- Overall and minority recruitment plans detailed
- Non-English speakers included
- Participant Advisory Boards required for trials >10,000

Accrual: Milestones & Monitoring



- Expected overall and minority accrual milestone dates stated
- Overall and minority accrual monitoring described
- Stopping rules are addressed

CCDR Portfolio Overview (DCCPS)

30 Protocols

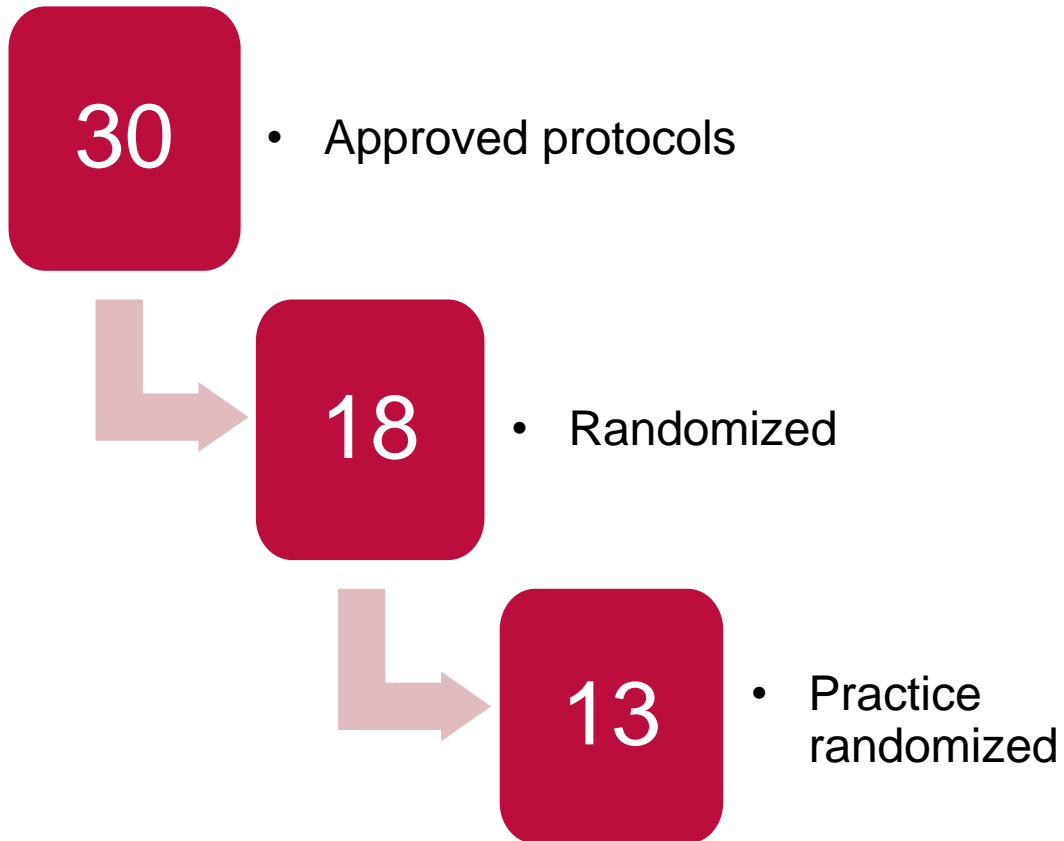
- 12 Open and accruing
- 9 Closed to accrual
- 9 Completed

Care delivery gaps addressed*

- Guideline Adherence (6)
- Health Expenditures (6)
- Health Service Accessibility (6)
- Decision-Making, Shared (3)
- Implementation Science (3)
- Case Management (2)
- Health Disparate, Minority & Vulnerable Populations (2)
- Drug utilization (1)
- Treatment Adherence and Compliance (1)

*MeSH-defined (# of protocols)

CCDR Studies & Accrual to Date



Accrual:

- Patients = 12,116
- Non-Patients = 2,295
- Practices = 839*
- Minority Patient Accrual = 23.4%

*Not unique; a practice is counted multiple times if they provided data for multiple studies.

Outcome data collected:	# of Trials
Patients and Non-Patients	10
Patients, Non-Patients, and Practices	7
Patients only	6
Practices only	3
Non-Patients and Practices	3
Patients and Practices	1

NCORP Impact/Summary

- Community-academic partnership that increases diversity of accrual and generalizability of results
- Better adoption for improved clinical practice and patient care in the community
- Focus on importance of quality of life and incorporating patient experience and develop interventions to improve the cancer experience
- NCORP is Trans-NCI Collaboration with DCTD, DCCPS, and CCHE
- Future: Re-competition will be presented at the December 2024 Board Meeting:
 - We aspire to launch a NCORP Incubator Program to help new applicants compete successfully to join NCORP.

Questions for NCAB Input on the Future of NCORP



How can we expand the NCORP to engage more people in clinical trials where they live?



How can we better engage LAPs sites in Cancer Control and Prevention trials?



How can we better collaborate internationally to conduct Cancer Prevention and Control trials?



How can we reduce the workload at the sites while enhancing the research impact of our trials?



How can we connect data and biospecimens from prior trials and QoL studies to contribute to new research?



How can we help outside investigators with great ideas engage with the network?



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