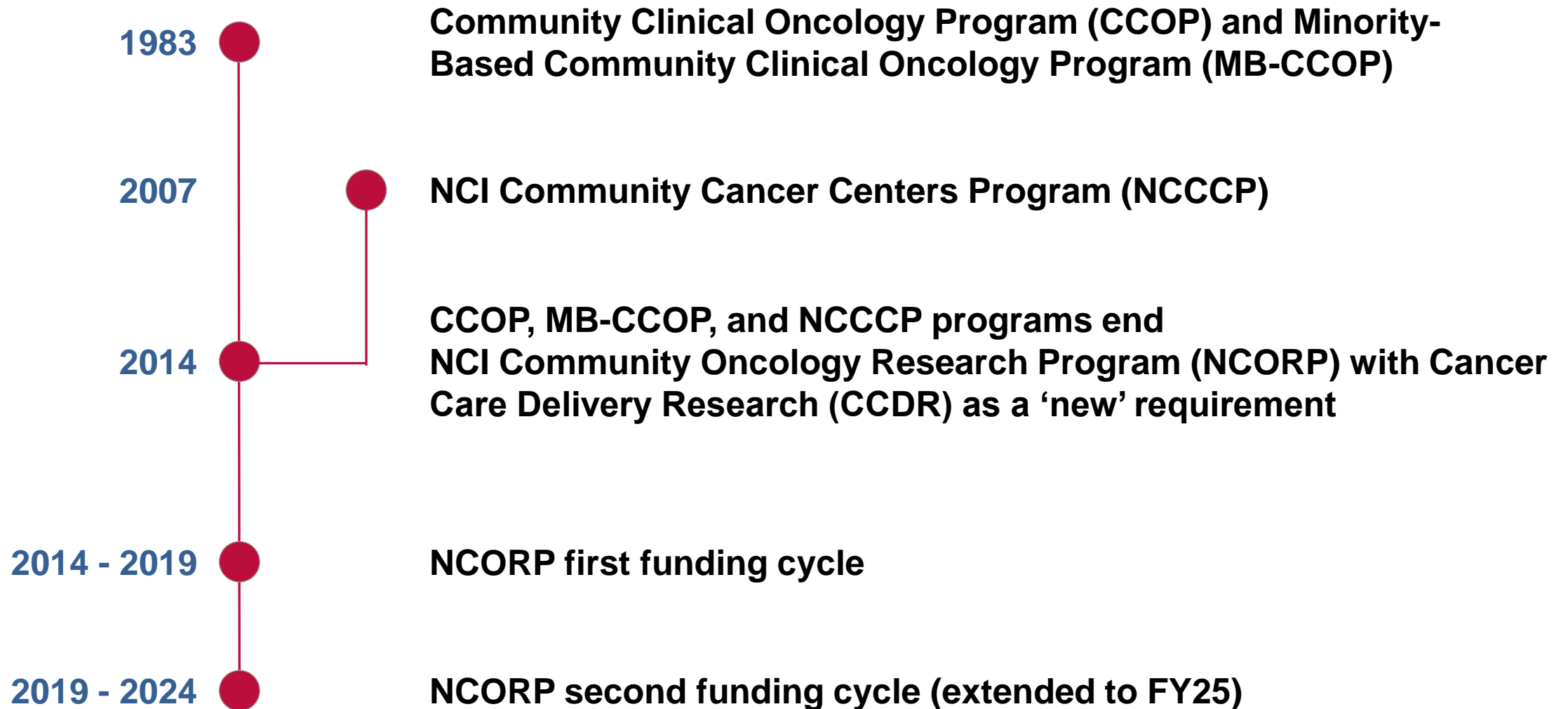


# NCI Community Oncology Research Program (NCORP) Update

*Brandy Heckman-Stoddard, PhD, MPH  
Acting Director NCORP*

# History of NCI Community Oncology Research Programs



# NCORP Overview – Launched August 2014:

- 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
- 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.**

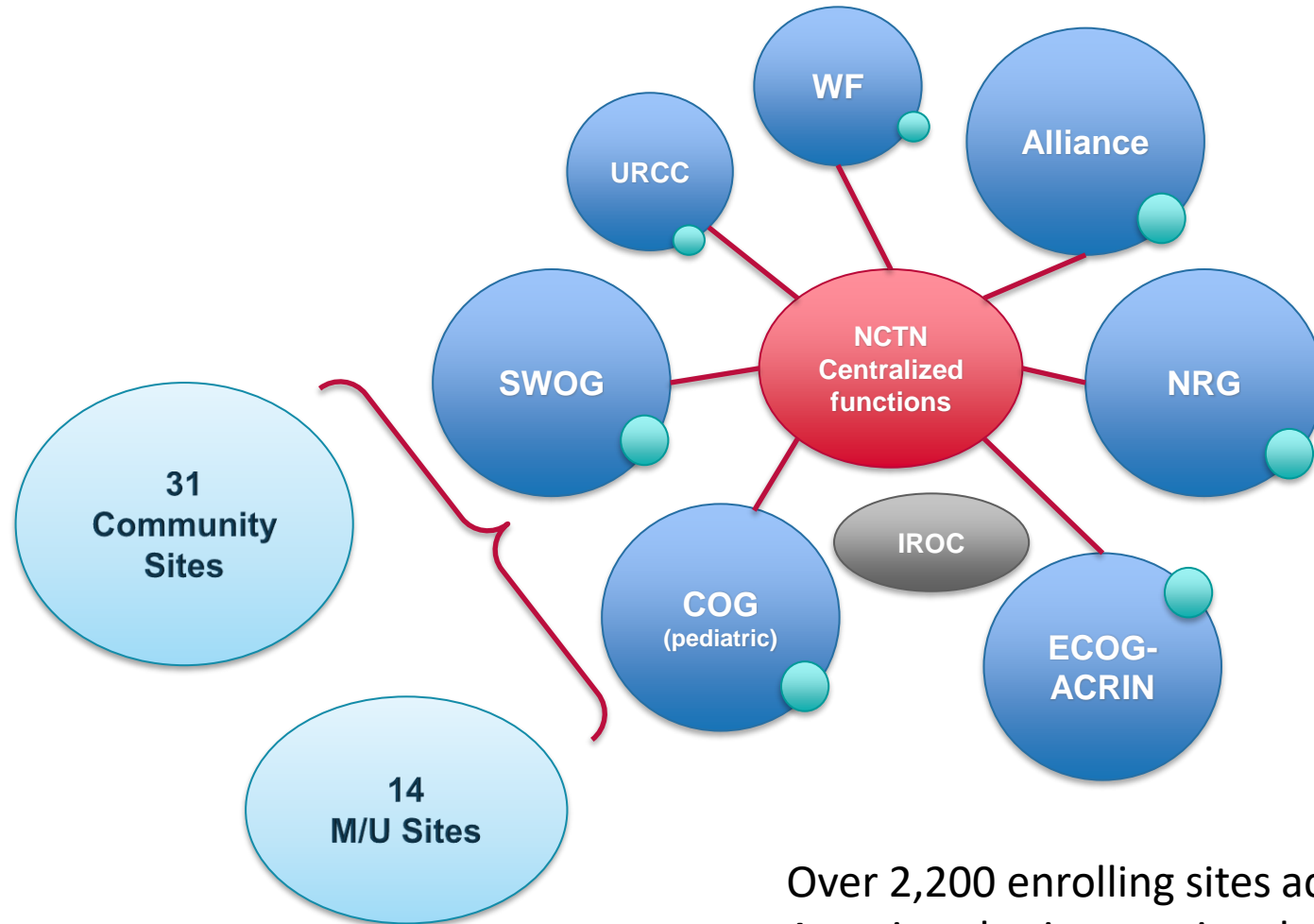
**NCORP Director**

**PAR-24-153 (K12)**

## New Funding Opportunity

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

# Current NCORP Infrastructure

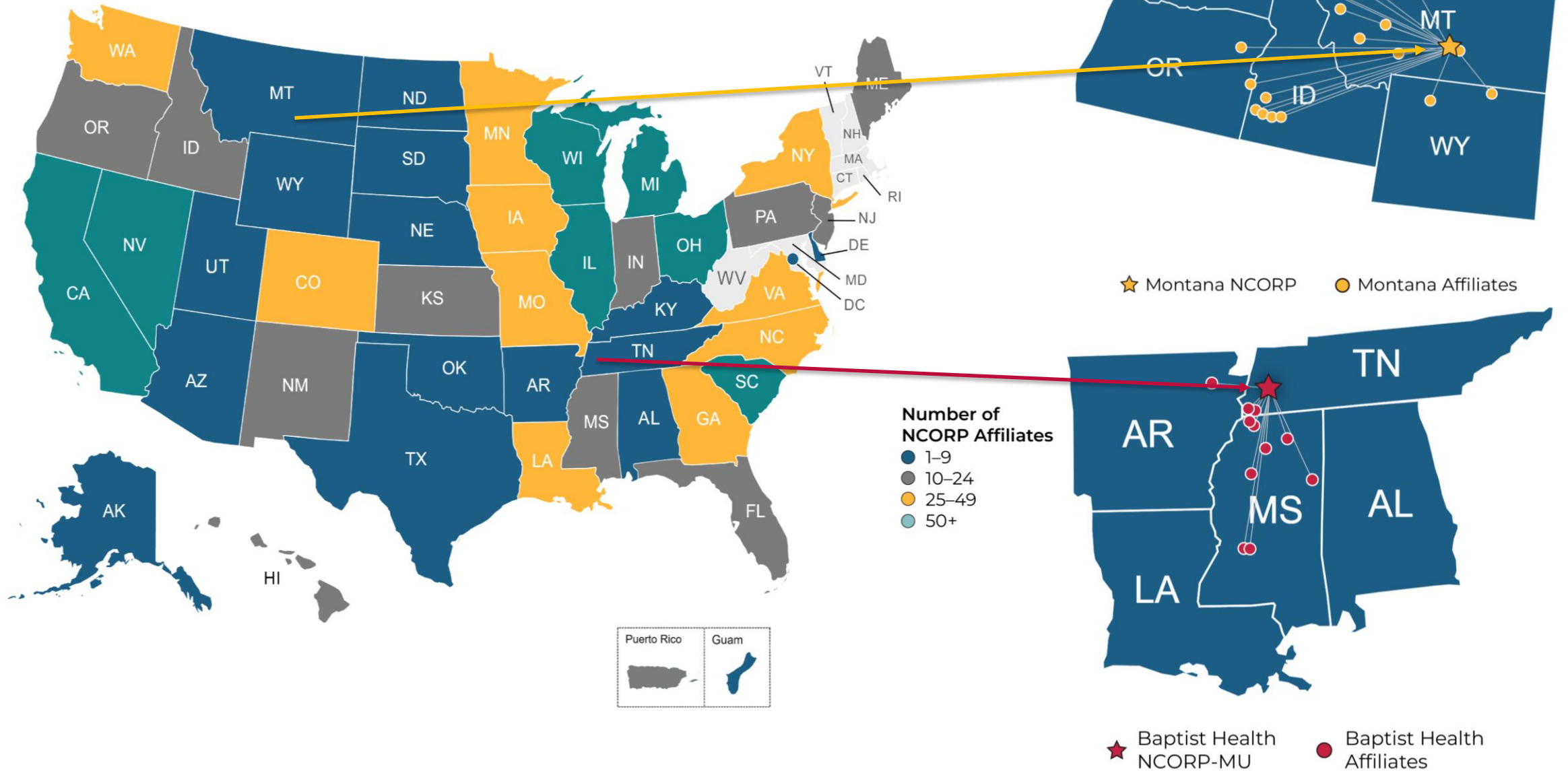


## LEGEND:

- Centralized Functions:
  - CIRB
  - Clinical Trials Support Unit
  - 3 NCI Steering Committees
  - Common Data Mgt with System Central Hosting
  - Rostering and Registration
  - BIQSFP
  - PRO electronic data capture
- Biobanks
- Imaging and Radiation Oncology Core (IROC)

Over 2,200 enrolling sites across North America plus international sites

# NCORP Coverage Map



# NCORP Growth 2019-2024

Metric	2019	2024 (8/27/2024)	% increase
Number of physicians	4,104	4,274	4%
Number of non-physician investigators	309	1,292	418%
Registered Research Staff	4,399	4,791	9%
Number of Affiliate and sub-affiliate sites	990	1,019	3%
Number of Affiliate and sub affiliate sites that accrued to CPC and Treatment Trials	565	685	21%
Number of Affiliate and sub-Affiliate Sites that participated in CCDR Trials	351	559	59%

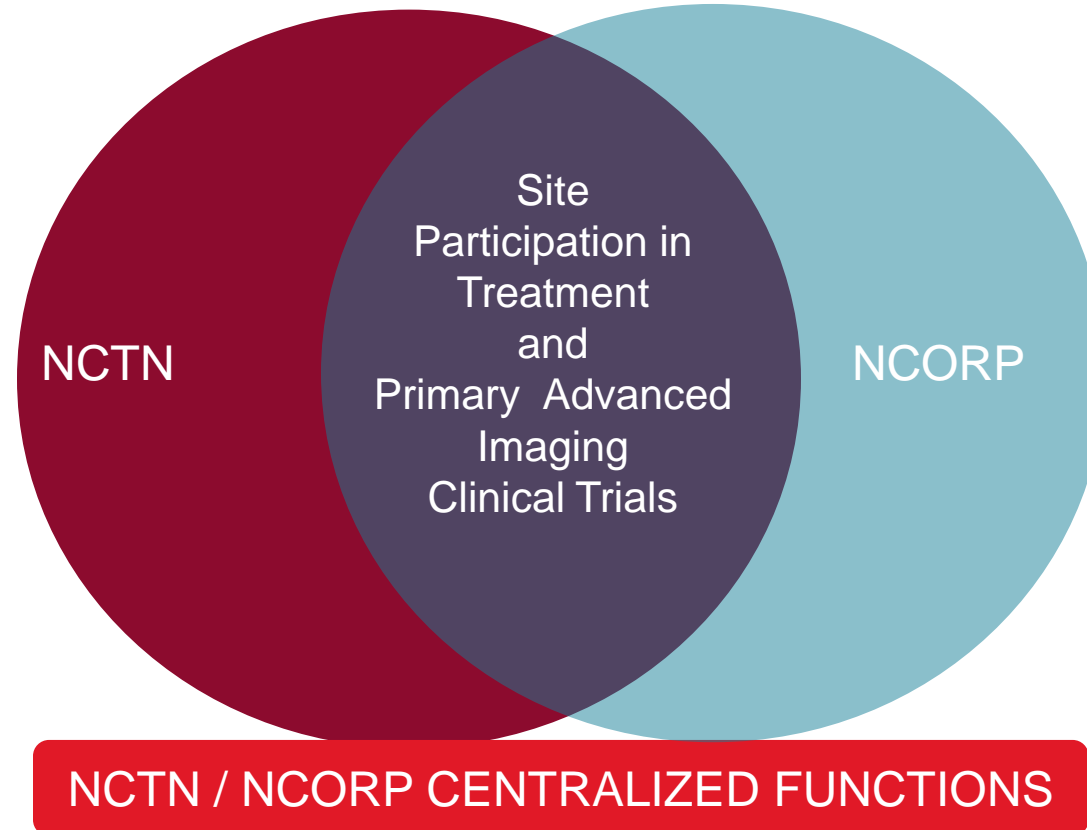
# Relationship of NCTN and NCORP

## NCTN Focus (CTEP):

- Late-Phase Treatment Trials
- Primary Advanced Imaging Trials

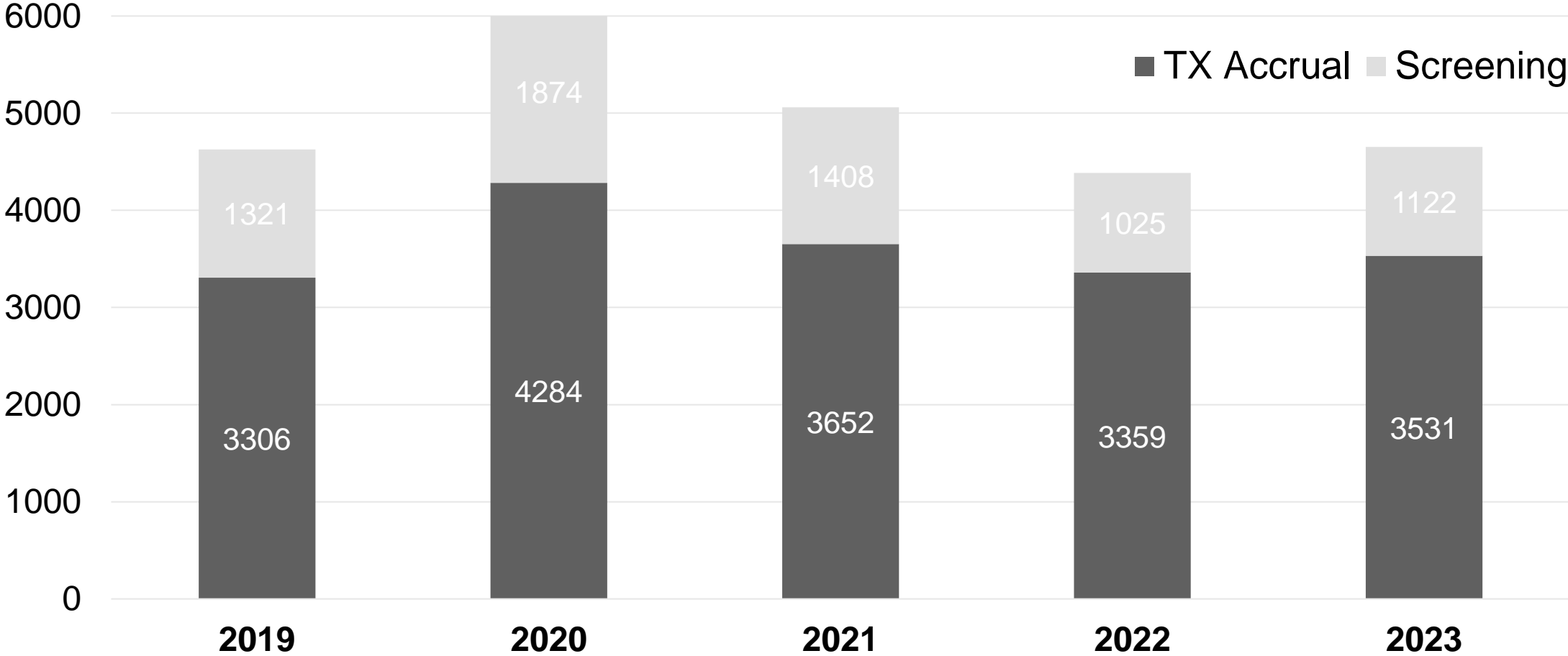
## NCORP Focus (DCP/DCCPS):

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

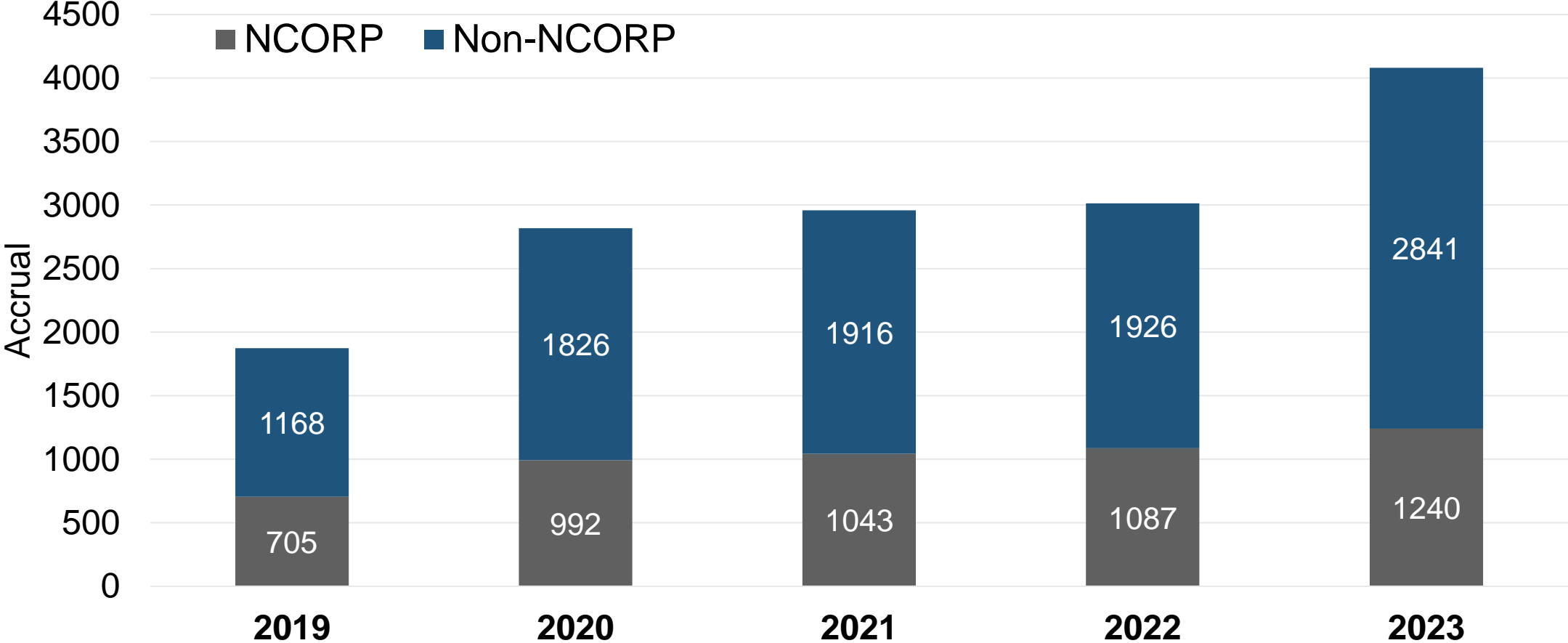




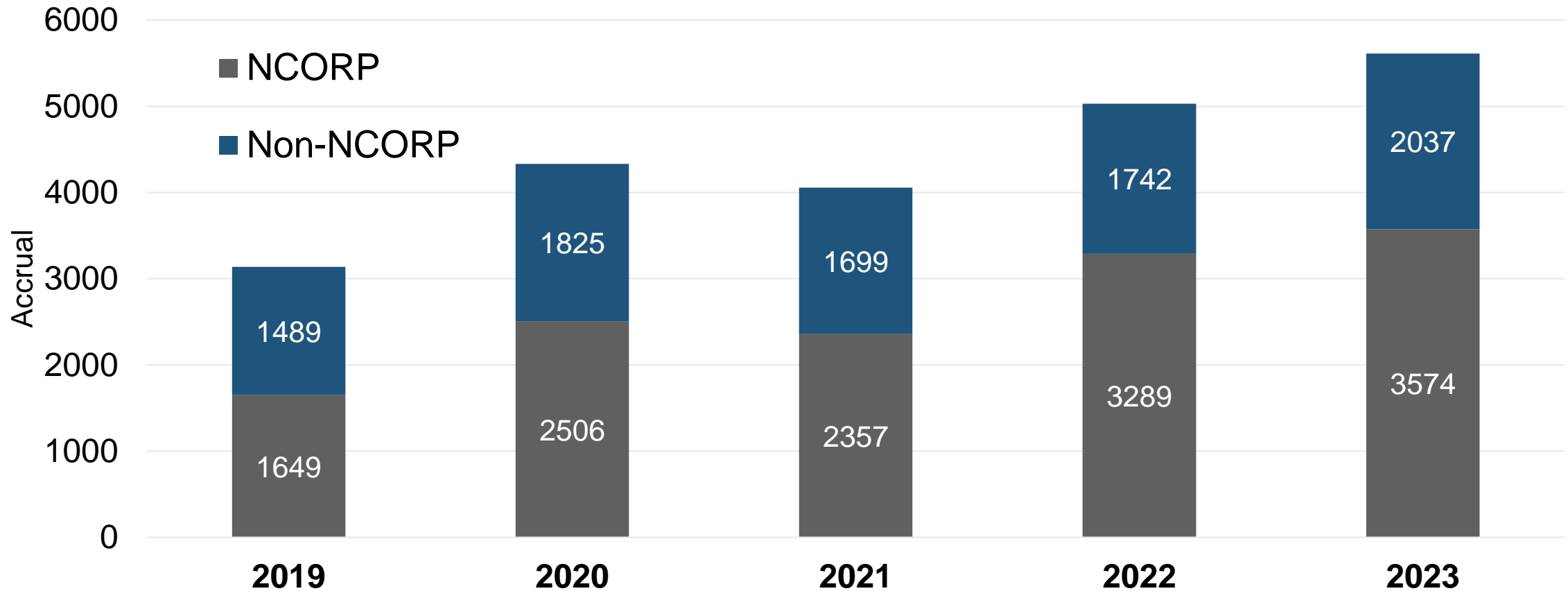
# NCORP Accrual to Treatment Trials



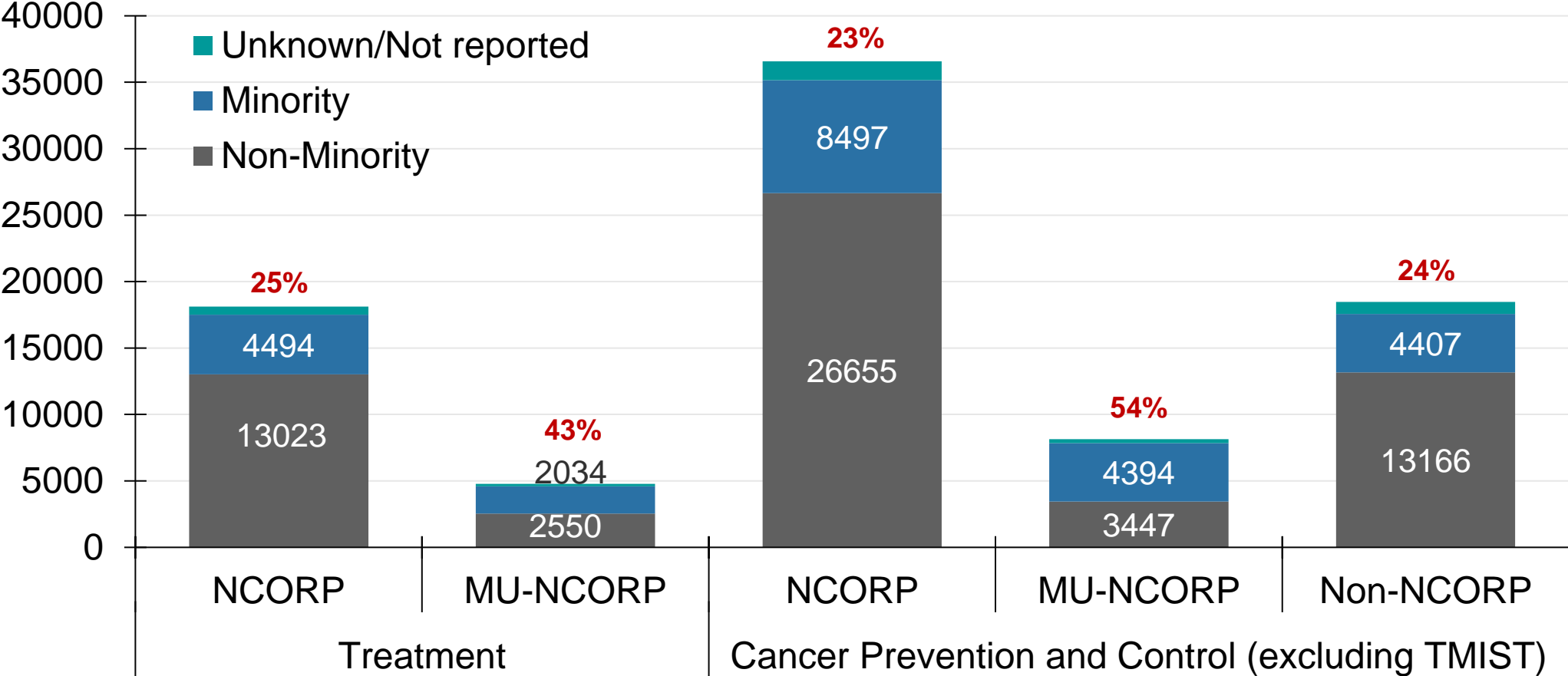
# Quality of Life Accruals



# Cancer Prevention and Control Study Accrual (except TMIST)



# Overall and Minority Accrual within the NCORP Program (2019-2023)



# 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

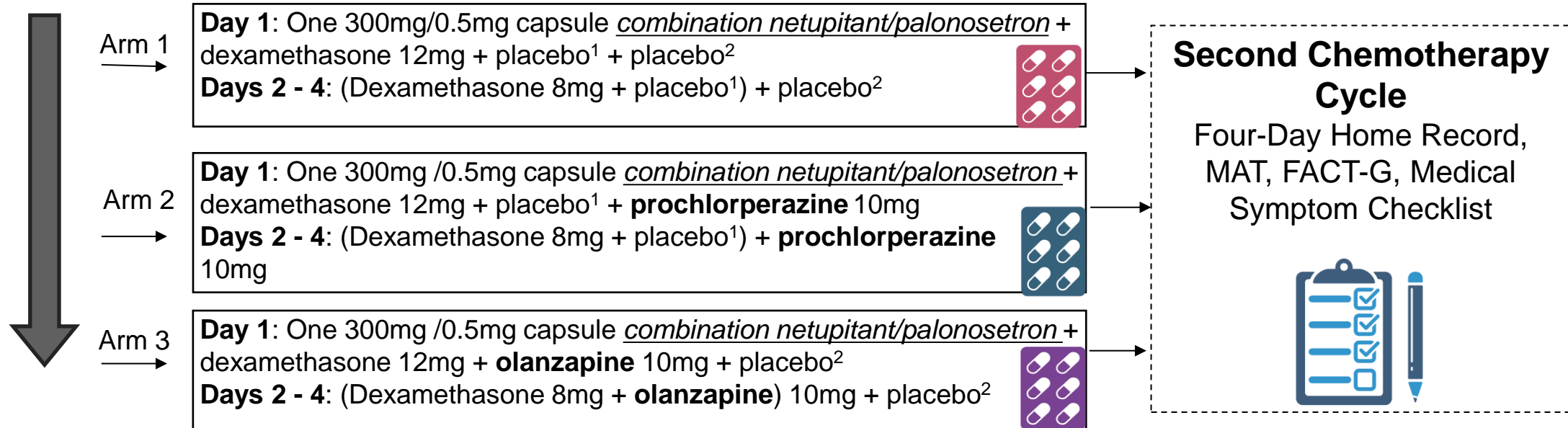
## Cardiotoxicity

- 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

# URCC-16070: Treatment of Refractory Nausea

Plenary Session presentation  
ASCO Quality Care 2024

If nausea  $\geq 3$  (on a 1-7 scale)



- Both Olanzapine and Prochlorperazine significantly reduced refractory nausea
- Olanzapine demonstrated superior efficacy - Greater control over peak nausea and significantly improving patients' (QOL)



# Prevention Research in NCORP

## Prevention Trials

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- A211102: Metformin in Preventing Breast Cancer in Women with Atypical Hyperplasia, LCIS, or DCIS
- S0820: Adenoma and Second Primary Prevention Trial (Eflornithine/Sulindac in reducing 3 year event rate)

## Precision Prevention Trials

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- BRCA-P: A randomized, double-blind, placebo-controlled, phase 3 study to determine the preventive effect of denosumab on breast cancer in women carrying a BRCA1 germline mutation
- Comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers

## Prevention Delivery

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- MiChoice: Cluster RCT of patient and provider decision support to increase chemoprevention informed choice among women with atypical hyperplasia or lobular carcinoma in situ

# 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

# NCORP Currently Active Large Screening Trials

Protocol	Actual Accrual (10/27/2024)/ Planned Accrual
EA1151 (TMIST) - Randomized to 2D digital mammography versus 3D tomosynthesis mammography for 4 years; primary endpoint is reduction in advanced cancers	106,612/ 108,508
NRG-CC005 (FORTE)- <b>Five- or Ten-Year</b> 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	2,157/ 9,500

# Cancer Care Delivery in NCORP

Seeks to improve clinical outcomes and patient well-being by intervening on oncology patient, clinician, and practice setting factors that influence care delivery, with an emphasis on diagnosis through treatment, survivorship, and end-of-life care.

## ■ Care delivery gaps addressed – 30 Protocols

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

## Accrual:

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

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

# CCDR Portfolio Highlight: S2108CD

JCO® Oncology Practice  
An American Society of Clinical Oncology Journal

CURI

ASCO Quality Care Symposium 2023: Featured Abstracts



***A Cluster Randomized Trial Comparing An Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy***

- *Accrual to date:*
  - *Practices: 67*
  - *Patients: 1241 / 1282*
  - *Non-patients: 120 physicians*
- *On track to complete accrual in 2024*



# National Cancer Plan

*Everyone has a role.*

## 8 goals:

*Prevent Cancer*

*Detect Cancers Early*

*Develop Effective Treatments*

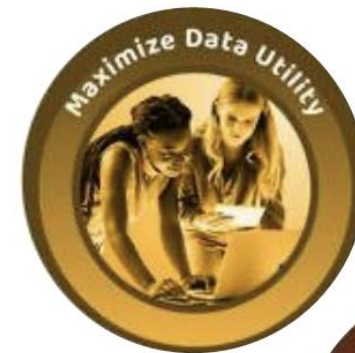
*Deliver Optimal Care*

*Eliminate Inequities*

*Maximize Data Utility*

*Optimize the Workforce*

*Engage Every Person*



- *Changing how we know cancer today.*
- *Reducing cancer mortality.*
- *Improving lives of people with cancer.*

# 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 reduce the risk of cancer and improve the cancer experience
- Trans-NCI Collaboration with DCTD, DCCPS, and CCHE
- Future: Re-competition to be presented at the December 2024 Board Meeting

# Questions for CTAC 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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