NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG Oncology NCORP Town Hall

Lisa Kachnic, MD, FASTRO, NCORP PI

NRG 2025 Summer Meeting
July 25, 2025

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Disclosures

- UpToDateTM - royalties
- Varian Medical Systems – research trial funding
- NRG Board of Directors
- RTOG Foundation Board

Deputy NCORP PI

Julie Bauman, MD, MPH

Director, George Washington University Cancer Canter

Associate Dean of Cancer and Professor of Medicine at George Washington School of Medicine and Health

CPC Leadership

Tracy Crane, PhD

Cancer Control Committee Chair

Co-Leader, Cancer Control Research Program, Sylvester Comprehensive Cancer Center

Mylin Torres, MD,

Cancer Control Committee Vice-Chair

Co-Leader, Cancer Prevention and Control Research Program, Winship Cancer Institute of Emory University

Open NRG NCORP Trials

Study #	Title	Accrual
NRG-CC005	FORTE – Five- or Ten-Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen, J. Dueker)	**3144 / 9000**
NRG-CC008	Non-randomized Prospective Trial Comparing Non-inferiority of **S**alpingectomy to salpingo-**O**ophorectomy to **R**educe the risk of **O**varian **C**a among *BRCA1* carriers (SOROCk) (K. Pennington, W. Huh)	**839 / 2262**
NRG-CC009	Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer (V. Gondi, C. Rusthoven)	**133 / 200**
NRG-CC010	Ph III Trial of the Impact of Sentinel Lymph Node Mapping On Patient Reported Lower Extremity Limb Dysfunction in Endometrial Cancer (E. Tanner, B. Erickson)	**228 / 428**
NRG-CC011	Cognitive Training for Cancer-related Cognitive Impairment in Breast Cancer Survivors: A Multi-Center Randomized Double-Blind Controlled Trial (D. Von Ah, P. Ganz)	**280 / 386 Temporarily closed to accrual**

*Accrual as of 7/23/25

Open NRG NCORP Trials

Study #	Title	Accrual
NRG-CC012CD	Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment	Practices = 13 Participants = 150 Personnel = 48
NRG-CC013	A Randomized, Masked, Placebo Controlled, Ph II Trial of Concurrent ChemoRT with BMX-001 in Patients with HNSCC Receiving Concurrent ChemoRT (D. Brizel, S. Yom)	3 / 98
NRG-CC014	Radiation Therapy for High-risk Asymptomatic Bone Metastases: A Pragmatic Multicenter Randomized Phase 3 Clinical Trial (E. Gillespie, J. Yang)	16 / 280
NRG-CC015	Harnessing E-Mindfulness Approaches for Living-After Breast Cancer – HEAL-ABC (J. Bower, P. Ganz)	Activation June 2025 11 participants consented

*Accrual as of 7/23/25

DCP Approved NRG NCORP Trials

Study # / Title	Status
NRG-CC016: PH III Randomized Trial: **A**ssessment of **B**iosignature **C**lassification for **DCIS** **R**adio**T**herapy Benefit Post Lumpectomy (ABCD RT) (R. Rabinovitch)	7/21/25: Consensus review received 5/28/25: Protocol submitted to DCP
NRG-CC017: Randomized Ph III Study Comparing Temporally Modulated Pulsed Radiation Therapy (TMPRT) vs Standard Radiation Therapy with Temozolomide for Adults with Newly Diagnosed MGMT-Unmethylated Glioblastoma (J. Huang)	Protocol submitted to DCP 6/9/25

NRG Approved NCORP Concepts

Concept	Status
NRG-CC2342: Phase II Randomized, Placebo-controlled Trial Testing the Efficacy of Broccoli Seed and Sprout Extract (Avmacol Extra Strength) in Prevention of Secondary Primary Tumors (SPTs) after an Index Tobacco Related Head and Neck SCC (HNSCC) (S. Sheth, J. Bauman)	Received pending with the first NCI review, resubmission declined until a trial in the CP-CTNet is completed
NRG-CC2421: Phase II Randomized Trial of Nanogenistein in Combination with Chemoradiotherapy and Immunotherapy for Locally Advanced and Oligometastatic NSCLC (C. Simone)	5/27/25: submitted to NCI; disapproved; further discussion pending
NRG-CC2402: Mi Sleep Coach App for Cancer-Related Insomnia (N. Arring)	R01 reviewed June 2025
NRG-CC2341CD: WRITE Symptoms 4 -Self Management: A Hybrid Type 1 Effectiveness Trial of the Self-Directed WRITE Symptoms Intervention for Survivors Living with Advanced or Recurrent Gynecologic Cancers	R01 Submission July 2025

Pipeline of NRG Concepts

Title	Comments
NRG-CC2444: 4DCT Functional Lung Avoidance to Decrease Radiation Induced Lung Injury (A. Baschnagel)	Pending submission
Seamless Randomized Phase II/III Trial of Reduced-Dose versus Standard-Dose Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) (M. Khandekar, V. Gondi)	NCORP Revie: revise and resubmit
Celiac Plexus Radiosurgery for Pain Management – A Randomized Trial (Y. Lawrence, J. Kharofa)	NCORP Review July 2025

32 NRG Oncology Trials with PROs

Study	PRO measures
NRG-BN003	HVLT-R, TMT (A&B), COWA, MDASI-BT
NRG-BN011	MDASI-BT
NRG-BN012	MDASI-BT, Montreal Cognitive Assessment (MoCA)
NRG-BN014	MDASI-BT, MDASI-SP
NRG-BR007	BCTOS, Breast cancer worry, PROMIS Global, Global Cosmesis Score, PROMIS-Fatigue, B39 breast symptom checklist, BCPT symptom checklist, QLACS, Extent of Nonadherence
NRG-BR008	BCTOS, Breast cancer worry, Global Cosmesis Score, PROMIS-Fatigue, B39 Breast Symptom Checklist, PROMISGlobal, QLACS
NRG-BR009	FACT G-GP5, PROMIS-29, PROMIS Cognitive Function short form, FACT-ES ESS, PRO-CTCAE, Extent of Nonadherence
NRG-CC005 (FORTE)	PROMIS Questionnaire, Lifestyle Questionnaire, Family History Questionnaire, Dietary Questionnaire, Health Questionnaire, Participant History Questionnaire, Stool Sample Questionnaire
NRG-CC008 (SOROCk)	FACT-ES, EQ-5D-5L, FSFI, MSCL, PROMIS screener and external sexual function items, IES, SDM-Q-9, RR-MDMb
NRG-CC009	HVLT-R, TMT, COWA, MDASI- BT, EQ-5D-5L, PROMIS cognitive function
NRG-CC010	EQ-5D-5L, Gynecologic Cancer Lymphedema Questionnaire (GCLG), Patient Questionnaire for Lymphedema-Associated Costs
NRG-CC011	CEQ, Client Satisfaction Survey, FACT-Cog, MOS-SSS, PROMIS-Global, PROMIS-SF Meaning and Purpose, PSS, Work Ability Index, WPAI:GH, TBANS Battery Assessment, PROMIS-SF scales: Depression, Anxiety, Fatigue, Sleep Disturbance, Pain Interference, & Neuropathic Pain
NRG-CC012CD	Bayliss Comorbid Conditions, COST-FACIT, PRO-CTCAE, Unscheduled Health Services Use
NRG-CC013	OMWQ-HN, PRO-CTCAE
NRG-CC014	BPI-short, EQ-5D-5L
NRG-CC015	EQ-5D-5L, CES-D, Fatigue SF, Sleep disturbance SF, BCPT symptom checklist/vasomotor scale, MHC-SF, QOL among cancer survivors scale, self compassion scale, rumination and reflection scale
NRG-GI003	PROMIS fatigue short form, FACT-Hep, EQ-5D-5L
NRG-GI006	MDASI-GI+,EQ-5D-5L, PROMIS-Fatigue
NRG-GI011	FACT-Hep
NRG-GU008	EPIC-26, EQ-5D-5L, Brief Pain Inventory, PROMIS-Fatigue SF
NRG-GU009	EPIC-26, FACT-Cog, PROMIS-Fatigue Short Form, PROMIS-Depression, PRO-CTCAE
NRG-GU010	EPIC-26, FACT-Cog, EQ-5D-5L, PROMIS-Fatigue Short Form
NRG-GU011	EPIC-Hormonal domain, EPIC-sexual domain, EQ5D-5L, EORTC QLQ-30, PROMIS Fatigue, PRO-CTCAE
NRG-GU013	EPIC-26 urinary, bowel and sexual domains, PROMIS-Fatigue short form, EQ5D-5L, FACIT-Cost
NRG-GU014	Bladder cancer index, EORTC QLQ-C30, EQ-5D-5L, PROMIS fatigue
NRG-GY026	FACT-En, PROMIS-Fatigue, PRO-CTCAE
NRG-HN006	NDII, QuickDASH, FACT-H&N, EQ-5D-5L
NRG-HN009	FACT-H&N, HHIA-S
NRG-HN010	PRO-CTCAE
NRG-HN014	EORTC QLQ-C30, PROMIS Fatigue SF7a, PROMIS Anxiety SF4a, EQ-5D-5L, CSCC Specific Supplemental, PGIS
NRG-LU008	FACT-L, EQ-5D-5L, PRO-CTCAE
RTOG-1216	MDASI-HN, FACT-H&N TOI

Quality Improvements in PRO Compliance

Improvements at NCORP sites can be used in grant renewals

- PRO compliance discussed at monthly NCORP leadership meetings
- PRO quarterly delinquency reports and review by PCOR and NCORP
- PRO NRG staff champions Kandie Dempsey and Marcie Ritter
- PRO education at research associates meetings
- NRG NCORP worked with DCP to get QOL forms more easily accessible on CTSU
- ePROs have increased compliance in some disease sites

Example of Success, Dr. Movsas, PCOR chair completed QOL analysis of two lung studies that used the same primary QOL endpoint, the FACT TOI. One 0617, started before quality improvement measures were fully implemented. and the other, LU005 after quality improvement measures:

RTOG 0617

PRO compliance 87% at baseline, 70% at 3 months, **57% at 1 year after baseline and were alive.**

LU005

PRO compliance exceeded 85% at baseline and stabilized at **60-68%** of those who completed baseline AND were alive through 21 months after completion of chemo/RT or **2 years after baseline**.

New Process for NCORP Pilot Project Applications

Goal: to prepare investigators to develop NCORP pilot concepts that are aligned with the aims of NCORP committees including CPC, CCDR and HDR. Pilot projects are funded specifically to lead to full NCORP concepts.

- Application requires investigators to submit a two-page LOI form.
- NCORP committee chairs will review LOIs and select those best aligned with the committee goals, NCORP priorities, and deemed most feasible for future Phase II – III NCORP concepts.
- Selected investigators will be invited to attend a 1-hour workshop during an NRG meeting and paired with a mentor.

The LOI process is a prerequisite for pilot grant application submission in 2025.

- The request for funding application (RFA) for NCORP pilot projects will be released in Spring 2025.
- This year we selected 11 LOI applications for the workshop
- While workshop selection and enrollment does not guarantee pilot funding, the activities are designed to facilitate successful submissions.

The next LOI announcement will be coming August 2025!

NRG Oncology NCORP Boot Camp

Mandatory for anyone submitting for NCORP pilot grants
Important for NRG new investigators
Encouraged for all APPs new to NRG
All NRG Members WELCOME!!

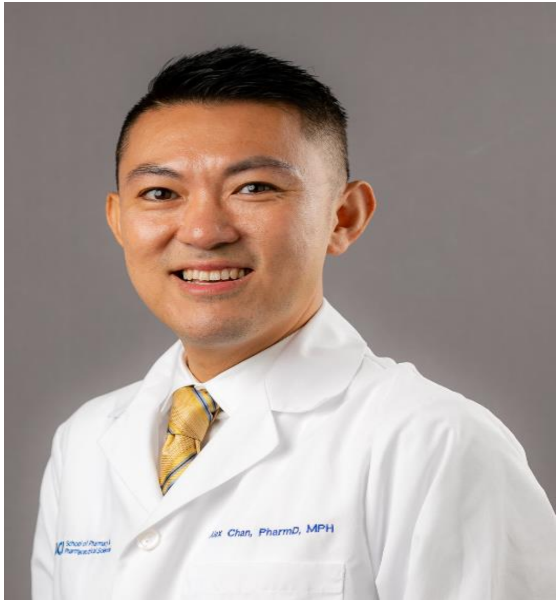
Workshop goal: to provide an overview of NRG Oncology NCORP and prepare investigators to develop committee aim-aligned NCORP concepts

Topics will include:

- Overview of NRG Oncology NCORP
- Introduction to Cancer Prevention and Control (CPC), Cancer Care Delivery Research (CCDR) and Health Disparities (HD) committee aims
- Statistical considerations
- Running an R01 via NRG NCORP

Next Session: January 2026 at the NRG Winter Meeting in San Francisco

NCORP Pilot Grant Award



Alexandre Chan, PharmD, MPH

Department Chair & Professor of Clinical Pharmacy Practice,
School of Pharmacy & Pharmaceutical Sciences
University of California, Irvine

Riluzol**E** **FO**r Preventing **C**ognitive dysf**U**nction in Cancer Patient**S** receiving chemotherapy **(REFOCUS)**

- The proposed study will evaluate the neuroprotective role of riluzole to mitigate cancer-related cognitive impairment (CRCI).
- The aim is to repurpose riluzole, a drug that has been shown in preclinical studies to augment BDNF levels in preclinical models, for managing CRCI in cancer patients and survivors.

NRG Health Care Access Fellowship Program

The Health Care Access Fellowship Program outlines three strategic, high-level goals to provide a broader perspective in clinical trials research:

1. Increase young researchers' involvement with NRG, with an emphasis recruitment of researchers with a passion for improving health care access.

2. Mentor selected early-stage NRG Oncology investigators in clinical trials education and training. The program provides networking opportunities and pathways to leadership.

3. Develop successful clinical trials scientists who can compete in grant writing opportunities.

Announcement: July 18, 2025
Application deadline: September 19, 2025

Read more about this opportunity at:
https://www.nrgoncology.org/HealthCareAccessFellowship

Liaison Assignment Table

Disease Site	NCORP Liaisons	PCOR Liaisons	HCA Liaisons
Brain	Melin Khandekar	Vinai Gondi	Natosha Gatson
Breast	Mylin Torres	Patti Ganz, Reshma Jagsi	Noel Arring
Cervix	Kate Mills	Dana Chase	Parul Barry
GI Colorectal/non-colorectal	Jordan Kharofa	Farzan Siddiqui	Nina Sanford
GU	Andrew McDonald	Ron Chen	Dayssy Diaz-Pardo
H&N	Beth Beadle	Minh-Tam Troung	Evan Graboyes
Lung	Nitin Ohri	Ben Movsas	Nirav Kapadia
Ovarian	Kathryn Pennington	Alexi Wright	Kevin Albuquerque
Uterine Corpus	Britt Erickson	Elizabeth Jewell	Victoria Bae-Jump

Patient Advocates

Laurel Pracht
Cancer Prevention and Control
Cancer Care Delivery Research

Diane Rose
Cancer Prevention and Control

Tambre Leigh
Cancer Care Delivery Research

NCORP Travel Awards

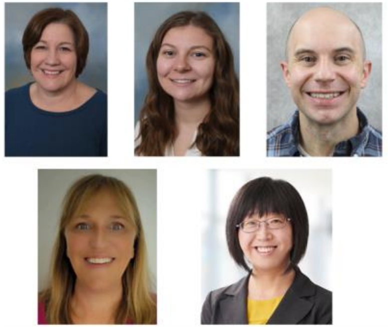
Haley Appel
Miami Cancer Institute

Valerie Ferguson
Hawaii NCORP

Top Accruing NCORP Sites to NRG NCORP Trials January 1, 2025 – June 30, 2025

Centro Comprensivo de Cancer de UPR

Regions Hospital



Augusta University Medical Center

Kaiser Permanente – Vallejo

Kaiser Permanente – San Diego Zion

Top Accruing NCORP Sites to NRG CTEP Trials January 1, 2025 – June 30, 2025

VCU/Massey Cancer Center

Aspirus Regional Cancer Center

University of New Mexico Cancer Center

Kaiser Permanente Dublin Medical Center

University of Kansas Cancer Center

Top Accruing NCORP Sites to NRG CTEP Trials with PROs January 1, 2025 – June 30, 2025

VCU/Massey Cancer Center

University of Kansas Cancer Center

Kaiser Permanente Dublin Medical Center

NRG Oncology NCORP Resources

NRG NCORP - Who We Are and How to Get Involved

FORTE

A COLORECTAL CANCER PREVENTION TRIAL

@FORTEStudy

SOROCK

Clinical Perspective: Just published!

Optimization of Timing for Risk-Reducing Salpingectomy and Oophorectomy

@NRGOnc

@NRGOnc.bsky.soci
al

YouTube

https://www.youtube.com/@NRGOnc

THE NRG ONCOLOGY PODCAST

Moving the needle in cancer care

THE NRG ONCOLOGY PODCAST

Moving the needle in cancer care

TOPIC:

Patient Advocates and the benefits of great patient-physician relationships when building stronger clinical trials.

NRG ONCOLOGY

Importance of Patient-Reported Outcomes in Clinical Trials

STUDY SPECIFIC VIDEOS

NRG ONCOLOGY'S NRG-CC008 "SOROCK" TRIAL

NRG ONCOLOGY'S NRG-CC009 TRIAL

NRG ONCOLOGY'S NRG-CC010 TRIAL

NRG ONCOLOGY'S NRG-CC011 TRIAL

Learning Modules Available in CLASS

https://www.nrgoncology.org/Committees-Programs/NRG-NCORP-Research-Base

FORTE is FUERTE

Robert E. Schoen, MD, MPH
Professor of Medicine & Epidemiology
UPMC Endowed Chair
PI, FORTE Trial
University of Pittsburgh | UPMC
Pittsburgh, PA

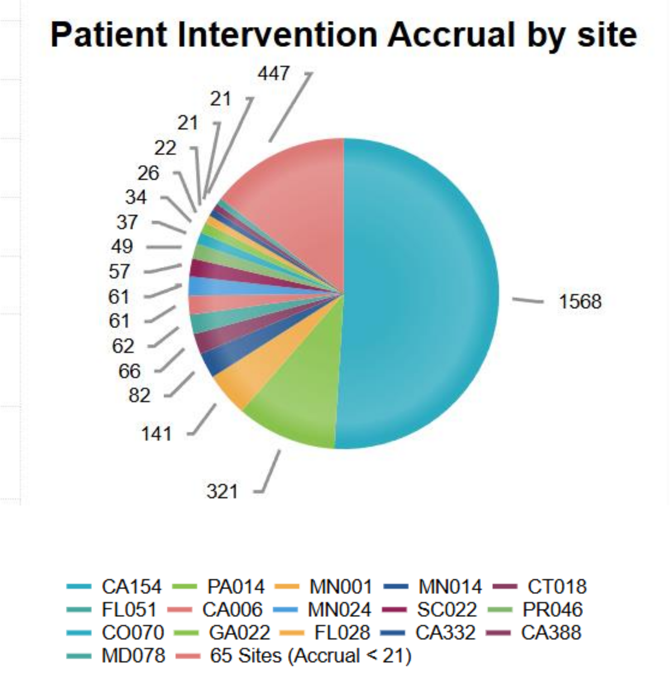
June Milestone

Enrollment as of 07/18/2025

NRG-CC005

FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)

Step Type	Step(s)	Planned	Actual
Intervention	1	9500	3144



Recruitment

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL

- Averaging around 120/month
- Increased Actively Recruiting Sites from 20s/mth → >30/mth
- Peak Recruitment Month: March 2025 - 143
- Planning to reach enrollment to 180-200/month

Recruitment

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL

Sites that Started Accruing in 2025: 4 More New in July

1	PA054	Saint Luke's University Hospital-Bethlehem Campus
2	OH028	Louis Stokes Cleveland VA Medical Center
3	SD004	Sanford Cancer Center Oncology Clinic
4	NM004	University of New Mexico Cancer Center
5	DC035	Kaiser Permanente-Capitol Hill Medical Center
6	CO034	Kaiser Permanente-Franklin
7	OK002	Veterans Administration Medical Center - Oklahoma City
8	WI067	Saint Vincent Hospital Cancer Center at Saint Mary's
9	AZ122	CTCA at Western Regional Medical Center

Recruitment

FORTE
A COLORECTAL CANCER PREVENTION TRIAL

Sites that Activated in 2025:

1	PR049	Pan American Center for Oncology Trials LLC
2	WI229	Tamarack Health Hayward Medical Center
3	MN153	Essentia Health - Saint Joseph's Pequot Lakes Clinic
4	MN154	Essentia Health - Saint Joseph's Pine River Clinic
5	MN155	Essentia Health - Saint Joseph's Crosslake Clinic
6	MN156	Essentia Health - Saint Joseph's Staples Clinic
7	PA209	Geisinger Medical Center-Cancer Center Hazleton
8	WI018	William S Middleton VA Medical Center
9	MA034	Massachusetts General Hospital Cancer Center
10	CA179	Saint Joseph's Medical Center
11	NE077	CHI Health Saint Francis
12	IL017	Loyola University Medical Center

13	OH028	Louis Stokes Cleveland VA Medical Center
14	DC005	MedStar Georgetown University Hospital
15	WV006	WVUH-Berkely Medical Center
16	WV013	Wheeling Hospital/Schiffler Cancer Center
17	WV017	United Hospital Center
18	WV023	Camden Clark Medical Center
19	UT005	George E Wahlen Department of Veterans Affairs Medical Center
20	MN026	Mayo Clinic
21	NM004	University of New Mexico Cancer Center
22	NM041	Lovelace Medical Center-Saint Joseph Square
23	CO153	Saint Anthony North Hospital

Supersite Initiative

Concept: Supply up-front SEED funding to select sites to significantly RAMP up recruitment

California

Accrual						
Total	May 2025	Apr 2025	Mar 2025	Feb 2025	Jan 2025	Dec 2024
116	23	13	11	4	1	3

VA Initiative

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL

Concept: Concerted Effort to get VA Hospitals Enrolling:

NRG-CC005 (FORTE)

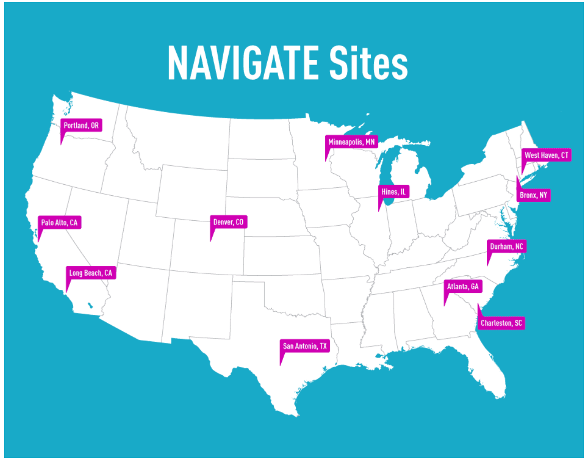
Table 4 Total accrual for the VA sites as of 6/30/2025

VA sites	Total	Jun 2025	May 2025	Apr 2025
Bay Pines VA Healthcare System	**62**	2	1	3
Boston Veteran's Affairs Medical Center	**5**	1	0	1
Kansas City Veterans Affairs Medical Center	**10**	1	2	1
Louis Stokes Cleveland VA Medical Center	**1**	1	---	---
Malcom Randall VA Medical Center	**4**	0	0	0
Minneapolis VA Medical Center	**13**	2	1	1
Providence Veterans Administration Hospital	**18**	1	4	2
Ralph H Johnson VA Medical Center	**57**	0	0	0
Rocky Mountain Regional VA Medical Center	**13**	2	0	3
VA Medical Center - Oklahoma City	**2**	1	0	1
Veterans Affairs Connecticut Healthcare System-West Haven Campus	**11**	0	1	3
Zablocki Veterans Administration Medical Center	**18**	0	0	1
Total	**214**	**11**	**9**	**16**

3 more VA's added: 15 total

VA Navigate

- VA as a Supersite
- Administered by NAVIGATE: Centralized VA Recruitment
- Electronic Identification of Eligibles
- 240,000 Colonoscopy Exams/yr
- 22,000 likely FORTE eligible/yr



Private Practice Initiative

FiveORTenE
A COLORECTAL CANCER PREVENTION TRIAL

- Gastro Health:
  - 400 gastroenterologists
  - 110K colonoscopies per year
  - 200 clinics in 7 states
- Aton Health:
  - 1,000 gastroenterologists
  - 60,000 colonoscopies per month
  - 250+ clinics in 25 states
  - Central Recruitment Coordinated by Aton

Remote Blood Draw

- Remote blood draw (Travalab)
- 8 sites certified
- Facilitates remote consent process
- 230 Completed Blood draws between March – June 2025

Protocol Updates

- USPSTF lowered age of recommended CRC screening to 45
- FORTE now captures these patients

As FUBU says,

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Join us!

NRG-CC015

Harnessing e-Mindfulness Approaches for Living---After Breast Cancer (HEAL-ABC)

Patricia A. Ganz, MD

Protocol Co-Chair

UCLA Jonsson Comprehensive Cancer Center

NCORP Town Hall

July 25, 2025

Funding Support

This research is being conducted in collaboration with the University of California, Los Angeles (UCLA) through funding from the National Cancer Institute Grant Number R01CA282416 “Mindfulness Meditation for Younger Breast Cancer Survivors: Testing Digital Interventions in Clinical and Community Settings” awarded to Julienne Bower, PhD and Patricia Ganz, MD as Multiple Principal Investigators.

My Disclosures

- Up-to-Date: Section Editor on Survivorship
- Medical Advisory Board: InformedDNA
- DSMB: Astellas

Study Team

Julienne Bower, PhD	mPI, Health Psychologist
Patricia Ganz, MD	mPI, Breast Oncologist
Reena Cecchini, PhD	Statistician
Catherine Crespi, PhD	Statistician
Tina Shih, PhD	Health Economics Chair

See Protocol for Full Details

Background

- Breast cancer is the most common cancer in younger women (<50 years) representing 19% of all incident cases.
- Depressive symptoms are common in younger women; linked to treatment non-adherence, cancer recurrence and shorter survival.
- Fatigue, insomnia, vasomotor symptoms and cancer-related stress co-occur and impair quality of life post-treatment.
- Mindfulness Awareness Practices (MAPs) significantly reduces depressive symptoms and improves other symptoms in breast cancer survivors (BCS).

Study Rationale

- Standard delivery of mindfulness training has been through in-person classes, which may limit access, especially for younger women and those who live in rural areas
- Digital approaches, such as live, synchronous online classes and an app-based, self-paced version, offer solutions by increasing accessibility for younger breast cancer survivors
- Assessing the cost-effectiveness of these interventions can facilitate future coverage decisions

Overview of the Trial

- In person class attendance/training is a dissemination barrier for this promising intervention; ***digital approaches are needed***
- This three-arm trial evaluates **two digital versions of the MAPs intervention** for young BCS vs. **guided meditations only**
- Participants will complete assessments **pre- and post-intervention** and at **3-month** and **6-month follow-ups** to determine short and longer-term effects on depression and related symptoms

Study Schema

Figure 1. NRG-CC015 Schema

REGISTRATION (Step 0*)

- Breast cancer survivors must:
  - have had stage 0-III, non-metastatic breast cancer,
  - be ≥ 18 and < 51 years of age at diagnosis,
  - be ≥ 6 months and ≤ 5 years post-treatment, and
  - speak English or Spanish
- Verbal consent obtained to administer the Patient Health Questionnaire-8 (PHQ-8) Depression Screen.
- Breast cancer survivors must have a score of 5-14 on the PHQ-8 Depression Screen.

Informed consent signed

Baseline Assessment Completed

STRATIFICATION

- Screening depression score (PHQ-8 < 10; ≥ 10)
- Language preference (English or Spanish)
- History of chemotherapy (yes, no)
- Current receipt of endocrine therapy (yes, no)

RANDOMIZATION (Step 1)**

ARM 1	ARM 2	ARM 3
Mindfulness (MAPs) Live Online	Mindfulness (MAPs) Digital (English speaking only)	Meditation Only Control Group

Stage 0-III, non-metastatic breast cancer patients

Shading represents the steps where NRG clinical sites are involved

Primary Objectives

- To determine the efficacy of **Mindful Awareness Practices (MAPs) Live Online (LO)** relative to the **Meditation Only (MO)** control group on depressive symptoms indicated by changes of scores in **Center for Epidemiologic Studies Depression Scale (CES-D)** from **baseline to post-intervention**

- To determine the efficacy of **Mindful Awareness Practices (MAPs) App** relative to the **Meditation Only (MO)** control group on depressive symptoms indicated by changes of scores in **CES-D from baseline to post-intervention**

Secondary Objectives

- To determine **persistence of MAPs LO and MAPs App effects** on depressive symptoms from **baseline to 3-month and 6-month follow-up** relative to the MO control group
- To determine the **efficacy of MAPs LO and MAPs App** relative to the MO control group **on fatigue, sleep disturbance, vasomotor symptoms, fear of recurrence, well-being, and work productivity**
- To assess the **cost-effectiveness of MAPs LO and MAPs App** relative to the MO control group

Exploratory Objectives

- To explore **potential mediators and moderators of intervention effects**, including rumination and self-kindness (mediators), and baseline depressive symptoms, demographics, and social determinants of health (moderators)

Trial Activities

- **NCTN and NCORP sites are responsible for:**
  - Identifying/screening potential participants for eligibility, including medical eligibility and level of depressive symptoms
  - Sites must have mental health resources available for participants with elevated depressive symptoms
  - Sites must explain the intervention trial to eligible participants, obtain informed consent, and send contact information to UCLA
  - After participant completes the baseline questionnaire, clinical site performs randomization
- **UCLA is responsible for:**
  - Administering the baseline questionnaire and all subsequent study questionnaires
  - Asking sites to randomize participants when baseline questionnaire is completed
  - Providing the intervention to participants after treatment arm is assigned

Overview of Study Methods

- **Design**: A Phase III RCT
- **Sample Size**: 402 Younger Breast Cancer Survivors
- **Stratification**:
  - Screening depression score (PHQ-8 < 10; ≥ 10)
  - Language preference (English or Spanish)
  - History of chemotherapy (yes, no)
  - Current receipt of endocrine therapy (yes, no)
- **Randomization**:
  - Randomization is 1:1:1 for English speaking participants
  - 1:1 to Arms 1 and 3 for Spanish speaking participants
- **Training Groups:** Arm 1-MAPS Live Online, Arm 2-MAPs Digital App, Arm 3- Meditation Only Control Group
- **Total training time**: 6-weeks (2 hours weekly for Live Online Groups)

Key Eligibility Criteria

Goal is to recruit Younger BCS with Increased Depressive SXs

- **Diagnosed** with Stage 0, I, II, or III breast cancer **at or before age 50**
- Completed all primary breast cancer treatments at least 6 months prior
- **Evidence of mild-moderate depressive symptoms (PHQ-8 score of 5-14)**
- Within 5 years of diagnosis
- English or Spanish speaking
- **Willing to participate in a 6-week program to receive training in mindfulness**

See protocol section 3.2 for full details

Ineligibility Criteria

- Breast cancer recurrence, metastasis, or another cancer diagnosis
- Unable to commit to intervention schedule (6-week training)
- Actively practicing mindfulness meditation
- Currently pregnant or planning to become pregnant in near future
- Enrolled in another cancer control or behavioral intervention trial with training activities
- **Does not meet medical eligibility criteria**
- **PHQ-8 score is too low or too high**

See protocol section 3.3 for full details

Study Treatments

Arm 1: MAPS Live Online (LO)

- Participants join live mindfulness classes on secure online videoconferencing platform facilitated by a mindfulness instructor
- Participants complete: 2 hours per week for 6 weeks for a total of 12 hours of training

Arm 2: MAPS Digital App (APP)

- Participants receive the same mindfulness training content through a mobile app, with training broken into smaller sessions that can be completed over the course of a week
- Same meditations and training as in Arm 1; planned to be delivered over the course of 6 weeks

Arm 3: Meditation Only (MO) Control Group

- Participants access meditations on a study-specific app with access to some of the same meditations being used in the other treatment groups
- There is no instruction or training included with the meditations

Study Treatment Assignment

- Participants will be contacted by UCLA Research Staff regarding their intervention assignment and set up **after randomization**
- Participants will complete the intervention and assessments via computer, tablet, or phone
  - Participants who do not have a home computer, smartphone, tablet, or internet to access the intervention will be provided with tablet and hotspot by the UCLA research team
  - UCLA research staff will be available via email or phone for technological support with the apps and scheduling support for the Live Online groups
- Spanish language participants will only be assigned to MAPS LO or MO
- The MO app meditations will be available to all treatment groups throughout the study (for 9 months)

Study Workflow Overview

Informed consent signed at clinical sites

↓

UCLA sends Welcome Letter

↓

Wait for Cohort Formation

Target cohort size is 40. This may take up to 8-12 weeks.

↓

Cohort Assembled

↓

Baseline Surveys

↓

Randomization

↓

Intervention Delivery

NRG Clinical Sites

UCLA Research Staff

Cohort Formation Process

Informed consent signed at clinical sites.

↓

UCLA sends Welcome Letter

↓

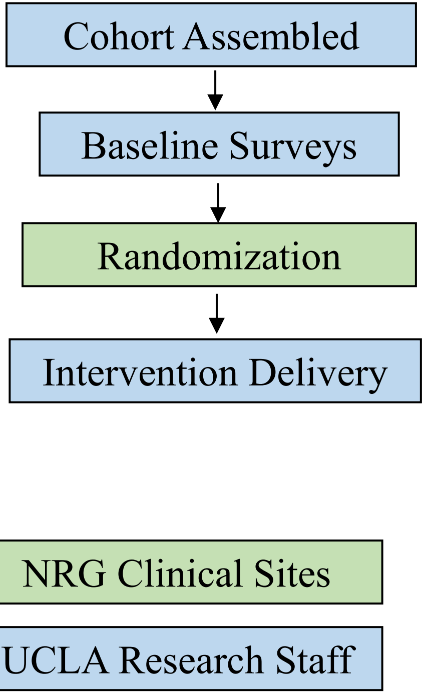
Wait for Cohort Formation

NRG Clinical Sites

UCLA Research Staff

- Based on previous studies, we anticipate accruing **10-15 participants per month** for English-speaking participants.
- Wait until **40 consented participants** across all clinical sites are available for a cohort. This process may take up to 8-12 weeks.
- For the Spanish speaking participants, we will need **20 consented participants** for a cohort randomized to 2 arms. This may take longer; UCLA will take steps to ensure timely enrollment.

After Cohort Formation



- **Once a cohort is assembled,** UCLA confirms availabilities with participants. **Once confirmed, Baseline Survey will be sent**.
  - **Baseline Survey is open for 2 weeks**.
  - Participants receive reminders until surveys are complete.
- After the 2 weeks, **clinical sites will be given 5 days to randomize** those participants who completed their Baseline Survey.
- UCLA receives treatment assignment from NRG and communicates to participant their mindfulness program assignment.

Overview of Data Collection

Study Assessments:

T1: Baseline

T2: 2 weeks post-intervention

T3: 3 months post-intervention

T4: 6 months post-intervention

- **Completed remotely through secure online interface for recording and sharing health information**
- **Managed by UCLA Research Team**

Assessments include:

Primary Outcome Measure:

- CES-D (depressive symptoms)

Secondary Outcomes Measures for fatigue, sleep problems, vasomotor symptoms, well-being, distress related to cancer recurrence, work productivity, health-related quality of life, healthcare resource use, self-kindness, and rumination

Data Collection

Time of Administration:

CC015 outcome assessments will be administered at these time points:

- **After consent, cohort formation and availability for intervention is confirmed, but prior to randomization**
  - Baseline (T1)
- **Following randomization**
  - 2 weeks post-intervention, 8-9 weeks after randomization (T2)
  - 3 months post-intervention, 18-19 weeks after randomization (T3)
  - 6 months post-intervention, 30-31 weeks after randomization (T4)

Data Collection

- Patient registration will occur via the NCI OPEN portal. Users (clinical site coordinators) will need to utilize their CTEP-IAM account.
- Data collection for this study will be done through Medidata Rave® & a secure online interface for recording and sharing health information
- Access to the trial in Rave is granted through the iMedidata application to all persons with the appropriate roles in the Regulatory Support System (RSS)

Screening and Step 0 Open Registration

- After verbal consent, use the screening script for CC015 to evaluate potential participants for eligibility
- Those who meet medical eligibility should be registered in Open and results of PHQ-8 depression screening recorded
- If the PHQ-8 score is between 5 and 14, participant should have an informed consent discussion of the study intervention and participant activities, including commitment to 6 weeks of training in mindfulness
- Results of the consent discussion should be recorded in Open
- Consenting participants must complete HEAL-ABC contact information form to send to UCLA

Decision Tree of Step 0 OPEN Registration

REGISTRATION (Step 0)

- Identify potential participants.
- Obtain verbal consent to administer the Patient Health Questionnaire-8-item (PHQ-8) Depression Screening.
- Breast cancer survivors must have a score of 5-14 on the PHQ-8 Depression screen.
- Speak English or Spanish.
- Document receipt of past chemotherapy.
- Document current endocrine therapy.

If participant is not medically eligible, they will not be added into OPEN.

If participant meets all above medical eligibility, does the participant meet the PHQ-8 score within the eligible range (scores 5-14) ?

YES

Does participant want to join the study that includes 6 weeks of mindfulness training?

YES

Participant signs the informed consent form.

Baseline Assessment Completed

Randomization (Step 1)

NO

Record the reason why the participant does not want to proceed on OPEN.

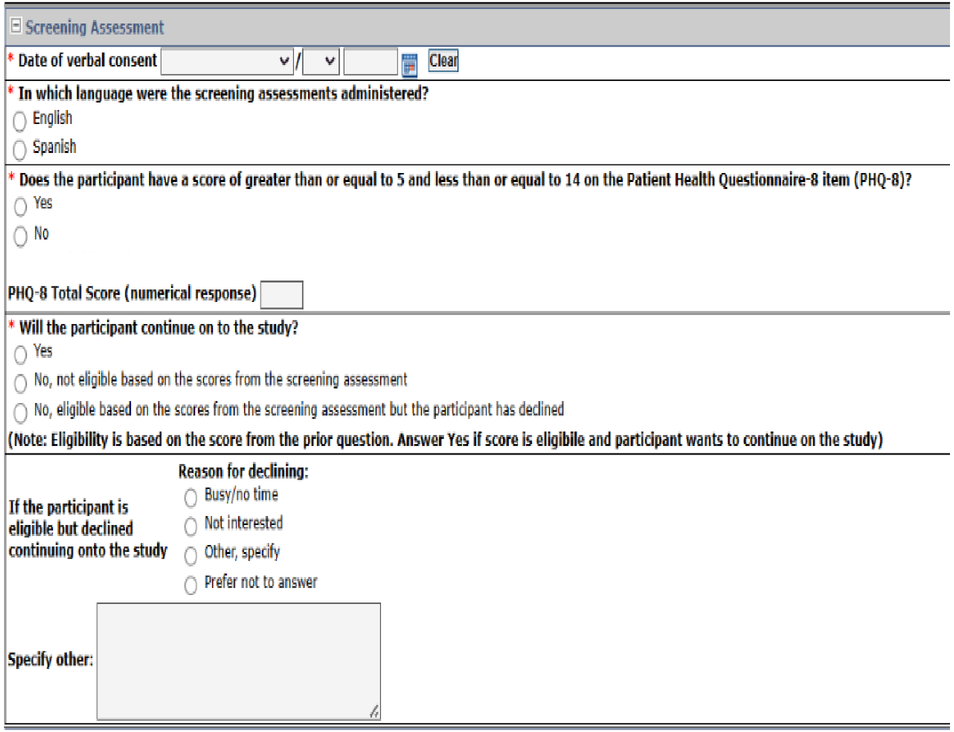
NO

Record the reason for ineligibility (OPEN) and do not proceed to Step 1.

Forms To Be Completed by Site Coordinator

If participant meets all eligibility and ineligibility criteria, but **does not consent to participate** or is not **eligible after PHQ-8 screening** (scores below 5 or above 14):

The **site staff must report this in OPEN** and select not eligible based on screening score or participant has declined (indicate reason for declining) in the **Checklist Form** located in the **Screening Assessment section**



Screening Assessment

* Date of verbal consent / / Clear

* In which language were the screening assessments administered?

- English
- Spanish

* Does the participant have a score of greater than or equal to 5 and less than or equal to 14 on the Patient Health Questionnaire-8 item (PHQ-8)?

- Yes
- No

PHQ-8 Total Score (numerical response)

* Will the participant continue on to the study?

- Yes
- No, not eligible based on the scores from the screening assessment
- No, eligible based on the scores from the screening assessment but the participant has declined

(Note: Eligibility is based on the score from the prior question. Answer Yes if score is eligibile and participant wants to continue on the study)

If the participant is eligible but declined continuing onto the study

Reason for declining:

- Busy/no time
- Not interested
- Other, specify
- Prefer not to answer

Specify other:

Forms To Be Completed by Site Coordinator

If participant is eligible for study and provides informed consent:

- The site staff must report this in OPEN.
- Clinical sites must collect participant contact information, complete the REDCap demographic form, and send securely to UCLA.
- REDCap: HEAL-ABC Demographics Information (NRG-CC015) form.
- Medidata Rave: Contact Information Form (confirms REDCap form has been completed)

Form in REDCap

After Step 0 (Registration), for **consented participants**, clinical site coordinators must complete ***Patient Contact Form*** on REDCap and send to UCLA.

Form in REDCap (cont.)

NRG-CC015 / HEAL-ABC Study Participant and Referral Site Contact Info

A A A

Thank you for enrolling a participant from your site in the NRG-CC015 HEAL-ABC Study!

Please carefully fill in all of the information below. We will use it to contact the participant, and also to stay in touch with you, the referring site.

If you have any difficulties with the form, please reach out to UCLA study coordinator Pamela Pichon at (310) 825-2520 or NRG-CC015.HEAL-ABC@mednet.ucla.edu.

1) **Please fill in today's date:** Today M-D-Y
You may click the Today button if you wish!

PARTICIPANT CONTACT INFORMATION

2) **What is the PARTICIPANT STUDY ID assigned by RAVE?**
Note: Please fill in only the 5 numeric digits following NRG-CC015, thank you!
These are the 5 numeric digits after NRG-CC015-

3) **Participant's FIRST NAME:**

4) **Participant's MIDDLE INITIAL (if none or unknown, leave this blank):**

5) **Participant's LAST NAME:**

[No Title]

6) **Participant's STREET ADDRESS:**
For example, 123 Maple Street

7) **CITY participant lives in:**

8) **STATE participant lives in:**

9) **Participant's ZIP CODE (5-digit):**
Please enter a 5-digit zip code

10) **Participant's E-MAIL ADDRESS:**

11) **Participant's CELL PHONE NUMBER:**

12) **Alternate phone number for participant, if applicable (leave blank if they don't have one):**

13) **TIME ZONE participant lives in:**

14) **What LANGUAGE should the materials be in for this participant?**
- English
- Spanish

reset

SITE CONTACT INFORMATION

15) **Please tell us the name of your site:**

16) **What CITY is your site located in?**

17) **What STATE is your site located in?**

18) **What is the FIRST NAME of the contact person at your site? This is the person we will be communicating with throughout this participant's time in the study!** [No Title]

19) **What is the LAST NAME of the contact person at your site?**

20) **When we want to e-mail you at the referral site, what E-MAIL ADDRESS should we use?**

21) **When we want to call you at the referral site, what PHONE NUMBER should we use?**

22) **What TIME ZONE is your site in?**

Submit

Forms To Be Completed by Site Coordinator

- **After cohort formation, if participant completes the Baseline Assessment,**
  - Sites will receive an email from NRG to randomize participants in OPEN

Protocol and Regulatory Requirements

- The NCI Central IRB has granted full board approval for NRG-CC015. All sites opening NRG-CC015 will be required to use the NCI CIRB as the IRB of record.
- **Before approval to open the study, all sites will have to complete the depression screening training slides and certify availability of a mental health professional to whom patients with elevated depressive symptoms can be referred.**
- Training materials are available in CTSU under protocol resources

See protocol section 8.2.1

Depression Safety Monitoring

- Prior to receiving clinical site approval, sites will need to identify and document mental health/supportive care services in network and affiliated clinical sites that will open the trial.
- Only women with PHQ-8 scores between 5-14 are eligible; however, scores may increase during the trial indicating clinically elevated depressive symptoms.
  - The PHQ-8 will be monitored throughout the study, independent of the assigned treatment.
  - Clinical site coordinators will be alerted if **a participant's score goes above 14.**
  - If this occurs, the participant should be **referred to the local mental health resource for evaluation**, and clinical site must **document** that this has occurred.

See protocol section 8.2.1

Activation Date

June 12, 2025

First participant consented on 6/27/2025!

As of July 22, 2025

21 sites activated and 11 eligible participants consented!!

Thank you!

pganz@mednet.ucla.edu

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Stereotactic radiation (SRS/SRT) versus hippocampal avoidance whole brain radiation (HA-WBRT) in patients with 5-20 brain metastases: A multicenter, phase 3 randomized trial

Ayal Aizer MD MHS, Shyam Tanguturi MD, Grant Benham, Paul Brown MD, Daniel Cagney MD, Paul Catalano ScD, Fallon Chipidza MD, Daphne Haas-Kogan MD, Jaroslaw Hepel MD, Monica Krishnan MD, Marciana Johnson BA MPH, Nayan Lamba MD, Jennifer Nosker PhD, Michael Parsons PhD, Luke Peng MD ScM, Ivy Ricca BA, Diana Shi MD, Kee-Young Shin MS, Patrick Wen MD, Rifaquat Rahman MD

Ayal Aizer MD, MHS
Director of Central Nervous System Radiation Oncology
Brigham and Women's Hospital / Dana-Farber Cancer Institute
Associate Professor, Harvard Medical School

NRG Oncology Semi-Annual Meeting

July 25, 2025

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

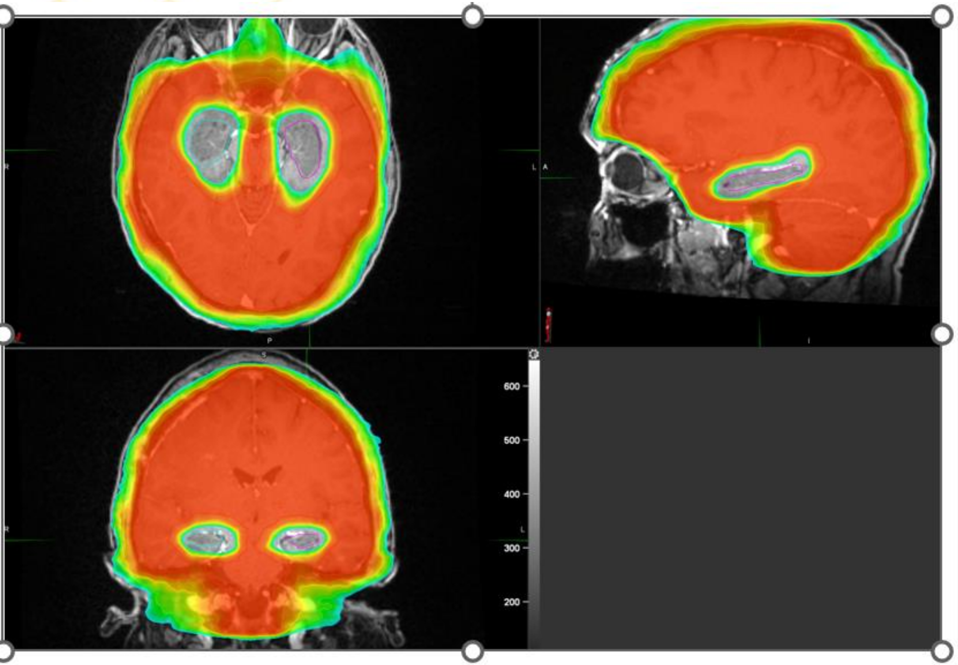
Disclosures

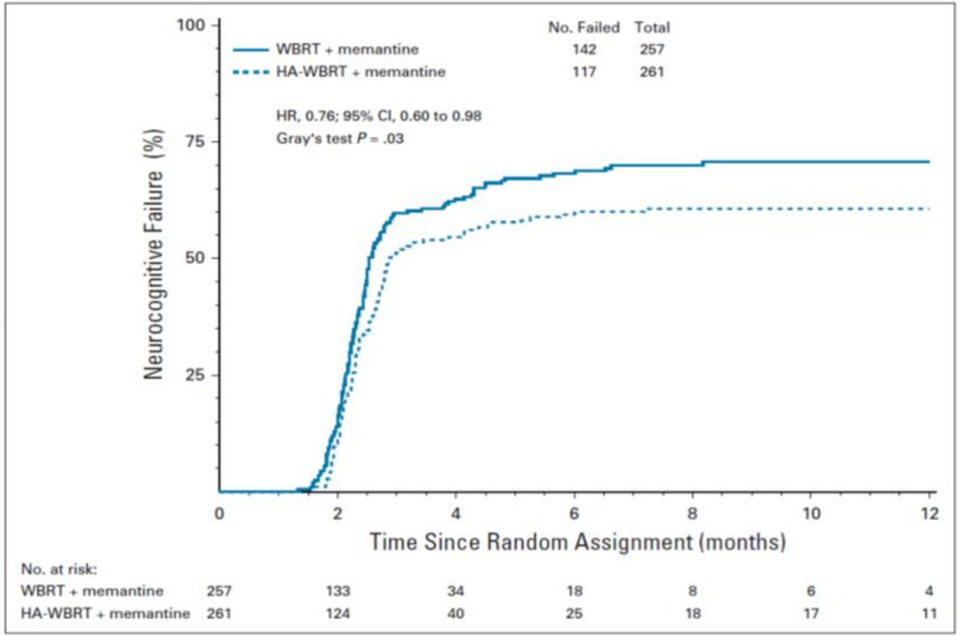
Research Funding from Varian and NH TherAguix

Local therapy +/- WBRT in patients with brain metastases

Study	N	Number BM	Hippocampal Avoidance WBRT	Arms	Years of Accrual	Intracranial Recurrence with WBRT	OS with WBRT	QoL with WBRT	Neurocog with WBRT
Patchell *JAMA 1998*	95	1	No	1. Surgery 2. Surgery + WBRT	1989-1997	Lower	No difference	No difference (KPS)	N/A
JROSG 99-1 *JAMA 2006*	132	1-4	No	1. SRS 2. SRS + WBRT	1999-2003	Lower	No difference	No difference (KPS)	No difference (MMSE)
MDACC *Lancet Oncol 2009*	58	1-3	No	1. SRS 2. SRS + WBRT	2001-2007	Lower	Worse	No difference	Inconclusive
EORTC 22952 *JCO 2011, 2013*	359	1-3	No	1. Local Therapy 2. Local Therapy + WBRT	1996-2007	Lower	No difference	Trend to worse	Worse
NCCTG N0574 *JAMA 2016*	213	1-3	No	1. SRS 2. SRS + WBRT	2002-2013	Lower	No difference	Worse	Worse
JCOG0504 *JCO 2018*	271	1-4	No	1. Resection + SRS 2. Resection + WBRT	2006-2014	Lower	No difference	N/A	Generally worse
Polish *Rad and Oncol 2016*	59	1	No	1. Resection + SRS 2. Resection + WBRT	2011-2015	No difference	Better	No difference	No difference
NCCTG 107C *Lancet Oncol 2017*	194	1-4	No	1. Resection + SRS 2. Resection + SRS + WBRT	2011-2015	Lower	No difference	No significant difference	Worse

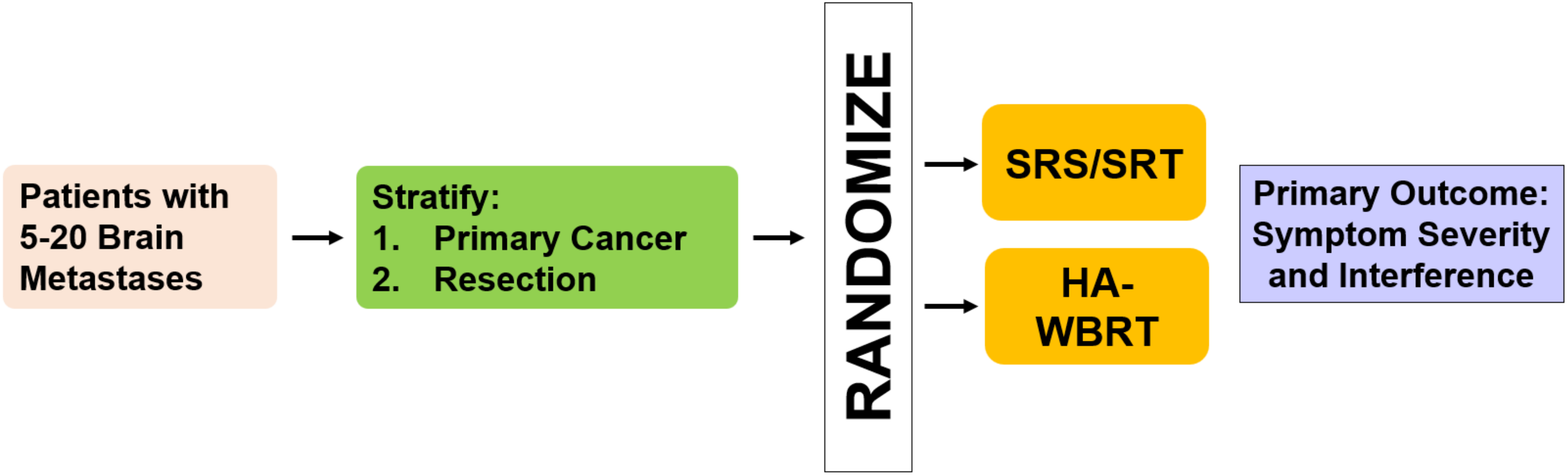
Hippocampal avoidance WBRT (HA-WBRT)





Brown et al. JCO. 2020

Study Design



Eligibility

- Eligible
  - Solid primary cancer other than SCLC
  - 5-20 brain metastases
  - Age 18-80
  - KPS ≥ 70 (capable of self-care)
- Ineligible
  - Prior RT for brain metastases
    - Surgery or systemic therapy permitted
  - LMD
  - Stage 5 CKD or ESRD
  - Intolerance of contrast-enhanced MRI brain
  - Unresected brain met > 5cm

Radiation

- SRS/SRT
  - Central credentialing
  - VMAT
  - 1-3 isocenters
  - SRS: 16-20 Gy
    - 96%: 20 Gy
  - SRT: 30 Gy in 5 Fx
    - Cavities with GTR: 25 Gy in 5 Fx
    - Dose reduction permitted for tumors near optics or brainstem
- HA-WBRT
  - Central credentialing
  - Similar to CC001
  - 30 Gy in 10 Fx
  - Hippocampal metrics
    - Max ≤ 16 Gy
    - D100% ≤ 9 Gy
  - Except
    - Metastases contoured and dosimetrically evaluated
    - Metastases in/near hippocampi treated, with sparing of remainder of ipsilateral and contralateral hippocampus
  - Memantine

Primary Outcome

- Symptom severity and interference (MDASI-BT)
  - Patient-reported
  - Severity: 22 questions
    - 13 core symptoms frequently reported by cancer patients
    - 9 neurologic symptoms common in patients with brain tumors
  - Interference: 6 questions
  - Weighted 50:50
  - Six months post-baseline relative to baseline
- Clinically significant difference (50% of difference between KPS 90-100 and ≤80) per Armstrong et al. JPSM 2009
  - Severity: 0.7
  - Interference: 1.25
- 80% power
- 2-sided alpha of 0.05
- 15% inflation for patients lacking at least 1 post-baseline assessment
- 196 patients

Date: ____________ Institution: ____________

Participant Initials: ____________ Hospital Chart #: ____________

Participant Number: ____________

MD Anderson Symptom Inventory - Brain Tumor (MDASI - BT)

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please select a number from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

	0 Not Present	1	2	3	4	5	6	7	8	9	10 As Bad As You Can Imagine
1. Your pain at its WORST?											
2. Your fatigue (tiredness) at its WORST?											
3. Your nausea at its WORST?											
4. Your disturbed sleep at its WORST?											
5. Your feelings of being distressed (upset) at its WORST?											
6. Your shortness of breath at its WORST?											
7. Your problem with remembering things at its WORST?											
8. Your problem with lack of appetite at its WORST?											
9. Your feeling drowsy (sleepy) at its WORST?											
10. Your having a dry mouth at its WORST?											
11. Your feeling sad at its WORST?											
12. Your vomiting at its WORST?											
13. Your numbness or tingling at its WORST?											
14. Your weakness on one side of the body at its WORST?											
15. Your difficulty understanding at its WORST?											
16. Your difficulty speaking (finding the words) at its WORST?											

Date: ____________ Institution: ____________

Participant Initials: ____________ Hospital Chart #: ____________

Participant Number: ____________

	0 Not Present	1	2	3	4	5	6	7	8	9	10 As Bad As You Can Imagine
17. Your seizures at its WORST?											
18. Your difficulty concentrating at its WORST?											
19. Your vision at its WORST?											
20. Your change in appearance at its WORST?											
21. Your change in bowel pattern (diarrhea or constipation) at its WORST?											
22. Your irritability at its WORST?											

Part II. How have your symptoms **interfered** with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items ***in the last 24 hours***? Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

	0 Did Not Interfere	1	2	3	4	5	6	7	8	9	10 Interfered Completely
23. General activity?											
24. Mood?											
25. Work (including work around the house)?											
26. Relations with other people?											
27. Walking?											
28. Enjoyment of life?											

Secondary Outcomes

Functional

- Performance status
  - 3 weeks, then q2 months for 1 year, then at subsequent visits
- Ability to complete ADLs
  - 4 + 12 months
- Neurocognitive function
  - 4 + 12 months

Survival-based

- Overall survival
- Neurologic survival

Recurrence-based

- Local recurrence
- Distant intracranial recurrence
- Leptomeningeal disease

Salvage therapy-based

- Salvage craniotomy
- Salvage SRS/SRT
- Salvage WBRT
- Salvage systemic therapy

Other

- Seizures
- Radiation necrosis

Study Parameters

- Investigator-initiated study (NCT03075072)
- Supported by Varian Medical Systems, a Siemens Healthineers company
- Activated in 4/2017
- Study sites
  - Brigham and Women's Hospital / Dana-Farber Cancer Institute (Boston, MA)
  - South Shore Health (Weymouth, MA)
  - Milford Regional Medical Center (Milford, MA)
  - Rhode Island Hospital / Brown University Health (Providence, RI)
- Originally open to patients with 5-15 brain metastases
  - In 11/2017, expanded to 5-20 brain metastases
- Final (196th) patient enrolled in 5/2024
- Data mature for primary endpoint in 11/2024; neurocognitive endpoints in 4/2025
- Intent to treat
- Comparable baseline characteristics by arm

CONSORT Diagram

Enrollment

Assessed For Eligibility (n = 399)

Excluded (n = 203)
- 34 did not meet inclusion criteria
- 2 died prior to enrollment
- 167 declined to participate

Consented, Enrolled, Randomized (n = 196)

Allocation

Allocated to HA-WBRT (n = 98)

Initiated allocated intervention (n = 89)

Did not receive allocated intervention (n = 9)
- 5 refused WBRT after randomization
- 2 died prior to RT
- 1 withdrew prior to RT
- 1 deferred to chemotherapy

Allocated to SRS/SRT (n = 98)

Initiated allocated intervention (n = 96)

Did not receive allocated intervention (n = 2)
- 1 died prior to RT
- 1 could not tolerate RT

Follow-Up

HA-WBRT:
Completed baseline MDASI-BT (n = 94)
Completed 3wk MDASI-BT (n = 83)
Completed 2mo MDASI-BT (n = 62)
Completed 4mo MDASI-BT (n = 50)
Completed 6mo MDASI-BT (n = 39)

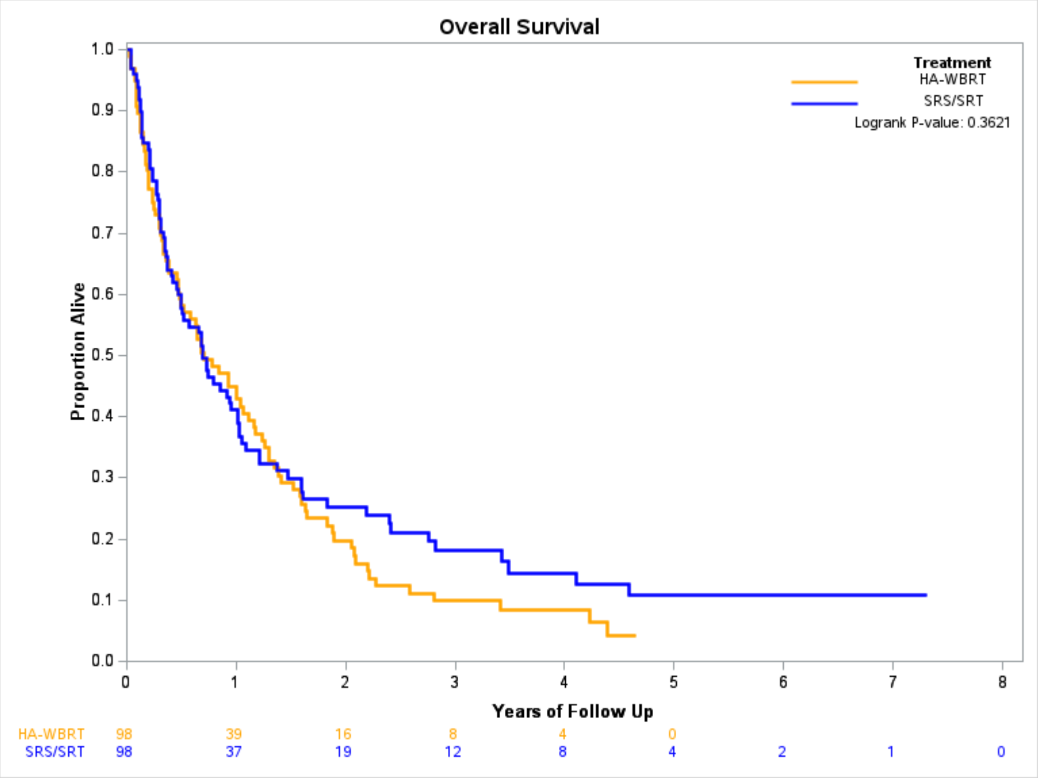
SRS/SRT:
Completed baseline MDASI-BT (n = 97)
Completed 3wk MDASI-BT (n = 77)
Completed 2mo MDASI-BT (n = 68)
Completed 4mo MDASI-BT (n = 55)
Completed 6mo MDASI-BT (n = 44)

Analysis

HA-WBRT:
Included in primary endpoint analysis (n = 88)
Excluded from primary endpoint analysis (n = 10)

SRS/SRT:
Included in primary endpoint analysis (n = 85)
Excluded from primary endpoint analysis (n = 13)

Overall Survival



	SRS/SRT	HA-WBRT
Median Survival, mo (95% CI)	8.3 (5.9 - 12.3)	8.5 (5.9 - 13.9)
12 Month Survival (95% CI)	41.1% (31.3% - 50.7%)	42.8% (32.7% - 52.6%)

NRG ONCOLOGY

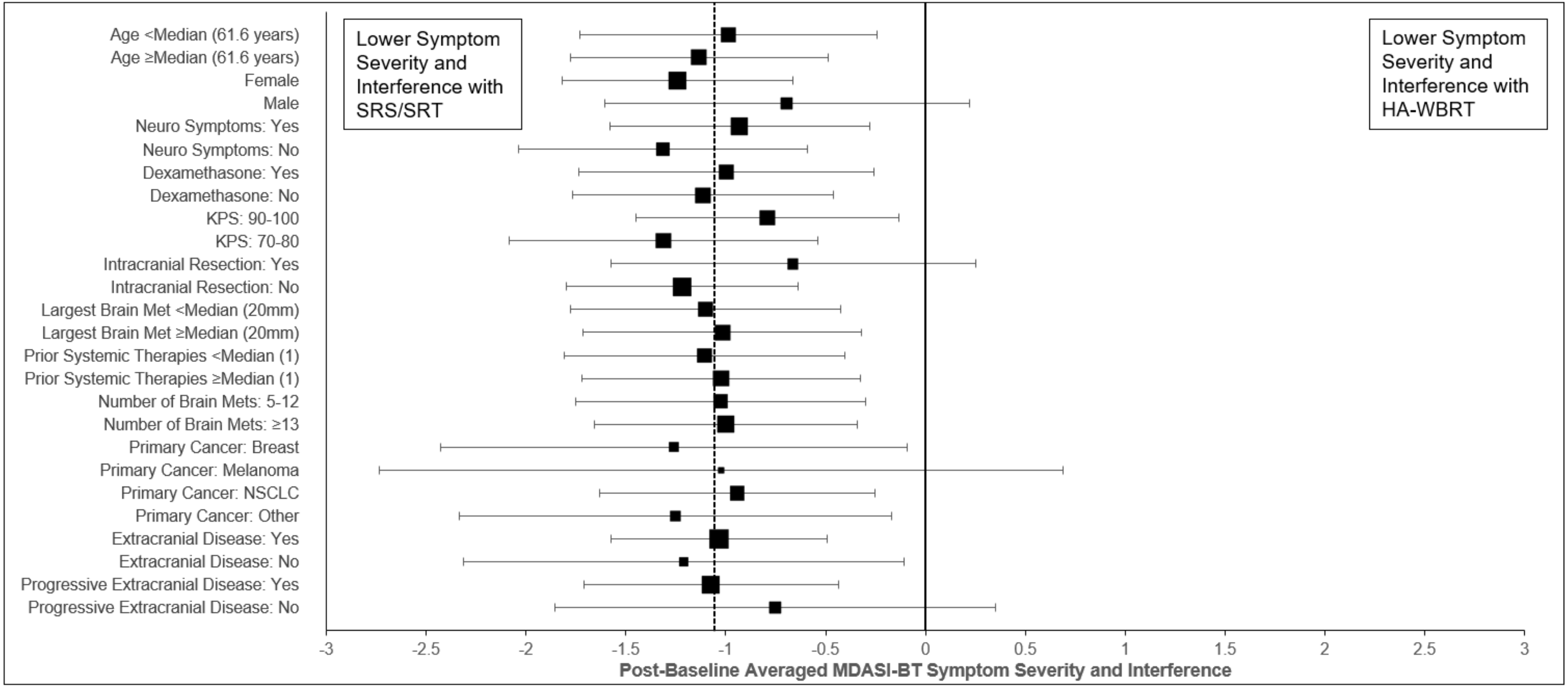
Primary Outcome

MDASI-BT Symptom Severity			
	SRS/SRT	**HA-WBRT**	**p**
Baseline (mean)	2.19	1.90	0.20
Post baseline minus baseline (weighted, mean)	-0.03	0.59	
Difference	**-0.62**		**<0.001**

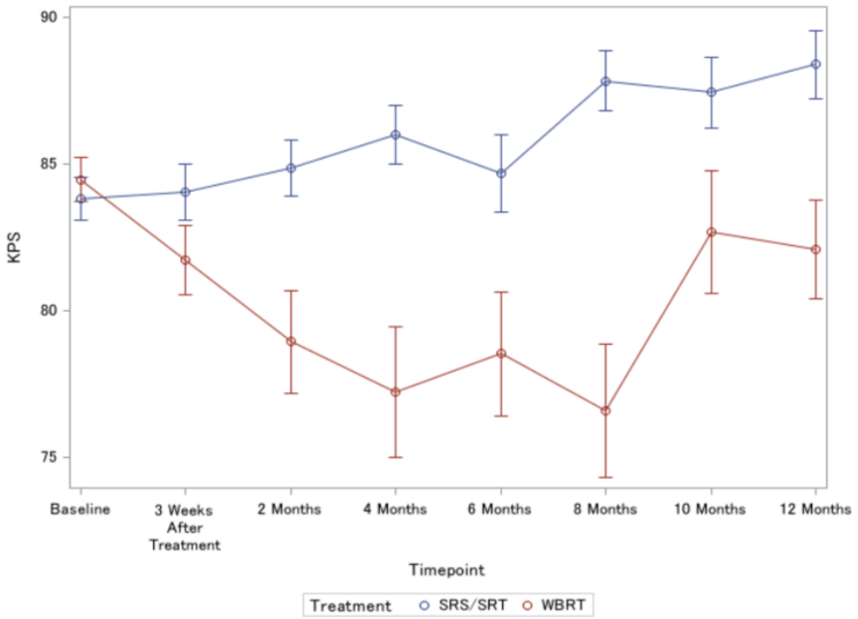
MDASI-BT Symptom Interference			
	SRS/SRT	**HA-WBRT**	**p**
Baseline (mean)	3.49	3.18	0.40
Post baseline minus baseline (weighted, mean)	-0.62	0.89	
Difference	**-1.50**		**<0.001**

Averaged Severity + Interference (N=172): -1.06 (95% CI -1.54, -0.58), indicating lower symptom burden and interference with daily function with SRS/SRT (p<0.001)

Primary Outcome



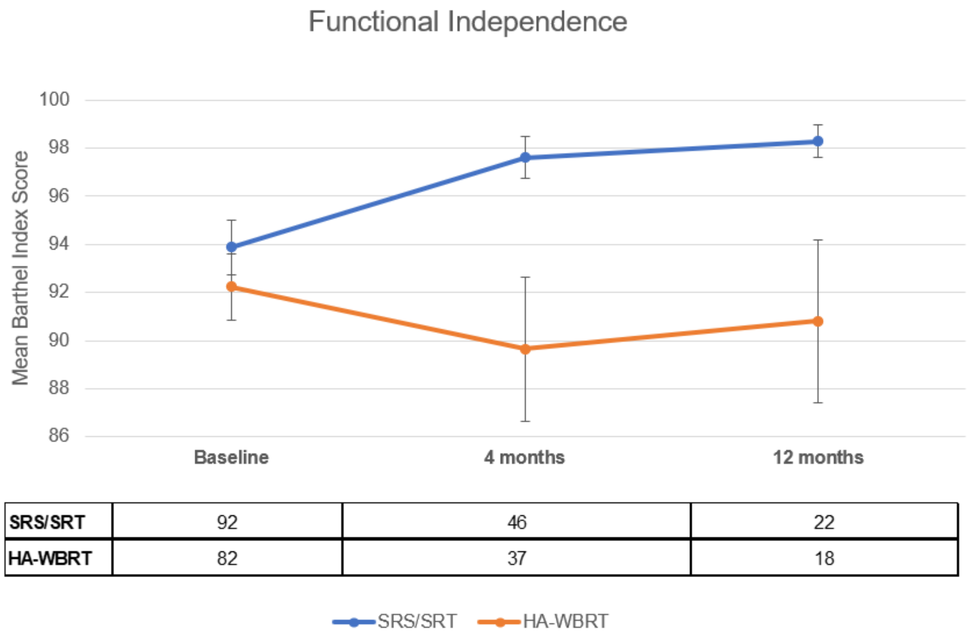
Performance Status



	BL	3 wk	2 mo	4 mo	6 mo	8 mo	10 mo	12 mo
SRS/SRT	97	79	70	55	45	37	35	31
HA-WBRT	92	76	65	50	47	35	30	29

Timepoint	Difference Between SRS/SRT and HA-WBRT Arms (95% CI)	p
Baseline	-0.87 (-2.91, 1.18)	0.41
3 Weeks	2.89 (-0.09, 5.87)	0.06
2 Months	6.53 (2.77, 10.28)	0.001
4 Months	9.51 (5.12, 13.90)	<0.001
6 Months	7.51 (2.87, 12.14)	0.002
8 Months	11.80 (7.29, 16.32)	<0.001
10 Months	7.76 (3.55, 11.98)	<0.001
12 Months	8.64 (4.62, 12.66)	<0.001

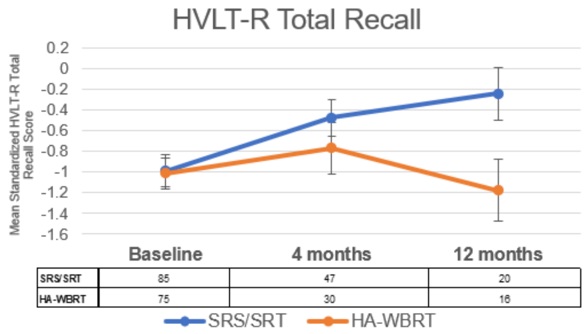
Functional Independence



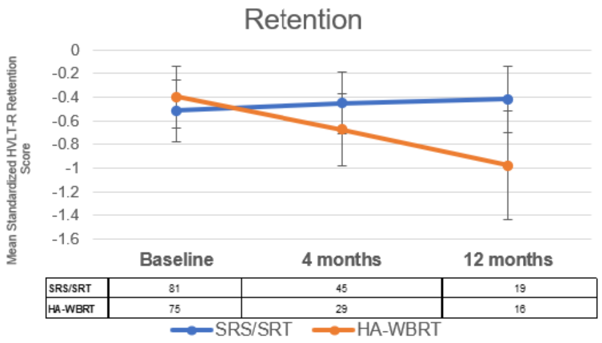
SRS/SRT	92	46	22
HA-WBRT	82	37	18

Timepoint	p
Baseline	0.39
4 Months	0.02
12 Months	0.02

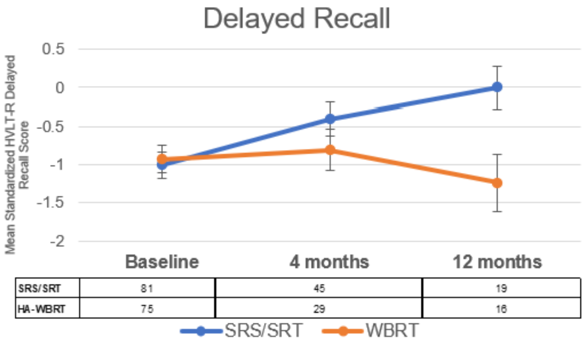
Neurocognitive Testing - HVLT



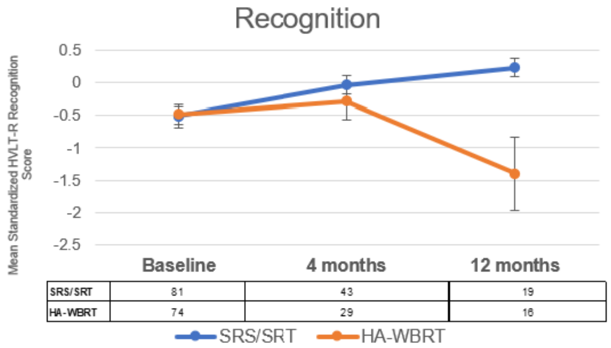
Timepoint	p
Baseline	0.39
4 Months	0.20
12 Months	0.03



Timepoint	p
Baseline	0.77
4 Months	0.69
12 Months	0.31

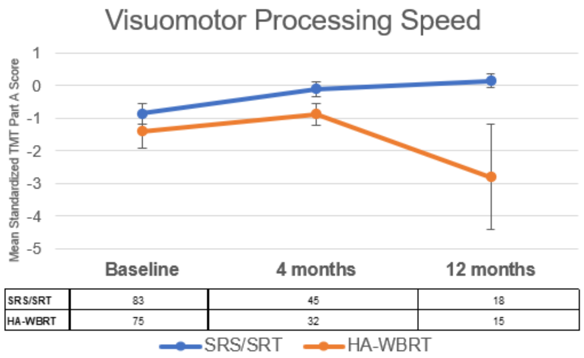


Timepoint	p
Baseline	0.82
4 Months	0.19
12 Months	0.01

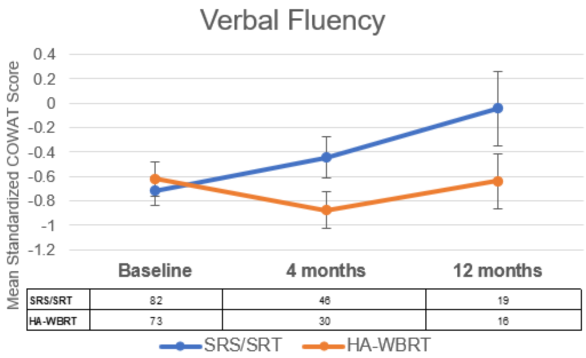


Timepoint	p
Baseline	0.91
4 Months	0.43
12 Months	0.004

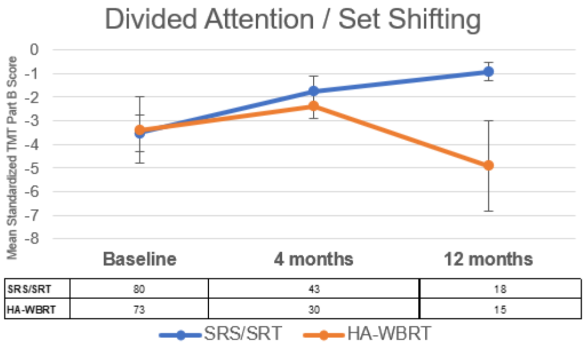
Neurocognitive Testing – TMT, COWAT, MMSE



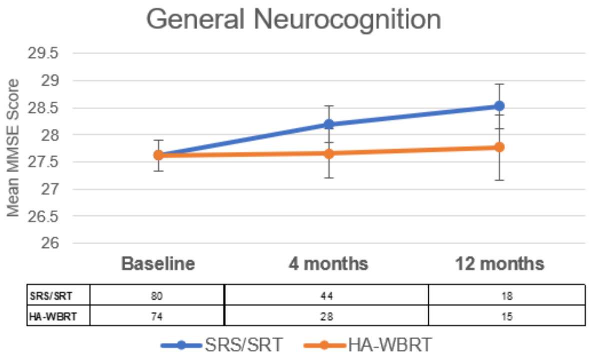
Timepoint	p
Baseline	0.36
4 Months	0.02
12 Months	0.06



Timepoint	p
Baseline	0.68
4 Months	0.007
12 Months	0.08



Timepoint	p
Baseline	0.94
4 Months	0.35
12 Months	0.03



Timepoint	p
Baseline	0.99
4 Months	0.33
12 Months	0.21

Conclusions

- Patients with 5-20 brain metastases experience less symptom burden and interference with daily function with SRS/SRT compared to HA-WBRT, without compromise of survival
- SRS/SRT likely also yields superior performance status, ability to complete ADLs, and neurocognitive function than HA-WBRT
- SRS/SRT now represents the radiotherapeutic standard of care for most patients with 20 or fewer brain metastases

Acknowledgements

- **Research Coordinators:** Allison Martin, Rachel Brigell, Luke Besse, Lacey Wickersham, Alex Gavrilovic, Ivy Ricca, Marci Johnson, Riley Maddox
- **Research Managers / Leaders:** Grant Benham, Kris Zhai, Kristin Roper, Paul Nguyen, Jon Schoenfeld
- **Research Nurses:** Bev Spicer, Eileen Mann
- **Statisticians:** Bhup Rawal, Kee-Young Shin, Paul Catalano
- **Neuropsychologists:** Jennifer Nosker, Michael Parsons
- **Collaborating Physicians:** Shyam Tanguturi , Paul Brown, Daniel Cagney, Fallon Chipidza, Daphne Haas-Kogan, Jaroslaw Hepel, Monica Krishnan, Nayan Lamba, Luke Peng, Patrick Wen, Rifaquat Rahman
- **Study Sites:** Rhode Island Hospital / Brown University Health, South Shore Health, Milford Regional Medical Center, Brigham and Women's Hospital / Dana-Farber Cancer Institute
- **Sponsor**: Varian Medical Systems, a Siemens Healthineers company
- **Patients as well as their families, loved ones, and caregivers**

Community Oncology Research Program

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

NCI NCORP Update

Brandy Heckman-Stoddard, PhD, MPH
Interim Director, NCORP

NATIONAL CANCER INSTITUTE

NRG NCORP Town Hall
July 25, 2025

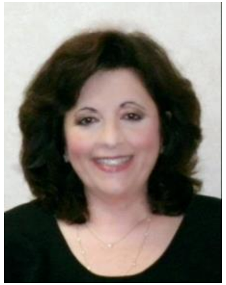
Disclosures

- Nothing to disclose

New NIH Director – Jay Bhattacharya, MD PhD

- NIH Council of Councils Meeting – Monday April 21, 2025 https://videocast.nih.gov/watch=56725 (1:50:50)
  - Real World Data Platform
  - Improve Population Health
  - Ensure Reliable Results
  - Make Big Advances
  - Maintain Safety and Transparency
  - Encourage Academic Freedom

NCORP CPC Staff Changes



Sandra Russo, MD, PhD, MPH
NRG, Alliance Prevention
NCI Lead for Prevention Steering Committee
Retired May 9, 2025

Wendy Rubinstein, MD, PhD
Alliance Prevention
NCI Lead for Prevention Steering Committee

Cecilia Lee, DrPH, RN
ECOG-ACRIN, Treatment QOL, NCI Lead for Symptom Management Steering Committee

Brennan Streck, PhD, MPH
Wake Forest, Treatment QOL

Changes to NCI NCORP Site Support

- Each NCORP Site will have a <u>single</u> NCORP Project Scientist
  - Work with your Site on all areas of science (prevention, control & CCDR)
  - Increase continuity and engagement with Site staff
- The Project Scientist will meet with you regularly and be responsible for approving changes in NCORP-SYS
- Each NCORP Site has a Program Officer who is responsible for administrative oversight of the award and work with OGA
- Sites will be informed of their Project Scientist in August after NoA's are issued

Updates to NCORP Guidelines

- U34 Planning Grants
  - To allow opportunity for diverse participation in these small planning studies each CTEP ID may participate in one planning study per scientific area (prevention, symptom science, CCDR).
  - Research Bases will indicate which protocols are supported by a planning grant
- Publications:
  - All publications and abstracts supported by the NCORP grant must be submitted to NCI NCORP@mail.nih.gov for NCORP review prior to submission to journal or meeting
  - NCORP grant must be cited as funding source

NCORP Extension

- NCI Program Officials and Project Scientists have completed their reviews
- NCI Office of Grants Administration is working on the awards
- Successful NCORP Sites will receive full funding for the next year

NCORP Recompetition

- Forecasts have been published
  - NOT-CA-25-042 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Research Bases (UG1 Clinical Trial Required)
  - NOT-CA-25-043 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Community Sites (UG1 Clinical Trial Not Allowed)
  - NOT-CA-25-044 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Academic Community Sites (UG1 Clinical Trials Not Allowed)
- RFAs are still working their way through the approval process
- Key Dates

Estimated Post Date:	Aug 29, 2025
Estimated Application Due Date:	Nov 14, 2025
Estimated Award Date:	Aug 01, 2026

Protocols Closed to Accrual

- ACCL2031, 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, closed 5/7/2025, (162/192)
- URCC-19075, Multi-Center Randomized Controlled Phase II Trial of Exercise to Treat Chemotherapy-Induced Peripheral Neuropathy (CIPN), closed 5/27/25, (133/132)

Cancer Control Trials Pending Activation

Trial Number	Title	Status	Sample Size
A212101	Evaluation of Provider vs. Patient Mediated Cascade Genetic Testing of First-Degree Relatives of Patients With Newly Diagnosed Colorectal Cancer	Pending	182
A221801	The Revitalized Trial: Reducing Vaginal Atrophy with Fractional CO2 Laser for Breast Cancer	Pending	250
A222302	Distance-Based Exercise to Preserve Function and Prevent Disability (DEFEND)	Pending	80 Limited Site Enrollment
EA6232	Phase II Double-Blind Trial of Sulforaphane for Therapeutic Prevention of Melanoma in Patients with Multiple Atypical Nevi and a Prior History of Melanoma	Pending	378

Cancer Control Trials Recently Activated

Trial Number	Title	Activation Date	Sample Size
A222301	High-Dose Prophylactic Gabapentin (HOPE) to Prevent Opioid Use for Oral Mucositis Pain During Head and Neck Chemoradiotherapy: A Phase III Clinical Trial	6/4/2025	0/228
NRG-CC013	A Randomized, Masked, Placebo Controlled, Phase II Trial Of Concurrent Chemoradiation With BMX-001 In Patients With Head And Neck Squamous Cell Carcinoma Receiving Concurrent Chemoradiation	6/2/2025	3/98
NRG-CC014	Radiation Therapy for High-Risk Asymptomatic Bone Metastases: A Pragmatic Multicenter Randomized Phase 3 Clinical Trial (PREEMPT)	4/14/2025	15378
NRG-CC015	Harnessing E-Mindfulness Approaches for Living After Breast Cancer HEAL-ABC: Harnessing E-Mindfulness Approaches for Living-After Breast Cancer	6/15/25	0/402
SWOG-S2408	A Randomized Phase III Blinded Trial of Lanreotide for the Prevention of Postoperative Pancreatic Fistula	2/14/2025	5/274
WF-2304/ A172401	Complementary Options for Symptom Management in Cancer (COSMIC)	1/15/2025	612/2000
WF-2403	Building Capacity within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP)	4/21/2025	Mentors: 7/7 APPs: 0/97

Highlighted study: NRG-CC005 FORTE

Protocol Number	Title	Phase	Lead RB	Participating RBs	CIRB Approved	Date Activated	Accrual Goal	Current Accrual
NRG-CC005	FORTE (Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)	Phase III	NRG	ALLIANCE, ECOG-ACRIN, NRG, SWOG	4/6/20	10/6/21	9500	3070

Target Enrollment = 9,500 Enrollment Period = 48 Months						
Day-Month-Year	Time Months	% Enrollment Period	% Accrual	$N_{minimum}$	N_{Delta}	N_{Delta}/Month
1-Oct-22	0	0%	0%	200*		
29-Sep-23	12	25%	10%	950	750	63
27-Sep-24	24	50%	25%	2,375	1,425	119
26-Sep-25	36	75%	50%	4,750	2,375	198
19-Feb-26	40.8	85%	65%	6,175	1,425	297
30-Sep-26	48	100%	90%	8,550	2,375	330

Sept 24	131
Jan 25	90
Feb 25	119
Mar 25	141
April 25	115
May 25	119
Jun 25	251
July 25	57

Revised monthly goal: 130

Recently Activated NCTN Studies

Feb 26, 2025 to June 29, 2025 - Sorted by Phase & Study

Study #	Phase	Study Title	Activation Date	Planned Accrual
AALL2321	2	A Phase 2 Study of Blinatumomab in Combination with Chemotherapy for Infants with Newly Diagnosed Acute Lymphoblastic Leukemia with Randomization of KMT2A-Rearranged Patients to Addition of Venetoclax	4/25/2025	153
ARAR2331	3	Prospective Treatment of Types I, II and III Pleuropulmonary Blastoma (PPB)	3/17/2025	110
AREN2231	3	Risk Adapted Treatment of Unilateral Favorable Histology Wilms Tumors (FHWT)	3/28/2025	1,656
AALL2131	3	An International Pilot Study of Chemotherapy and Tyrosine Kinase Inhibitors with Blinatumomab in Patients with Newly-Diagnosed Philadelphia Chromosome-Positive or ABL-Class Philadelphia Chromosome-Like B-Cell Acute Lymphoblastic Leukemia	5/23/2025	222
MM1MDS-A01	2	A Randomized Phase II Trial of Enasidenib-Based Therapies Versus Cedazuridine-Decitabine in Higher-Risk IDH2-Mutated Myelodysplastic Syndrome: A MyeloMATCH Sub-Study	4/1/2025	54
MM1OA-S03	2	A Randomized Phase II Trial of ASTX727 and Venetoclax Compared with ASTX727, Venetoclax, and Enasidenib for Newly Diagnosed Older Adults with IDH2 Mutant Acute Myeloid Leukemia: A MyeloMATCH Substudy	4/1/2025	93

Recently Activated NCTN Studies

Feb 26, 2025 to June 29, 2025 - Sorted by Phase & Study

Study #	Phase	Study Title	Activation Date	Planned Accrual
EA4231	2	A Phase 2 Study of Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Revlimid (ViPOR) in Relapsed or Refractory CD10-Negative Diffuse-Large B-Cell Lymphoma (DLBCL) and High-Grade B-Cell Lymphoma with MYC and BCL2 Rearrangements (HGBCL-DH-BCL2)	6/24/2025	120
EA5231	3	A Randomized Phase III Trial of Checkpoint Blockade in Lung CancEr Patients in the Adjuvant Setting Based on Pathologic Response Following Neoadjuvant Therapy (CLEAR)	6/13/2025	630 (Screen 860 Patients)
NRG-GI011	3 (QoL)	A Phase III Randomized Trial of Dose Escalated Radiation in Locally Advanced Pancreas Cancer (LAPC) Patients (LAP100)	6/11/2025	356
NRG-GU014	2 (QoL)	Randomized Phase II Trial of Pembrolizumab and Radiation vs. Radiation and Concurrent Chemotherapy for High-Grade T1 Bladder Cancer (PARRC Trial)	3/7/2025	160
S2414	3 (QoL)	A Randomized Phase III Trial INcorporating Pathologic Complete ReSponse in Participants with Early StaGe Non Small Cell Lung Cancer to Optimize ImmunotHerapy in the AdjuvanT Setting (INSIGHT)	3/14/2025	306
S1800E	2/3	A Randomized Phase II/III Study of Docetaxel and Ramucirumab with or Without Cemiplimab (REGN2810) for Participants Previously Treated with Platinum-Based Chemotherapy and Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study)	4/28/2025	378

Non-Investigational New Drug/Non-Treatment (NINT) Registration Type

NCI Registration and Credential Repository (RCR) utilizes 6 person registration types

- Investigator (IVR) — MD, DO, or international equivalent;
- Non-Physician Investigator (NPIVR) — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD);
- Non-Investigational New Drug (IND)/Non-Treatment (NINT) - (e.g., MD, DO, NP, PA, PharmD, PhD, EdD) investigators who wish to exclusively participate in non-IND/non-treatment studies flagged for NINT participation;
- Associate Plus (AP) — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications such as the Roster Update Management System [RUMS], OPEN, Rave, acting as a primary site contact, or with consenting privileges;
- Associate (A) — other clinical site staff involved in the conduct of NCI-sponsored trials; and
- Associate Basic (AB) — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems.

Rationale for NINT Registration Type

- Simplify the registration process for individuals who wish to exclusively participate in non-IND/non-treatment studies in an investigator role
- Encourage participation in screening, surveillance, and Cancer Care Delivery Research (CCDR) studies
- Ensure regulatory requirements are met by vetting participating staff and not using workarounds (e.g., enrolling under NCORP PI)

Registration Types – Documentation Requirements

Documentation Required	IVR	NPIVR	NINT	AP	A	AB
CTEP-IAM Account with ID.me credentials	✓	✓	✓	✓	✓	✓
FDA Form 1572 • Practice sites, IRBs, and labs	✓	✓				
Financial Disclosure Form	✓	✓		✓		
NCI Biosketch (education, training, employment, certification, licensure, ABMS certification, GCP Training, personal statement, memberships, honors, publications, research support)	✓	✓		✓		
NINT Investigator Acceptance Form • Practice sites, IRBs, and labs • NINT Biosketch (education, licensure, ABMS certification, GCP Training)			✓			
GCP Training Certificated (mandatory file upload)	✓	✓	✓	✓		
Agent Shipment Form (if applicable)	✓					
CV (optional file upload)	✓	✓		✓		
Annual Re-registration	✓	✓	✓	✓	✓	✓

Checking in a Year Later

- To date - no NINT’s have been rostered to an NCORP site
- Have you attempted to register an NINT?
- What are the barriers to registering NINT’s at your NCORP’s?

PAR-24-274: NCI Research Specialist (Clinician Scientist) Award (R50 Clinical Trial Not Allowed)

The Research Specialist Award is designed to encourage the development of stable research career opportunities for exceptional clinician scientists who want to continue to participate in the NCI clinical trials networks through leadership in the:

1) development of national clinical trials

2) implementation of NCI clinical trials in their institutions

3) national service to the NCI clinical trials networks through participation in the scientific review committees, monitoring committees and other activities

Budget:

1. salary support for the Research Specialist commensurate with their level of effort on NCI funded clinical trials with a minimum of 2.4 and a maximum of 4.8 person-months funded by this award;
2. travel costs to attend research meetings/conferences: not to exceed $2,500 per year; and
3. $2,000 per year for travel costs for the Principal Investigator to attend an annual meeting for Research Specialist (Clinician Scientist) Award recipients

- **Application due dates:** November 4, 2024, November 4, 2025
- **Pre-Application Webinar:** Access the pre-application webinar recording.

NCI Community Oncology Research Program

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

2025 NCORP

ANNUAL MEETING

You are invited to attend the

2025 NCORP Annual Meeting

August 25 – 26th

NIH Natcher Conference Center

Bethesda, MD

Draft agenda, meeting information, resources, and registration available on the meeting webpage at:

https://events.cancer.gov/nci/ncorp

Note: This meeting is not open to the public; it is for NCORP grantee and pertinent NCI staff participation only.

NIH Visitor ID Requirements

One form of government-issued, unexpired photo identification is required. Identification **must** be compliant with the Congressionally mandated REAL ID Act of 2005.

Approved forms of ID to enter NIH facilities include:

- **REAL ID** State Driver's License or Identification Card
- U.S. Government Common Access Card, Military Identification Card, or Personal Identification Verification Card
- U.S. Passport or Passport Card
- USCIS Employment Authorization Card (I-766)
- Foreign Passport
- Permanent Resident Card or Alien Registration Receipt Card
- Native American Tribal Document
- U.S. Border Crossing Card

For additional information: visit.nih.gov

Sample REAL ID
U.S. Driver's License
Star in upper right
corner = key indicator

Real ID Act of 2005

The REAL ID Act of 2005 establishes minimum security standards for state-issued driver’s licenses and identification cards and prohibits federal agencies, such as NIH, from accepting for official purposes licenses and identification cards that do not meet these standards.

Under the REAL ID ACT, NIH may only accept state-issued driver’s licenses and identification cards that meet the standards required by the ACT to access our facilities. **Enhanced Driver's Licenses (EDL)** issued by **Michigan**, **Minnesota**, **New York**, **Vermont**, and **Washington** are considered acceptable alternatives to REAL ID-compliant cards and will also be accepted for official REAL ID purposes. Most EDLs do not contain the star marking and this is acceptable. The EDLs do however state they are enhanced driver’s licenses and have an American flag either overlapping the picture or at the bottom right-hand corner.

Thank you!

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NCORP CCDR Updates

NATIONAL CANCER INSTITUTE

NRG Townhall Meeting
July 25, 2025

Disclosures

- None

CCDR Project Scientists and Project Manager

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Sarah Barranger, BA

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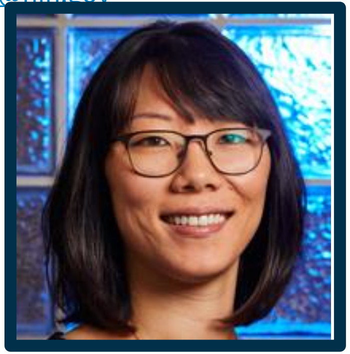

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Thank You!

WE APPRECIATE YOU

AND

YOUR HARD WORK IS NOTICED

CCDR Portfolio Review

CCDR Portfolio Overview

36 Protocols

- 4 Under review
- 2 Awaiting activation at Base
- **6 Open and accruing**
- 11 Closed to accrual
- 13 Completed

Care delivery gaps addressed*

- Guideline Adherence (8)
- 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)
- Precision Medicine (1)
- Treatment Adherence and Compliance (1)
- Awaiting Assignment (2)

*MeSH-defined (# of protocols)

CCDR Studies & Accrual to Date

32
- Approved protocols

20
- Randomized

13
- Practice randomized

Accrual:

- Patients = 13,045
- Non-Patients = 2,525
- Practices = 914*

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

Outcome data collected:	# of Studies
Patients and Non-Patients	13
Patients, Non-Patients, and Practices	7
Patients only	6
Practices only	3
Non-Patients and Practices	3
Patients and Practices	1

Accrual data is as of 05/31/2025

Protocols Meeting Target Accrual

- **S2108CD** *Educational Genomic Tumor Board*
  - Closed to accrual 11/23/24
- **S1912CD** *CREDIT*
  - Closed to accrual 12/16/24
- **URCC-18110CD** *ENABLE*
  - Closed to accrual 4/9/25
- **WF-1805CD** *HN-STAR*
  - Patient enrollment closed to accrual 4/15/25
  - Non-patient accrual of PCP continues

NRG CCDR Protocols

NRG–CC012CD *Managing Symptoms and Psychological Distress During Oral Anti-cancer Treatment (SYMON)*

- Patient: 148 / 516
- Non-Patient: 48 / 84
- Practices: 13 / 13

Amendment activated 5/29/25:

Expanded eligibility criteria to include individuals on immune checkpoint inhibitors

Practice
Anmed Health Cancer Center
Aspirus Regional Cancer Center
Cancer Center at Saint Joseph's
Carle Cancer Center
Georgia CaRes M/U NCORP
John H Stroger Jr Hospital of Cook County
Lake Regional Hospital
Central Arkansas Radiation Therapy Institute (CARTI)
Prisma Health Cancer Institute
Puerto Rico NCORP
University of New Mexico Cancer Centre
Medical University of South Carolina – Hollings Cancer Center
Hawaii NCORP

CCDR Protocols Actively Recruiting (n=5)

- **EAQ221CD** *Improving Medication Adherence in Metastatic Breast Cancer using a CONnected CUstomized Treatment Platform (CONCURxP)*
  - *Current accrual: 136/390 patients*
  - Amendment activated 4/4/25
    - Expanded eligibility criteria to include early-stage breast cancer
  - Participation open to all interested practices

- **EAQ222CD** *Effectiveness of Out-of-Pocket Cost COMmunication and Financial Navigation in Cancer Patients (CostCOM)*
  - *Current accrual: 395/720 patients*
0/40 non-patients

CCDR Protocols Actively Recruiting (n=5) (continued)

WF-2301CD *Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers*

- *Current accrual: 65/120 patient/caregiver dyads*

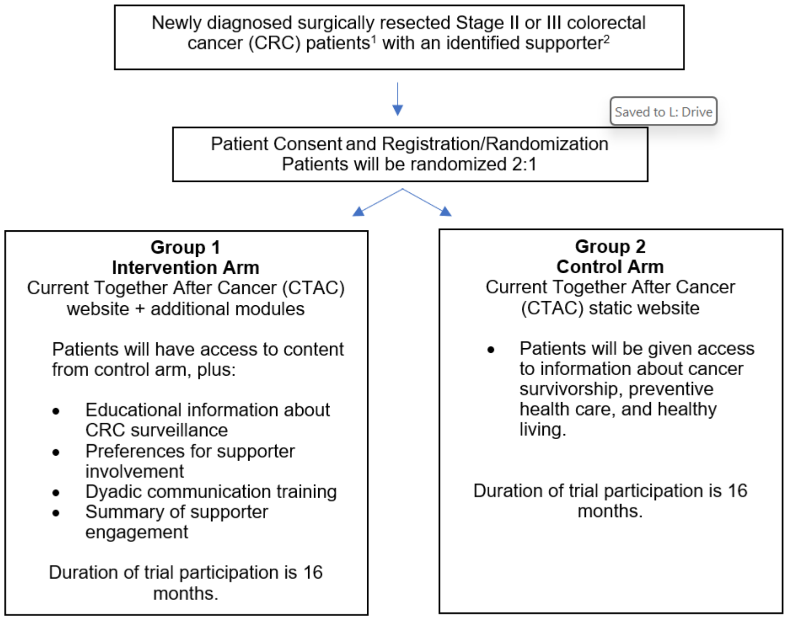
WF-2303CD *Understanding and Enhancing Health-related Social Needs (HRSN) Screening Among Community Oncology Practice*

- *Current accrual: 0/8 patients*
  73/136 non-patients
  39/80 practices

CCDR Protocols ACTIVATING AUGUST 2025

S2417CD *RCT to Evaluate the Effectiveness of an Intervention to Promote Guideline Concordant Colorectal Cancer Surveillance (R01 CA293394)*

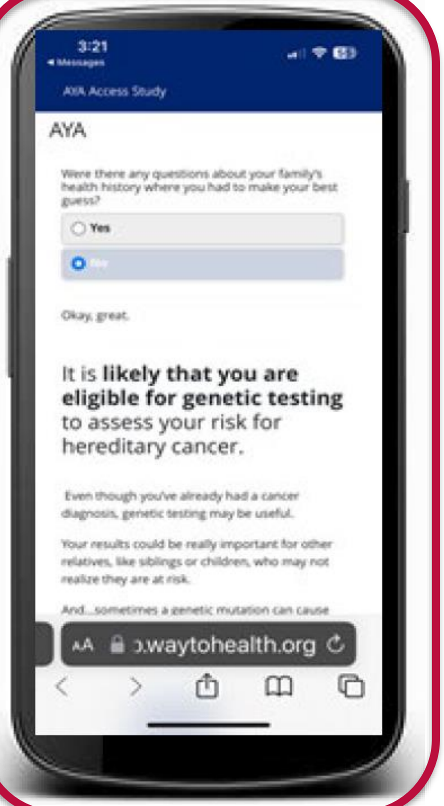
- Recruiting:
  - 654 Newly diagnosed surgically resected Stage II or III colorectal cancer (CRC) survivors with an identified supporter
  - 393 Patient Supporters (Spouse/partner, adult child, other family member, friend)
  - 10 Site Staff
- Intervention availability in English and Spanish languages
- July 2025 Administrator Webinar
- Anticipated Activation: August 1, 2025



CCDR Protocols ACTIVATING FALL 2025

A232301CD *AYA ACCESS: An enhanced eHealth and Chatbot enabled delivery model for Clinical genetic Services in Community AYA cancer patients (R01 CA284748)*

- *Recruiting 396 AYA cancer patients (18 – 39 y.o.), newly diagnosed, during or post-treatment, English or Spanish*
- *June 2025 Administrator Webinar*
- *Activating September 2025*



A232402CD *Randomized Trial of a Proactive Graduated Dose Modification Algorithm for FOLFOX Chemotherapy to Prevent Unplanned Delays*

- *Recruiting 420 GI cancer patients treated with FOLFOX chemotherapy regimen*
- *Activating September/October 2025*

CCDR Protocols Activating Fall/Winter 2025

Protocol	Population	Anticipated Activation
EAQ241CD FinFit: Addressing Financial Hardship in AYA Cancer Survivors	AYA cancer survivors	Winter 2025*
S2424CD Algorithm-enabled Patients Activated in Cancer care through Teams (APACT) to Improve Goals of Care Communication for People with Cancer	Adult cancer patients with planned or active receipt of systemic treatment	Winter 2025*

*R01 funded

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