

# Sheila Prindiville, MD, MPH

Director

Coordinating Center for Clinical Trials

National Cancer Institute



# NCI and VA Interagency Grop to Accelerate Trials Enrollment (NAVIGATE)



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development

*Sheila A. Prindiville, M.D., M.P.H.*  
*Coordinating Center for Clinical Trials*  
*October 5, 2018*

# NAVIGATE: NCI-VA Interagency Collaboration

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Collaboration between NCI and the VA to facilitate enrollment of Veterans into NCI national clinical trials.

- Opportunity for government agencies to partner at the national level to make clinical trials more accessible, *and*
- Accelerate cancer research by testing new cancer therapies to lessen the burden of cancer and its symptoms, as well as novel approaches to the prevention and early detection of cancer.

## NAVIGATE: Background

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- VA Medical Centers (VAMCs) are part of an extensive health care delivery system that has substantial expertise in the treatment of cancer.
- VA Cooperative Studies Program (CSP) has developed and effectively utilized a centralized approach to address site-level challenges to more efficiently recruit patients to national trials.
- VAMCs have historically been involved in NCI clinical trials, but participation has declined in the last decade.

## NAVIGATE: Background cont.

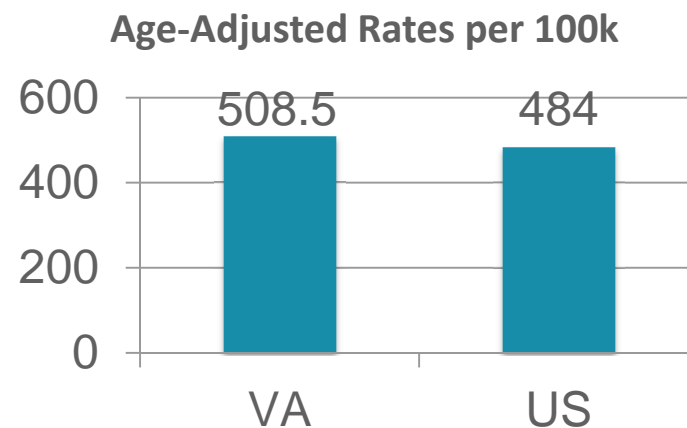
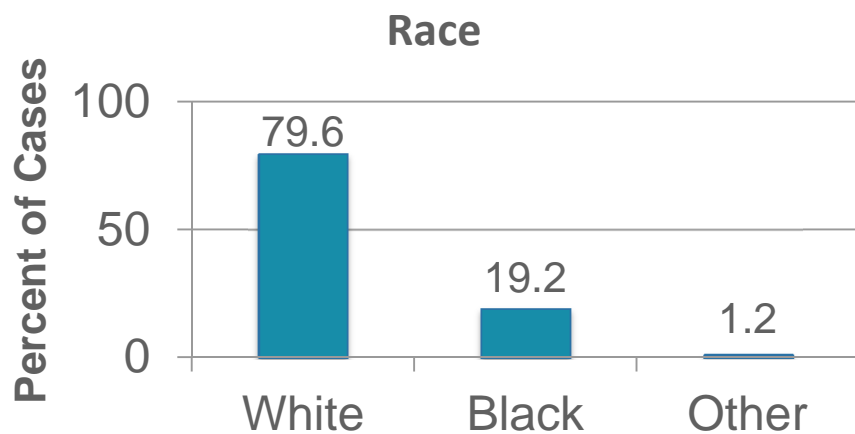
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- Inclusion of more VA patients in relevant NCTN and NCORP clinical trials is likely to advance the health of Veterans and aid NCI's national system in completing clinical trials more rapidly.
- Recently, there has been renewed interest among VA and NCI leadership to reinvigorate VA participation in NCI clinical trials.



# Cancer Incidence among Patients of the United States Veterans Affairs (VA) Healthcare System: 2010 Update

- Total cancers: 49,857
- Invasive cancers: 46,166

US Region	n	%
Midwestern	9,887	21.4
Northeastern	6,851	14.8
Southern	19,351	41.9
Western	10,080	21.8

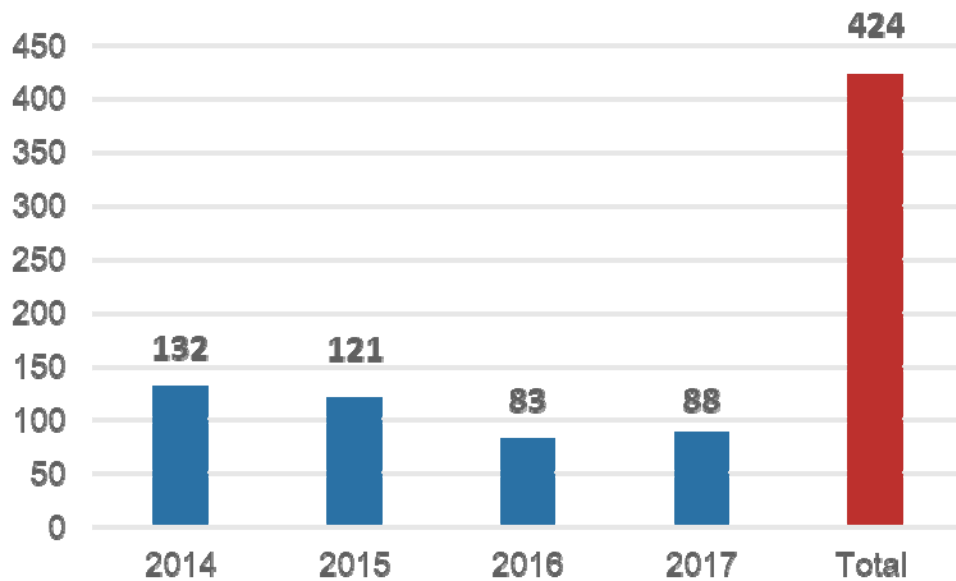


## Most Common Cancers by Sex in VA Patients, 2010

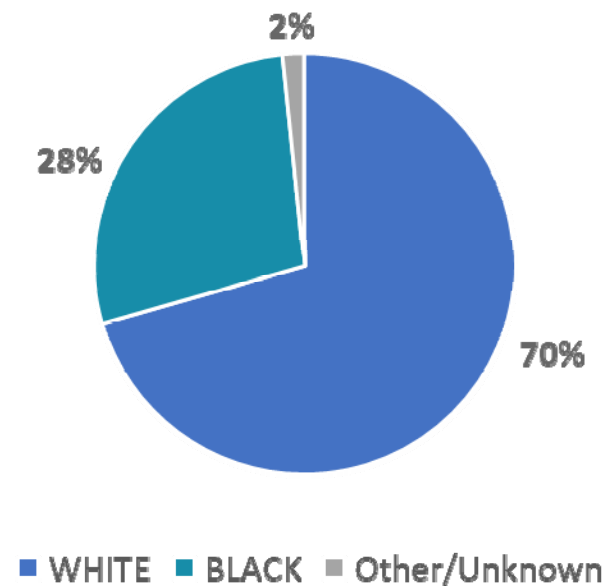
	n	%	Males	Females		n	%
Prostate	13,438	30%			Breast	402	30%
Lung & bronchus	8,019	18%			Lung & bronchus	197	15%
Colon & rectum	3,705	8%			Colon & rectum	88	7%
Kidney & pelvis	1,733	4%			Uterine corpus	75	6%
Melanoma	1,674	4%			Melanoma	59	4%
Liver	1,553	3%			Thyroid	53	4%
<b>All Sites</b>	<b>44,836</b>	<b>97%</b>			<b>All Sites</b>	<b>1,330</b>	<b>3%</b>

## VA Accrual to NCTN Trials Grant Years 1 to 4 (March 2014 – Feb 2018)

35 VA sites with  $\geq 1$  accrual



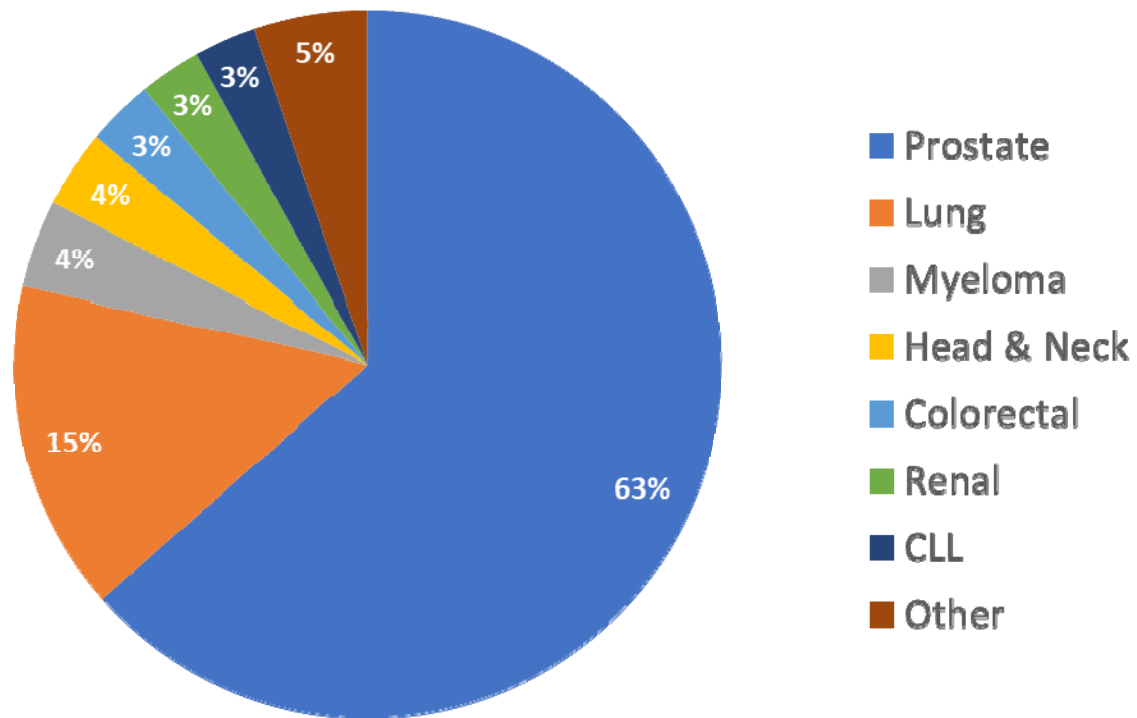
Race





## VA Accrual to NCTN Trials by Lead Disease (n=424) Grant Years 1 to 4 (March 2014 – Feb 2018)

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# Barriers to VA Participation in NCI Trials

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- Trial activation challenges
  - Regulatory and policy compliance
  - Use of technology, data sharing, and associated information security
  - Tissue banking
  - Lack of personnel and resources for recruitment
  - Variability in local culture and processes for conducting trials among VA sites
- Barriers to participation for Veterans
  - Travel and financial challenges
  - Awareness of trials and patient resources
  - Restrictive eligibility criteria (including co-morbidities)

## NAVIGATE Goals

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- Increase Veteran participation in NCI national clinical trials.
- Enhance operational activities to reduce barriers and facilitate participation of VA sites in NCTN and NCORP trials.
- Enable sustained, long-term capability for VA participation in NCTN and NCORP trials beyond the initial NAVIGATE support period.

# Primary Activities Supported by NAVIGATE

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- Establishment of a consortium of VA sites and a central coordinating office focused on increasing VA participation in NCTN and NCORP clinical trials.
- Infrastructure funding support to 12 VA sites for dedicated research staff for recruitment and enrollment.
  - \$150,000 total cost per site annually for 3 years

## Costs Not Supported by NAVIGATE

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- NCI will utilize established mechanisms for research costs associated with trials (e.g. investigational agents, research tests).
- VA provides standard, non-research medical care for eligible Veterans in accordance with applicable statute and policy.

# NAVIGATE Components

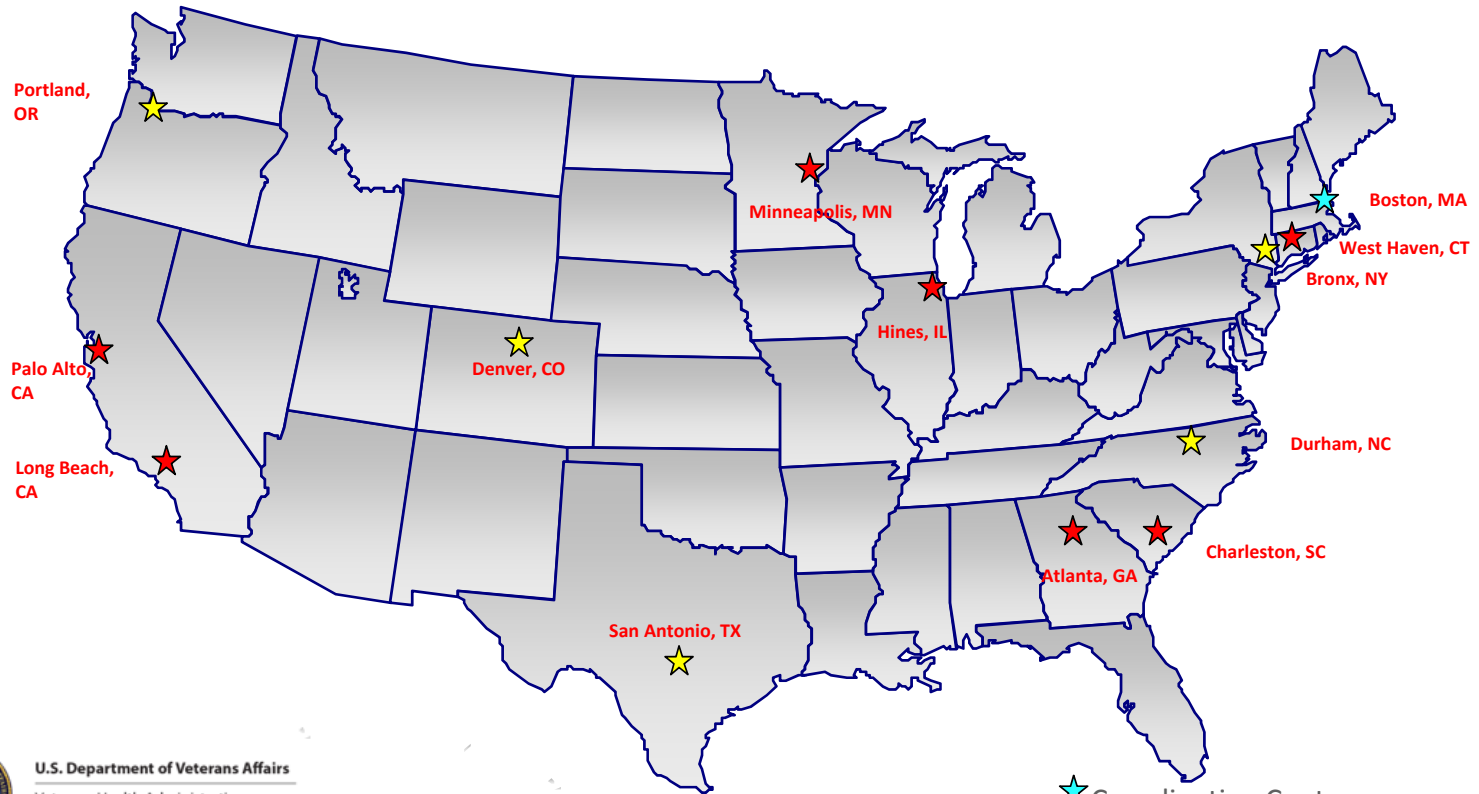
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- 12 VA sites
- Coordinating Center
- Steering Committee
  - Provides guidance and assistance to the VA coordinating center and sites with system-wide and site-level barriers such as Central IRB utilization, data collection, information security, and obtaining support letters from medical services.
- Executive Leadership Committee
  - Champions NAVIGATE activities with stakeholders.
  - Reviews overall program progress and direction towards enhancing the ability for Veterans to participate in cancer clinical trials.
  - Facilitates policy, operational, or other changes to promote a transformative effort for how cancer clinical trials are performed in the VA health care system.

# Executive Leadership Committee Members

Member	Title	Location / Institution
James Doroshow, MD	Director, Division of Cancer Treatment and Diagnosis NCI Deputy Director for Clinical and Translational Research	NCI
Rachel Ramoni, DMD, ScD	Chief Research and Development Officer	VHA Central Office
Jeff Abrams, MD	Acting Director for Clinical Research, Division of Cancer Treatment & Diagnosis Associate Director, Cancer Therapy Evaluation Program	NCI
Charles Blanke, MD	Chair, SWOG	Oregon Health Sciences University
Michael Kelley, MD	Director, National Oncology Program	Durham VA Medical Center
Laurence Meyer, MD, PhD	Chief Officer, Specialty Care Services	VHA Central Office
Lori Minasian, MD	Deputy Director, Division of Cancer Prevention	NCI
Grant Huang, MPH, PhD	Co-Chair NAVIGATE Steering Committee; Director, VA Cooperative Studies Program	VA Office of Research & Development
Sheila Prindiville, MD, MPH	Co-Chair NAVIGATE Steering Committee; Director, Coordinating Center for Clinical Trials	NCI
TBN	VA Patient Advocate	

# NAVIGATE Funded Sites



★ Coordinating Center

★ VA Integration Support Initiative  
SWOG HOPE Foundation Awardee

VA



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development

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# NAVIGATE Site Investigators

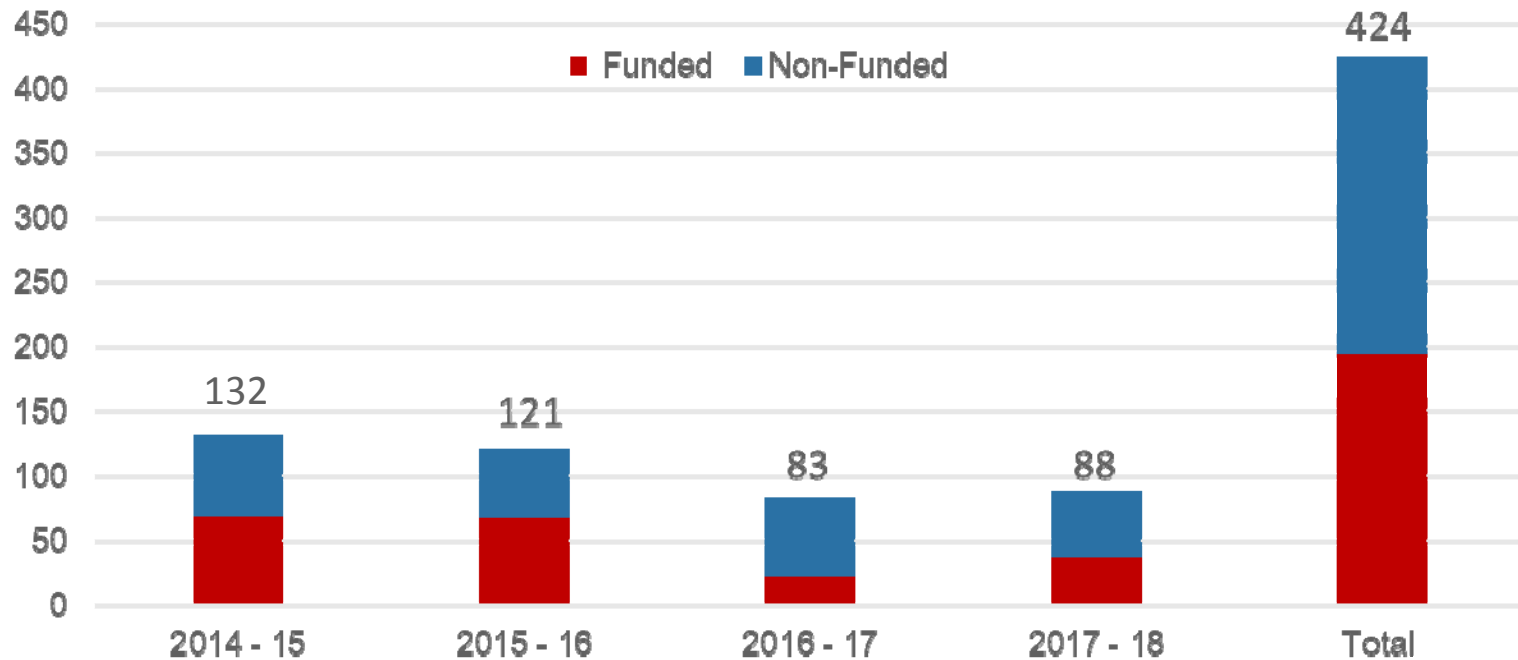
LOCATION	Facility Name	PI(s)
Atlanta, GA	Atlanta VA Health Care System	Wayne Harris, MD
Bronx, NY	James J. Peters VA Medical Center	Susan Bates, MD
Charleston, SC	Ralph H. Johnson VA Medical Center	Rinah Shopnik DO, Stephen Savage, MD
Denver, CO	Rocky Mountain Regional VA Medical Center	Daniel Bowles, MD
Durham, NC	Durham VA Medical Center	Daphne Friedman, MD
Hines, IL	Edward Hines Jr VA Hospital	Cheryl Czerlanis, MD
Long Beach (CA)	Tibor Rubin VA Medical Center	Pankaj Gupta MD, Homayoon Sanati, MD
Minneapolis, MN	Minneapolis VA Health Care System	Sharon Luikart, MD, Mark Klein, MD
Palo Alto, CA	VA Palo Alto Health Care System	Harlan Pinto, MD
Portland, OR	Portland VA Medical Center	Mark Garzotto, MD
San Antonio, TX	Audie L. Murphy VA Hospital / South Texas Veterans Health Care System	Michael Liss, MD, Paromita Datta, MD
West Haven, CT	VA Connecticut Healthcare System	Herta Chao, MD, PhD
Boston, MA (Coordinating Center)	VA Boston Healthcare System	Mary Brophy, MD, MPH

# NAVIGATE Network

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- Enthusiasm among VA sites for conducting NCI national clinical trials.
- 35 VA sites accrued patients to NCTN trials in the past 4 years.
- Once NAVIGATE is fully operational, plan to include any interested VA site in NAVIGATE best practices teleconferences addressing trial operational barriers.

## VA Accrual to NCTN Trials by NAVIGATE Funding Status Grant Years 1 to 4 (March 2014 - Feb 2018)



## NAVIGATE Recent Activities

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- Press release – July 2018
- NAVIGATE Kick-Off Meeting – September 2018
- Information Systems Security Officers (ISSOs) guidance to facilitate release of VA research data to Non-VA entities and external web portal reviews.
- Cancer.gov Clinical Trials Search – VA Tag
  - Cancer.gov search interface supports finding active NCI-supported cancer clinical trials.
  - VA tag on the advance search form allows limiting search to VA facilities.

# Cancer.gov Clinical Trials Search – VA Tag

**NIH** NATIONAL CANCER INSTITUTE

1-800-4-CANCER Live Chat Publications Dictionary

ABOUT CANCER CANCER TYPES RESEARCH GRANTS & TRAINING NEWS & EVENTS ABOUT NCI search

ESpañol

Find a Clinical Trial

**LOCATION**

Search for trials near a specific zip code; or in a country, state and city; or at a particular institution. The default selection will search for trials in all available locations.

Limit results to Veterans Affairs facilities:  Yes

Search all Locations

ZIP Code

U.S. ZIP Code

Radius

100 miles

# Anticipated Benefits of NAVIGATE

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- *Increasing access for Veterans* with cancer to promising new treatments through national cancer clinical trials, including ‘precision medicine’ and ‘immunotherapies’.
- *Accelerating accrual* to NCI-supported NCTN and NCORP trials resulting in more timely completion.
- Offering ways for *minority populations* within the VA to participate in NCI-supported trials.
- Increasing participation of *VA clinical investigators* in clinical cancer research.
- Provide opportunities for VA investigators to *contribute scientific expertise* and identify studies of importance to the VA cancer population.
- Enhance *VA’s overall leadership role* in cancer care and clinical research.

# NAVIGATE Steering Committee ... Many Thanks!

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Grant Huang, MPH, PhD – Co-Chair (VA)

Sheila Prindiville, MD, MPH – Co-Chair (NCI)

Mary Brophy, MD, MPH – Coordinating Center Director (VA)

Tawny Clark, Clinical Information Specialist / Executive Leadership Committee Coordinator (NCI)

Marisue Cody, PhD – Director, Operations – Office of Research & Development (VA)

Andrea Denicoff, RN, MS, ANP – Head, NCTN Clinical Trials Operations (NCI)

Marge Good, RN, MPH, OCN – NCORP Nurse Consultant (NCI)

Michael Kelley, MD – Director, National Oncology Program (VA)

Karen Pierce-Murray, RN – Program Manager / VISN1 Clinical Trials Network (VA)

Sara Schiller, MPH – NAVIGATE Program Manager (VA)

Colleen Shannon, MPH – Deputy Director, NAVIGATE Coordinating Center (VA)



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[www.cancer.gov](http://www.cancer.gov)

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