

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



*Sheila A. Prindiville, MD, MPH*  
*November 1, 2017*

# NAVIGATE: NCI-VA Interagency Agreement (IAA)

---

Collaboration between NCI and the VA to facilitate enrollment of Veterans into NCI funded 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 Team Members

---

## NCI

Andrea Denicoff	DCTD, NCTN
Marge Good	DCP, NCORP
Raymond Petryshyn	CCCT
Sheila Prindiville	CCCT

## VA



Mary Brophy	VA CSP & Director, VISN1 Clinical Trials Network (CTN)
Marisue Cody	VA ORD, Director of Operations
Grant Huang	VA ORD, Acting Director, Cooperative Studies Program
Michael Kelley	VA Director, National Oncology Program
Connie Lee	VA Director, BD-STEP Program
Laurence Meyer	VA Chief Officer, Patient Care Services
Karen Pierce-Murray	VA Program Manager, CSP/VISN1 CTN
Rachel Ramoni	VA Chief Research & Development Officer
Colleen Shannon	VA CSP & Deputy Director, VISN1 Clinical Trials Network
Sara Turek	VA CSP Project Manager/VISN1 CTN

# Background

---

- 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.
- Inclusion of more VA patients in relevant NCTN and NCORP clinical trials is likely to advance the health of the VA population 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.

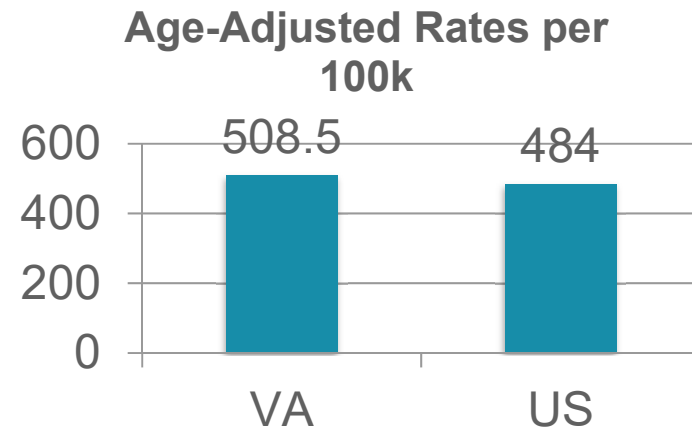
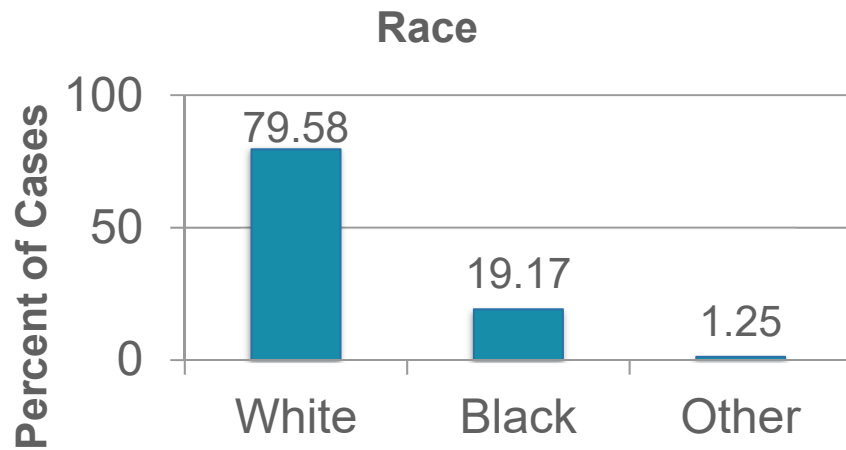
## Most Common Cancers by Sex in VA Patients, 2010

	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>

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

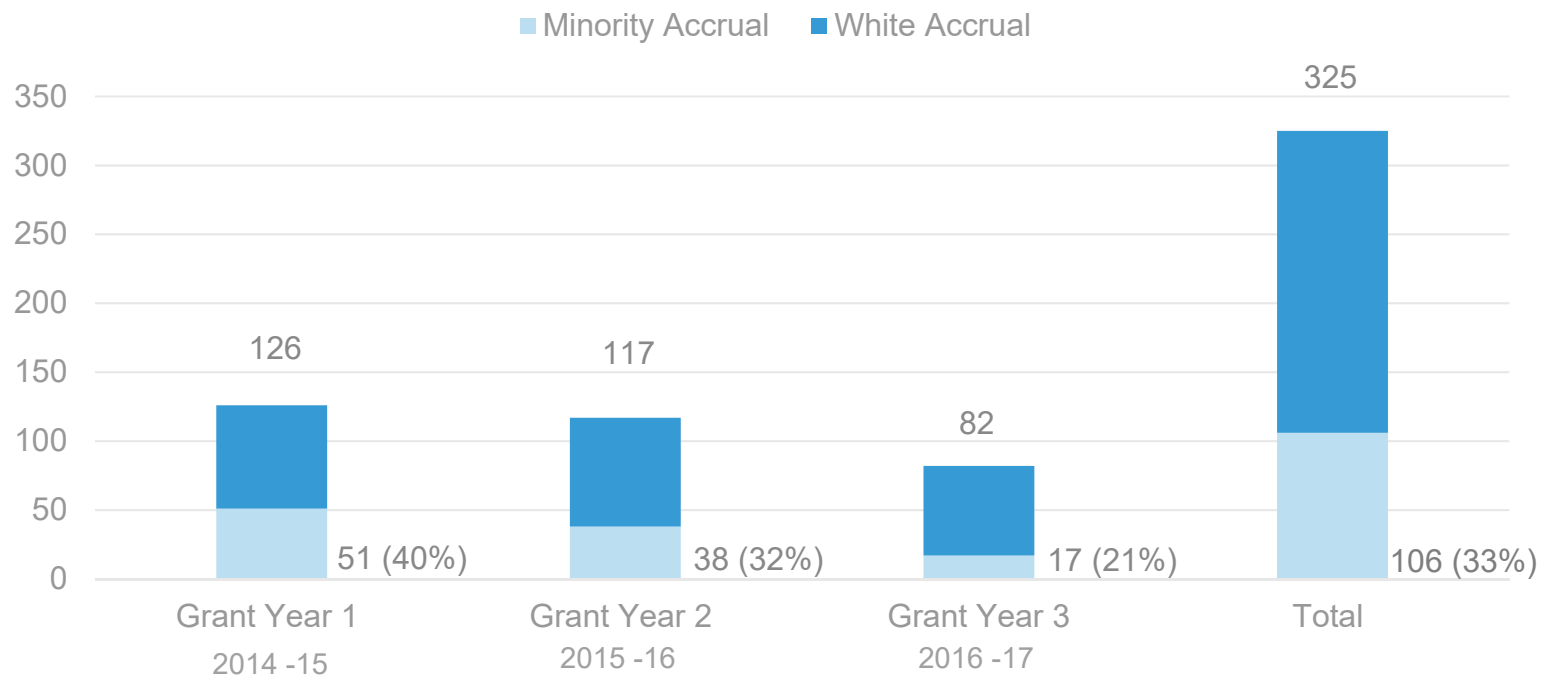
- Total cancers: 49,857
- Invasive cancers: 46,166

US Region	n	%
Midwestern	9887	21.4
Northeastern	6851	14.8
Southern	19351	41.9
Western	10080	21.8

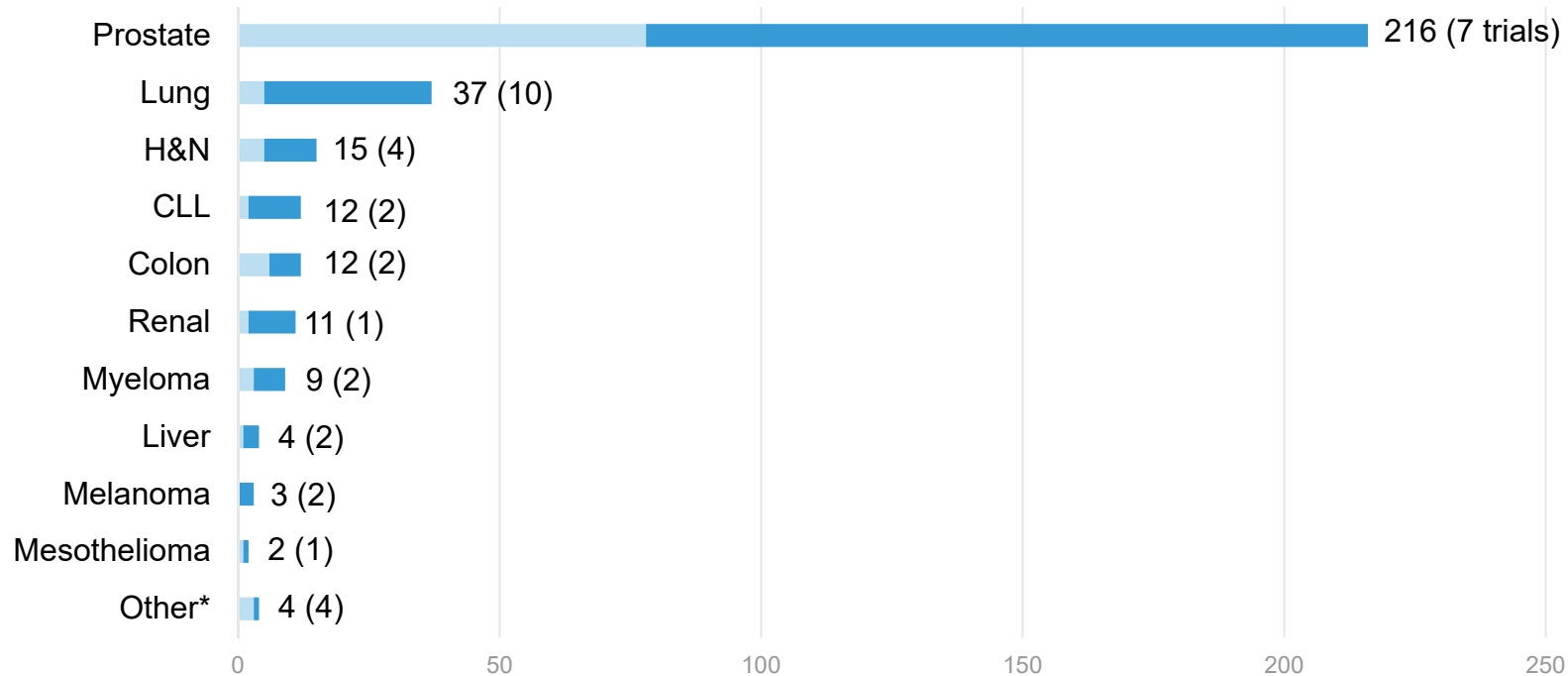


Zullig LL et al, *Military Medicine* 2017; 182: e1883-1891

# VA Accrual to NCTN Treatment Trials NCI Grant Years 1 to 3 (2014-2017)\*



## VA Accrual to Treatment Trials by Lead Disease (n=325) NCTN Grant Years 1 to 3 (2014 – 2017)



\*Bladder, Breast, Carcinoid, Esophagus

■ Minority ■ White



# Barriers to VA Participation in NCI Trials

---

- 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
- Barriers to participation for Veterans
  - Travel and financial challenges
  - Awareness of trials and patient resources
  - Restrictive eligibility criteria (including co-morbidities)

## NAVIGATE Overall Goal

---

Enable more VA patients to enroll in NCI national clinical trials.

- Initial focus is on activities to facilitate participation of VAMC sites in NCI trials.
- Longer term goals include seeking ways to sustain VAMC participation in NCI clinical trials beyond the IAA.

## Primary Activities Supported by the IAA

---

- Provide infrastructure funding support to 8 to 10 VA sites for enrollment of VA patients to NCTN and NCORP clinical trials.\*
- Organization of an Executive Committee composed of NCI and VA personnel, VA site representatives, and others to oversee the IAA activities.

\*Eligible trials are those NCTN and NCORP trials on the CTSU menu

# Executive Committee Responsibilities

---

- Oversee and provide coordinated direction for the IAA collaboration.
- Set timelines and milestones for IAA activities.
- Monitor progress and enrollment of funded sites.
- Review site and agency-level needs for conducting trials and patient enrollment.
- Provide guidance and assistance with system-wide and site-level barriers such as Central IRB utilization, data collection, information security, and obtaining support letters from medical services (pharmacy, radiology, pathology etc. )
- Leverage existing national clinical trials capabilities within the VA to more efficiently conduct cancer clinical trials.
- Identify models for long-term sustainability of VA sites beyond the IAA.

## Timeline for Initial Activities

---

- August, 2017 – Interagency agreement finalized
- November, 2017 – Release solicitation for NAVIGATE sites (8-10)
- November, 2017 – Form Executive Committee (EC)
- Winter-Spring, 2018 – NAVIGATE kickoff meeting with sites and EC

## Costs Not Supported by the IAA

---

- 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.

# Anticipated Benefits of the NAVIGATE IAA

---

- *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.
- Opening opportunities for VA investigators to *participate in NCI’s Scientific Steering Committees*; 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.



**NATIONAL  
CANCER  
INSTITUTE**

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

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



# Metrics of Success

---

- Increased accrual to NCI trials over baseline Increased inclusion of minority populations.
- Increase percentage of VA sites enrolling 5 or more patients annually.
  - Increase in number of NCI trials opened for which the site's target accrual is achieved.
- Number of patients screened/reasons for ineligibility documented.
- Reduction in barriers to VA participation in trials by Exec. Committee facilitation.
- Best practice guidance developed for overcoming barriers to accrual for VAMCs.
- Participation of VA investigators on NCI Scientific Steering Committees & associated task forces and working groups.
- Mechanisms for long-term sustainability of sites identified.