



NCI And VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE): Experiences and Future Directions

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AVAHO

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NAVIGATE

Collaboration between National Cancer Institute (NCI) and the VA to **facilitate enrollment of Veterans into NCI funded oncology clinical trials.**

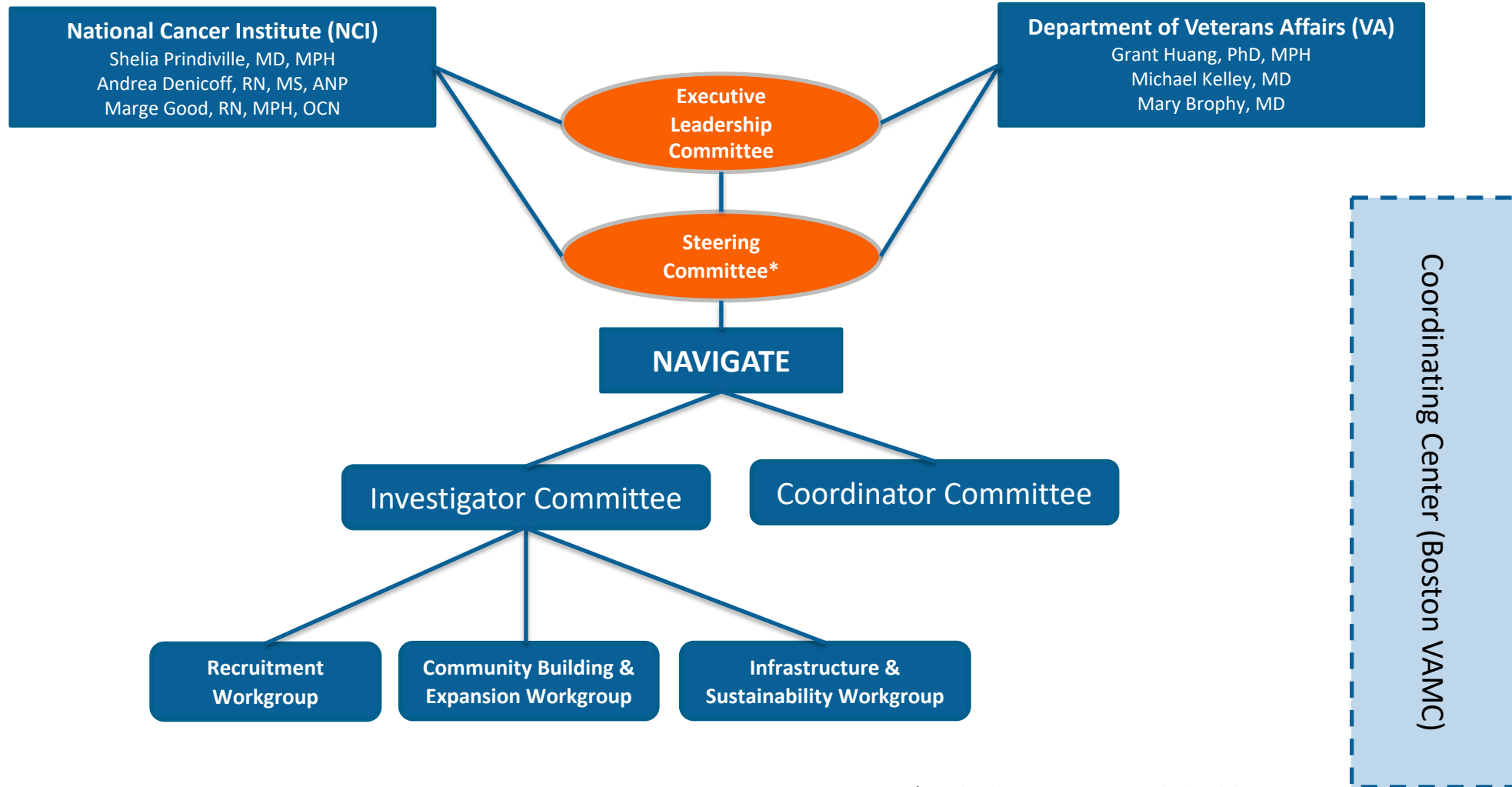
- Opportunity for government agencies to partner at the national level to make clinical trials more accessible, *and*
- Accelerate cancer research by testing new cancer therapies to lessen the burden of cancer and its symptoms, as well as novel approaches to the prevention and early detection of cancer

NAVIGATE GOALS

- Increase Veteran participation in NCI's National Clinical Trials Network (NCTN) and NCI's Community Oncology Research Program (NCORP) studies;
- Enable a sustained, long-term capability for participating in NCI clinical trials after the initial NAVIGATE support; and
- Establish the operation and organization of a national consortium of VA sites focused on improving VA participation in NCTN and NCORP studies.

To provide lasting efficiencies and effectively overcome barriers in **conducting multi-site cancer clinical trials** within the VA healthcare system through a national coordinated effort supported by VA and NCI leadership.

ORGANIZATIONAL STRUCTURE



*Includes Veteran stakeholder



NAVIGATE SITES



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NAVIGATE NETWORK

Location	Facility Name	Principal Investigators
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	Stephen Savage, MD
Denver, CO	VA Eastern Colorado Health Care System	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, Steve Lee, MD, PhD
Minneapolis, MN	Minneapolis VA Health Care System	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, PhD, MAS, FACS 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

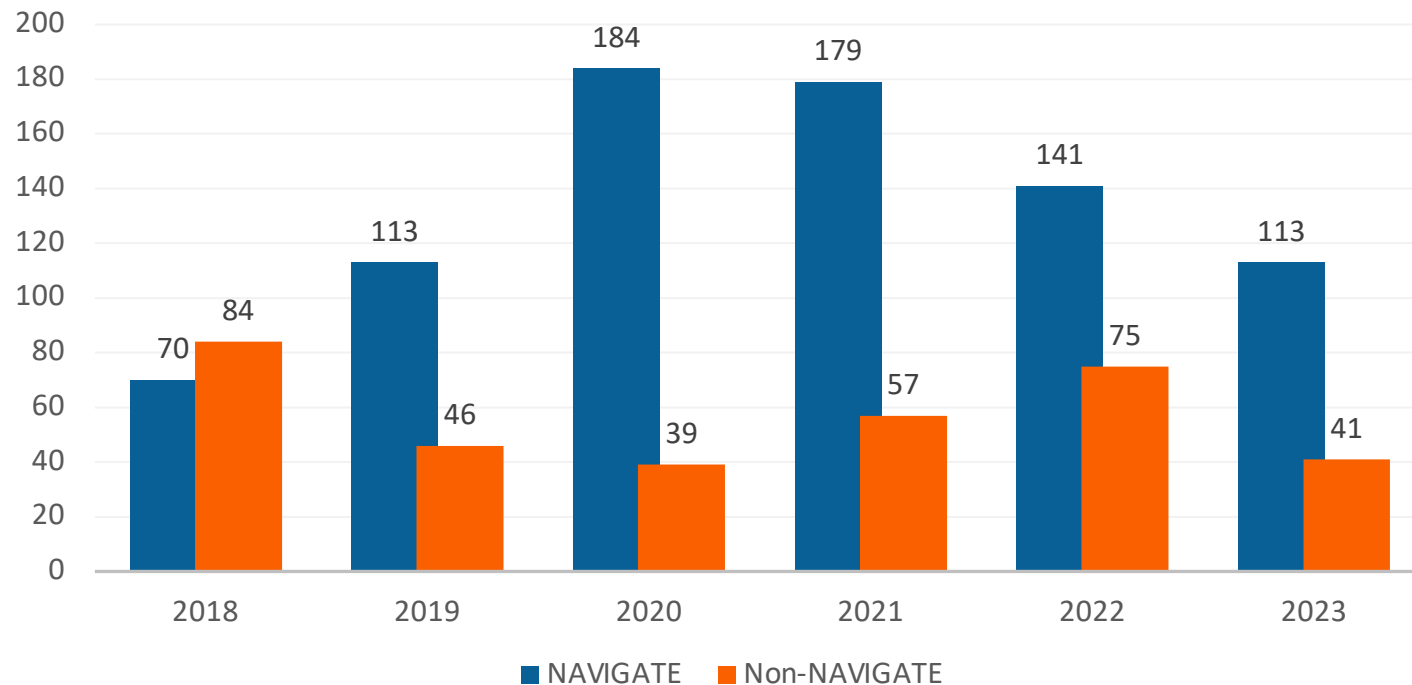


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VA ENROLLMENT to NCTN and NCORP TRIALS

Accrual NAVIGATE vs. Non-NAVIGATE
January 2018-June 2023



12 NAVIGATE Sites

Total accrual: 800 patients

(72% white, 22% black, 6% other/unknown)

25 Non-NAVIGATE Sites

Total accrual: 342 patients

(75% white, 19% black, 6% other/unknown)

Overall NCI trial enrollment by race

2019-2021: 65% white, 8% black



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Overall data from National Cancer Institute Triennial Report: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021. (included 10% Asian, 1.6% more than one race, 10-15% unknown/not reported)

TRIAL ENROLLMENT DETIALS

Trial	NCTN/NCORP	Disease Area	# NAVIGATE Sites	NAVIGATE Accrual^	# Non-NAVIGATE Sites	Non-NAVIGATE Accrual^
LUNGMAP	NCTN	LUNG	9	115	12	52
A151216 (ALCHEMIST)	NCTN	LUNG	8	96	10	33
A081801 (ALCHEMIST Chemo-IO)	NCTN	LUNG	6	14	3	2
S1602*	NCTN	BLADDER	4	20	0	0
NHLBI-MDS	NCORP	MDS	10	155	6	43
NCI COVID (NCCAPS)*	NCORP	ALL TYPES	8	77	7	45
S2013 (I-CHECKIT)	NCORP	SOLID TUMORS	7	54	3	10
A212102 (MCED)	NCORP	ALL TYPES	6	28	2	0

^Total accrual from January 2018-June 2023

*Trial is closed to accrual



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BUILDING RELATIONSHIPS and STREAMLINING TASKS

- NAVIGATE Coordinating Center facilitates communication between sites and VA offices (i.e., ORD, ORR, HRMACS); engages ORD leadership to bring awareness to barriers and work together to create solutions
- Develop and leverage relationships with other leaders in the VA research field to increase efficiencies across VA sites
 - ENTHRALL Matching Patients to Accelerate Clinical Trials (MPACT) – improved screening efficiency
 - Centralized ERDSP Pilot with Office of Research Reviews (ORR) – reduce regulatory burden and length of time to open trials
- Partner with others to develop or optimize tools that streamline tasks for the benefit of multiple research programs with similar goals
 - ENTHRALL Centralized Trial Tracker (in early development) – streamline tracking and reporting
- We are strengthening our relationship with VA SWOG Storefronts in effort to share knowledge and best practices across sites engaged in NCTN trials.

LESSONS LEARNED



- Infrastructure support varies by site; sites may experience challenges based on level of local leadership (i.e., facility director, service chiefs) support; this is true for University Affiliate support as well



- Significant variability in local regulatory processes across sites impacts time to open trials; limiting trial availability for Veterans at the right time (i.e., time of initial diagnosis or relapse)



- Limited in opening radiation oncology trials since many VAs don't have radiation oncology service onsite



- Maintaining a large portfolio of NCTN and NCORP trials takes a robust coordinator team led by highly engaged investigators



- Bringing investigators and NCI colleagues together to review trials reduces time to activation and mitigates challenges; evaluate trial feasibility; increased awareness of timely trials (e.g., NCI COVID/NCCAPS)



- NAVIGATE coordinator community provides sites with support and resources otherwise not available, increases coordinator engagement, reduces time in identifying challenges and solutions, leads to better understanding of NCTN and NCORP trials overall

FUTURE DIRECTIONS

- NAVIGATE expanding to include 4 new sites in Q1 FY24. (NAVIGATE RFA 4/3/2023)
- Increase engagement with other networks (e.g., LPOP, POPCaP, SWOG Storefronts) under enterprise-wide strategy toward research activities aimed at improving Veteran health
- Continue participation in Cancer Moonshot 2.0 ENACT Initiative
- Work with NCI and cooperative groups to make these trials more accessible to minorities and rural Veterans.
- Establish mechanism for sharing information and resources outside NAVIGATE
- Identify new areas for improvement and work with experts in the field to create efficiencies
- VA participation in NCI's Cancer Screening Research Network (CSRN) in 2024 to
 - conduct multi-center cancer screening trials
 - Improve early cancer detection
 - Evaluate emerging cancer screening modalities with the ultimate goal of reducing cancer-related morbidity and mortality

NAVIGATE LEADERSHIP



Department of Veterans Affairs

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