

# NAVIGATE

## NCI and VA Interagency Group to Accelerate Trials Enrollment

Update for NCI CTAC  
March 16, 2022

Michael Kelley, MD  
Grant Huang, MPH, PhD  
Sara Schiller, MPH



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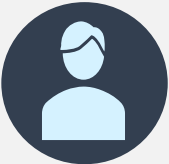

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# Who We Serve – Demographics

- In 2017, VHA looked across all facilities for the most common cancers of males and female Veterans.

	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>		

*Prostate cancer in men and breast cancer in women are almost double that of the next most commonly occurring cancer.*

- Race:** An estimated 46,000 Veterans are diagnosed with cancer annually:
  - 79% were White; 19% were Black; 1% were Other Race
- Residence:** Veterans are 2.5 times more likely to live in rural areas

Data Sources: VA Central Cancer Registry (VACCR)

# 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 Chronology

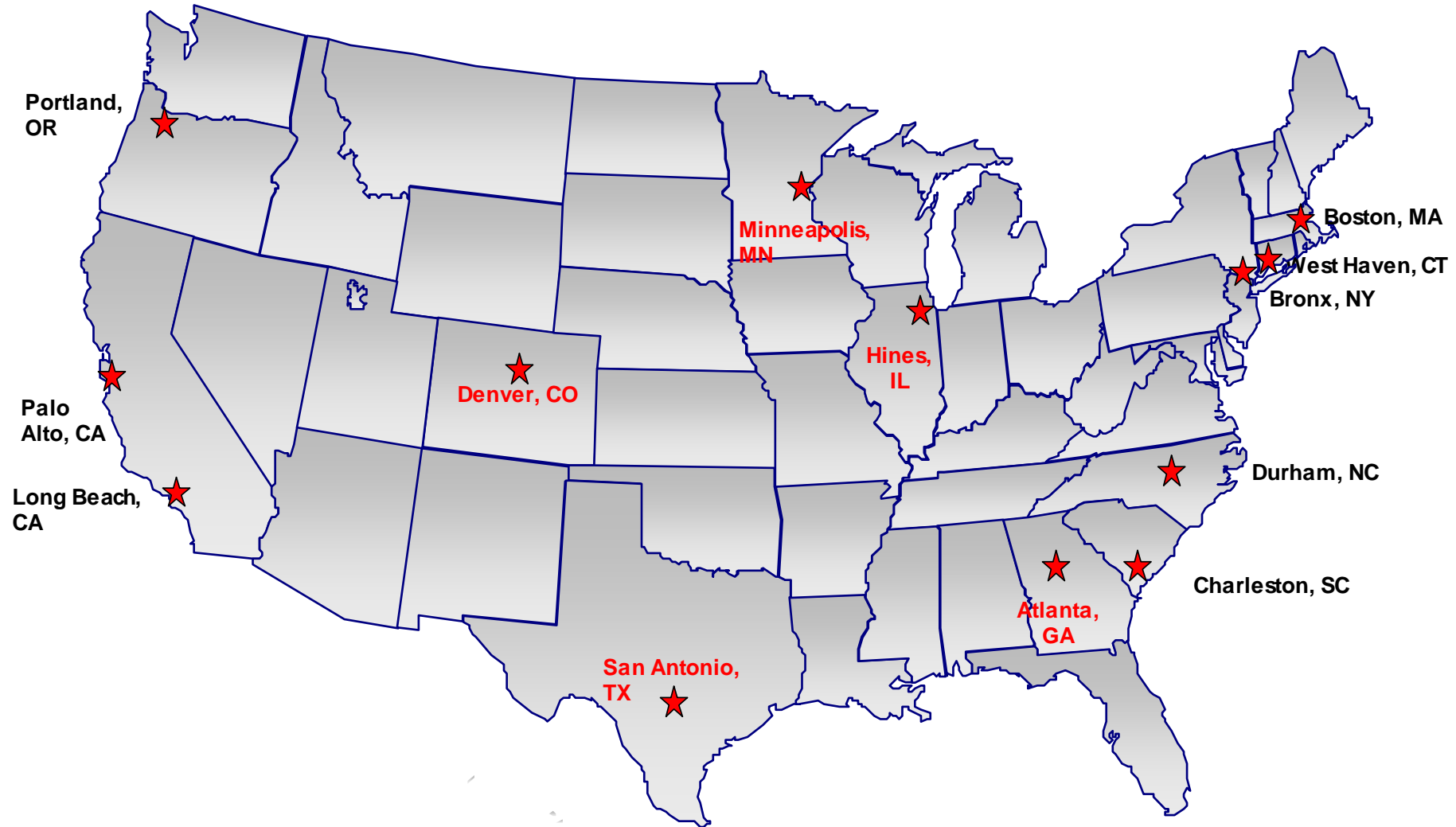
- July 17, 2016 CTAC discussion
- August 2016 – meeting with VHA and NCI leadership to address recruitment of Veterans into NCI trials
- July 2017 – Interagency Agreement between VA and NCI
- Nov 2017 – Solicitation/RFA released for site applications
- May 2018 – Sites selected
- September 2018 – Kickoff meeting held

# NAVIGATE Goals

- Increase Veteran participation in NCI supported studies
- Enable a sustained, long-term capability for participating in NCI clinical trials after the initial NAVIGATE support
- Establish the operation and organization of a national consortium of VA sites focused on improving VA participation in NCTN and NCORP studies and potentially other cancer trials by different sponsors.

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

# NAVIGATE Sites and Coordinating Center



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CANCER  
INSTITUTE



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# NAVIGATE Network

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	Stephen Savage, MD; Oleksandra Lupak, 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
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



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# Benefits of NAVIGATE Consortium Approach

- Development of Investigator and Coordinator groups to allow for sharing of resources, advice, support
  - Team pages, Email list serve, monthly teleconferences
  - PM as “connector” or “facilitator”
- “Strength in numbers” when issues arise that require escalation to national level
- Avoiding duplication of efforts – someone else has walked the same road
- New ideas and areas for innovation; consortium allows for collaboration





# Select Tools, Processes & Best Practices

- Centralized Information security approvals
- Central IRB Processes
- Local/facility approval process mapping to identify areas for improved efficiency
- Sharing of best practices among 12 NAVIGATE sites and beyond: NAVIGATE sites as leaders in VA
- Workgroups focusing on:
  - Community building and expansion
  - Recruitment
  - Infrastructure and sustainability
- Model is being used with National Institute on Aging for Alzheimer's Disease clinical research network

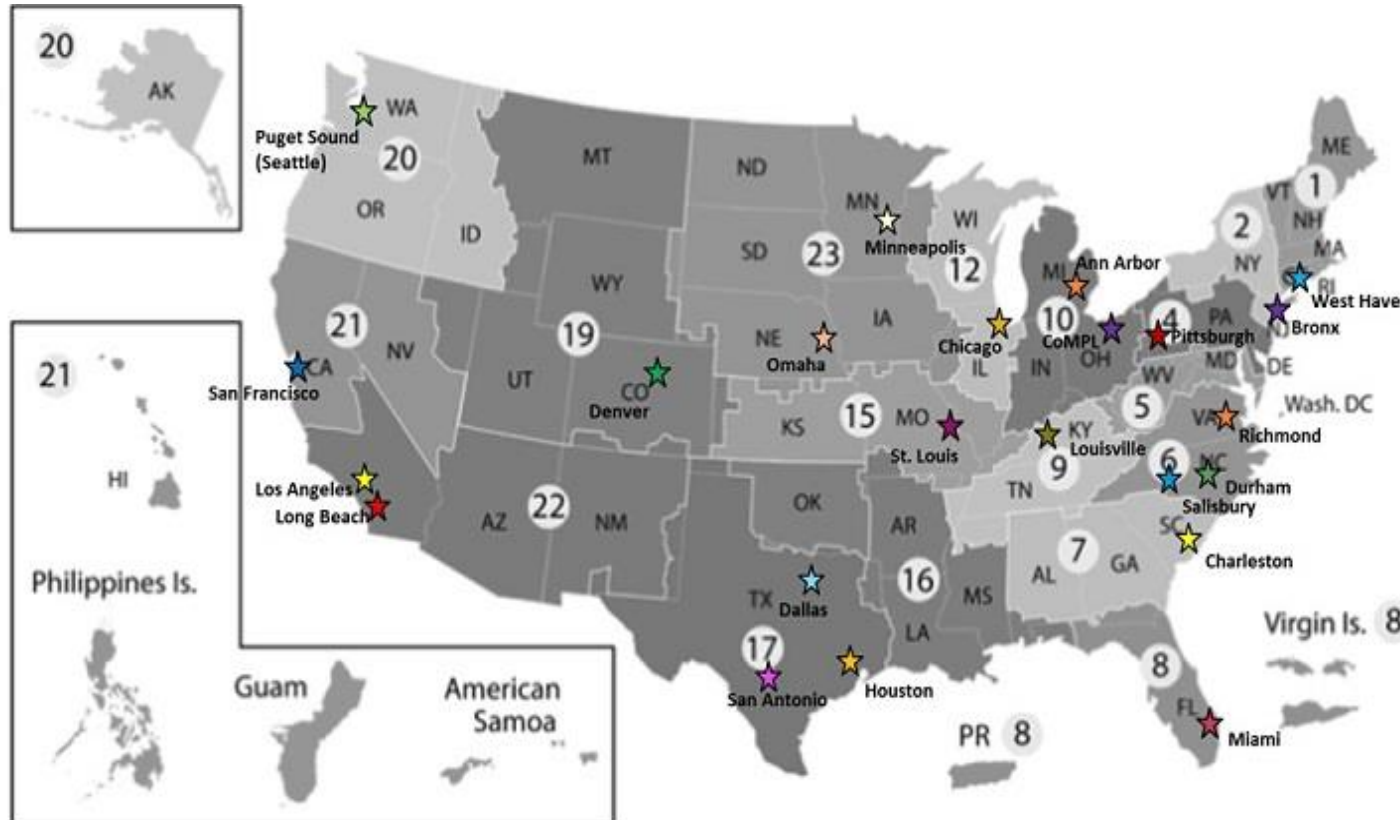


# VA Cancer Clinical Trials Enrollment

- Clinical Research Enterprise Partnerships / Networks
  - Cooperative Studies Program / Network of Dedicated Enrollment Sites
  - **NAVIGATE (NCI and VA Interagency Group to Accelerate Trials Enrollment)**
  - Lung Cancer Precision Oncology Program
  - **A**pply **P**roteogenomics **O**rganizational **L**earning and **O**utcomes (APOLLO)
  - Prostate Cancer Foundation Centers of Excellence
  - Genitourinary Precision Oncology Program
- ORD Bioinformatics
  - Boston MAVERIC Bioinformatics Team
  - Big Data Scientist Training and Enhancement Program
  - VA Informatics and Computing Infrastructure
- Partnered Research Program



# Lung Cancer Precision Oncology Program (LPOP)



## Nationwide Network

- 20 hubs
- 65 spoke sites

## Integrated Clinical Care and Research

- Treatment, focused PO and IO
- Screening, including smoking cessation



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# Genitourinary (POPCaP/GU) Program



A network of centers in the VISN ("Hub and spoke") focused on providing access to precision oncology for Veterans with advanced genitourinary cancers.

In Partnership with  
the Prostate Cancer  
Foundation

- Legend:
-  = Funded Prostate Cancer Foundation (PCF)-VA Centers of Excellence
  -  = GU sites: Atlanta, Charleston, Denver, Houston, Kansas City, Orlando, St Louis



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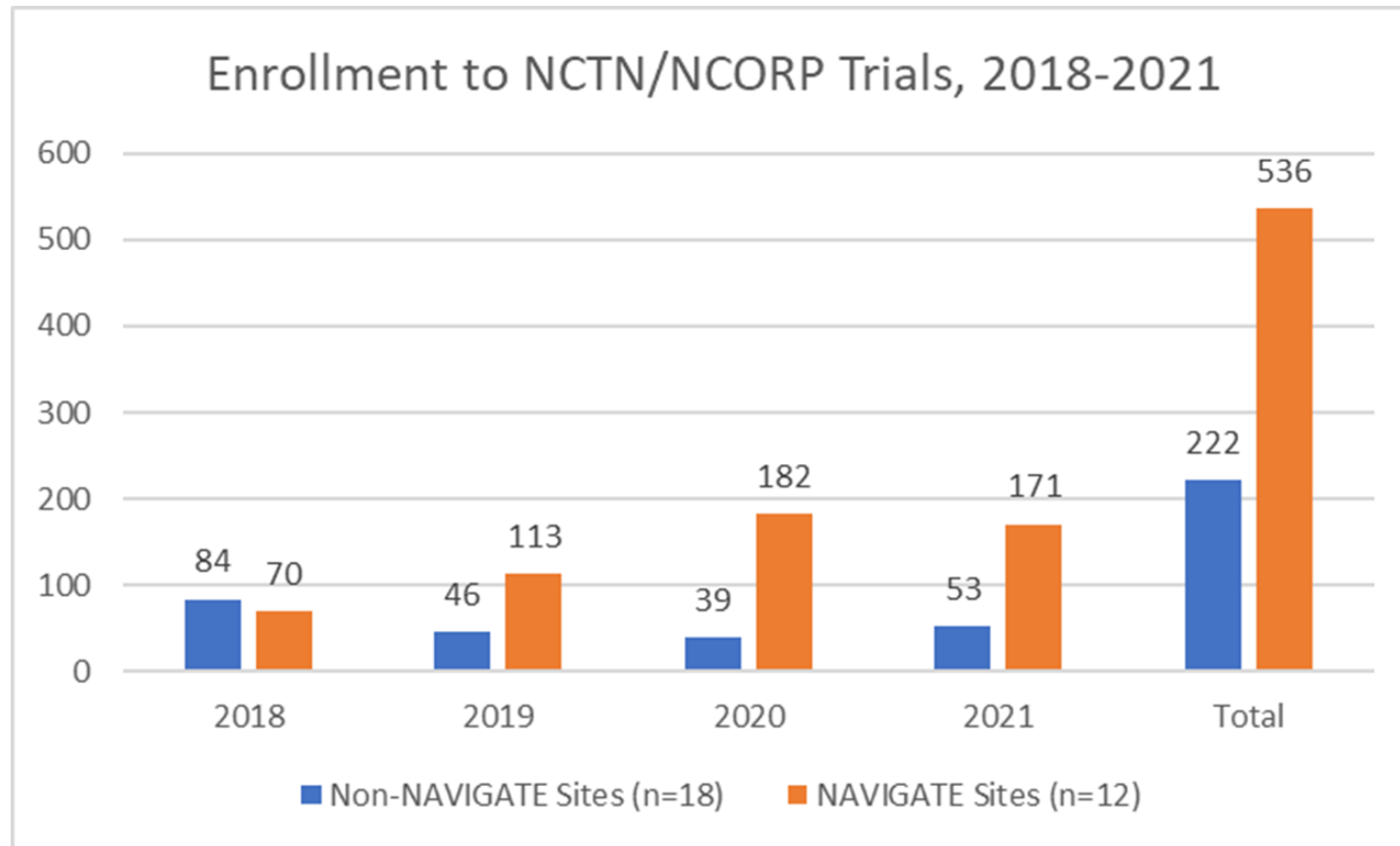
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# Accrual to NCTN/NCORP Trials at NAVIGATE and Non-NAVIGATE Sites, 2018 – 2021



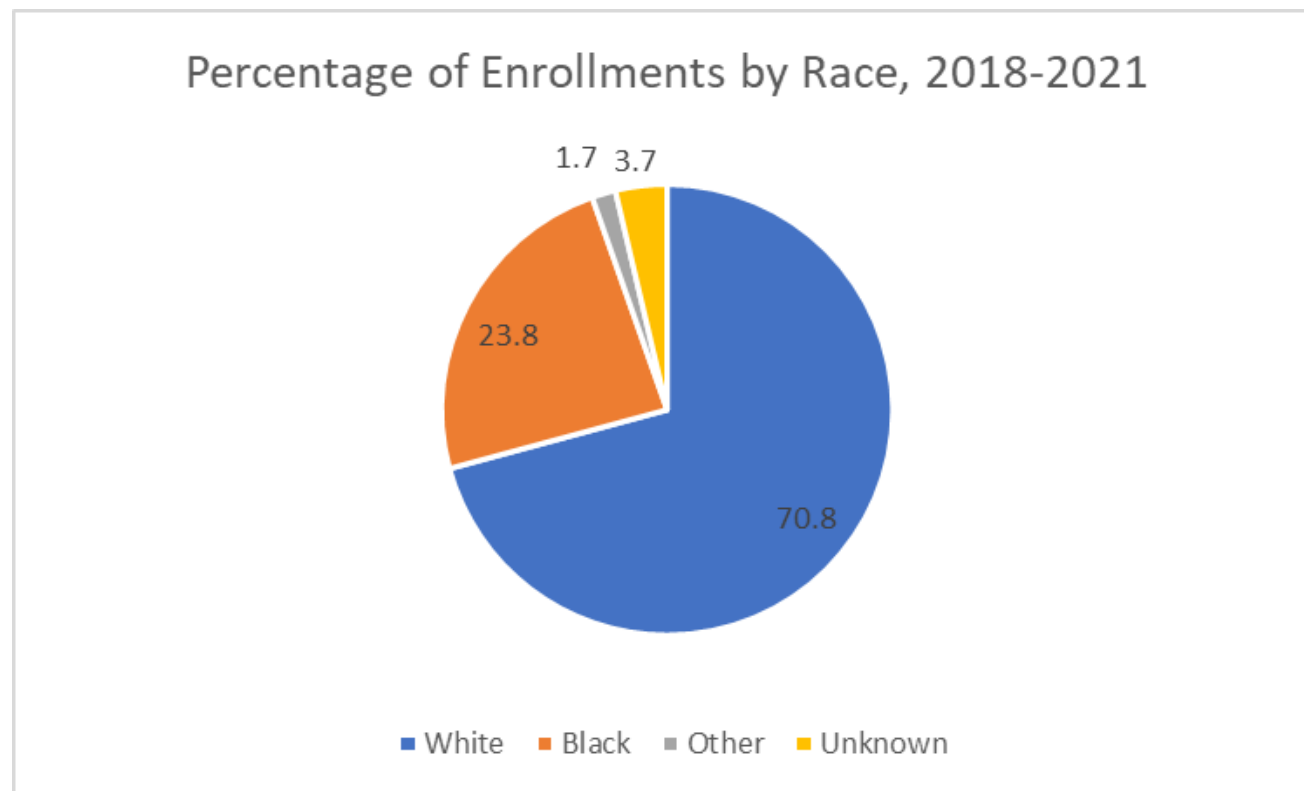
Total NAVIGATE  
Accrual:  
536 patients

Total Non-  
NAVIGATE  
Accrual:  
222 patients

Note: “Non-NAVIGATE sites includes any VAMC site that enrolled at least one patient between 2018 and 2021. VAMC sites that are NCTN/NCORP members, but enrolled no patients, are not included in this count.



# Minority Enrollment in NAVIGATE Trials



# Future Directions for NAVIGATE

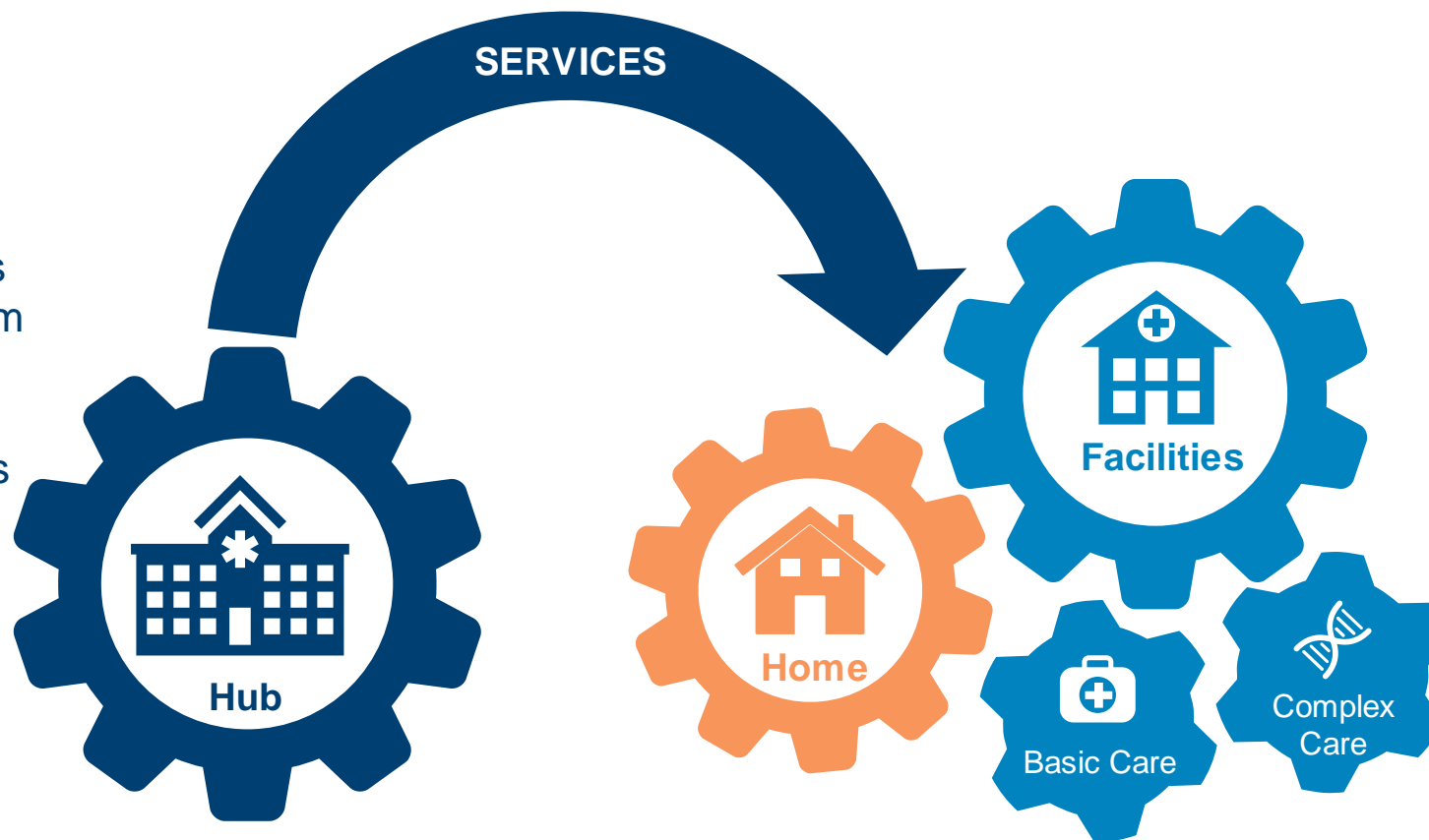
- Engagement with other networks (LPOP, POPCaP/GU, etc.) under enterprise-wide strategy toward research activities aimed at improving Veteran health
- Continued efforts with key partners (NCI)
- Dissemination of best practices to all sites wishing to engage in NCTN/NCORP trials
  - NAVIGATE sites and program as the primary source of guidance and support for sites developing their NCI trials portfolios



# VA National TeleOncology Service

## Hub Site :

- Physician Oncologists (Disease specific, from multiple NCI-affiliated VAMCs)
- RN Care Coordinators
- APPs
- Oncology Clinical Pharmacy Specialist



## Local Clinic / Infusion Site:

(may or may not have)

- Providers
- Registered Nurses
- APPs
- On-Site Pharmacy



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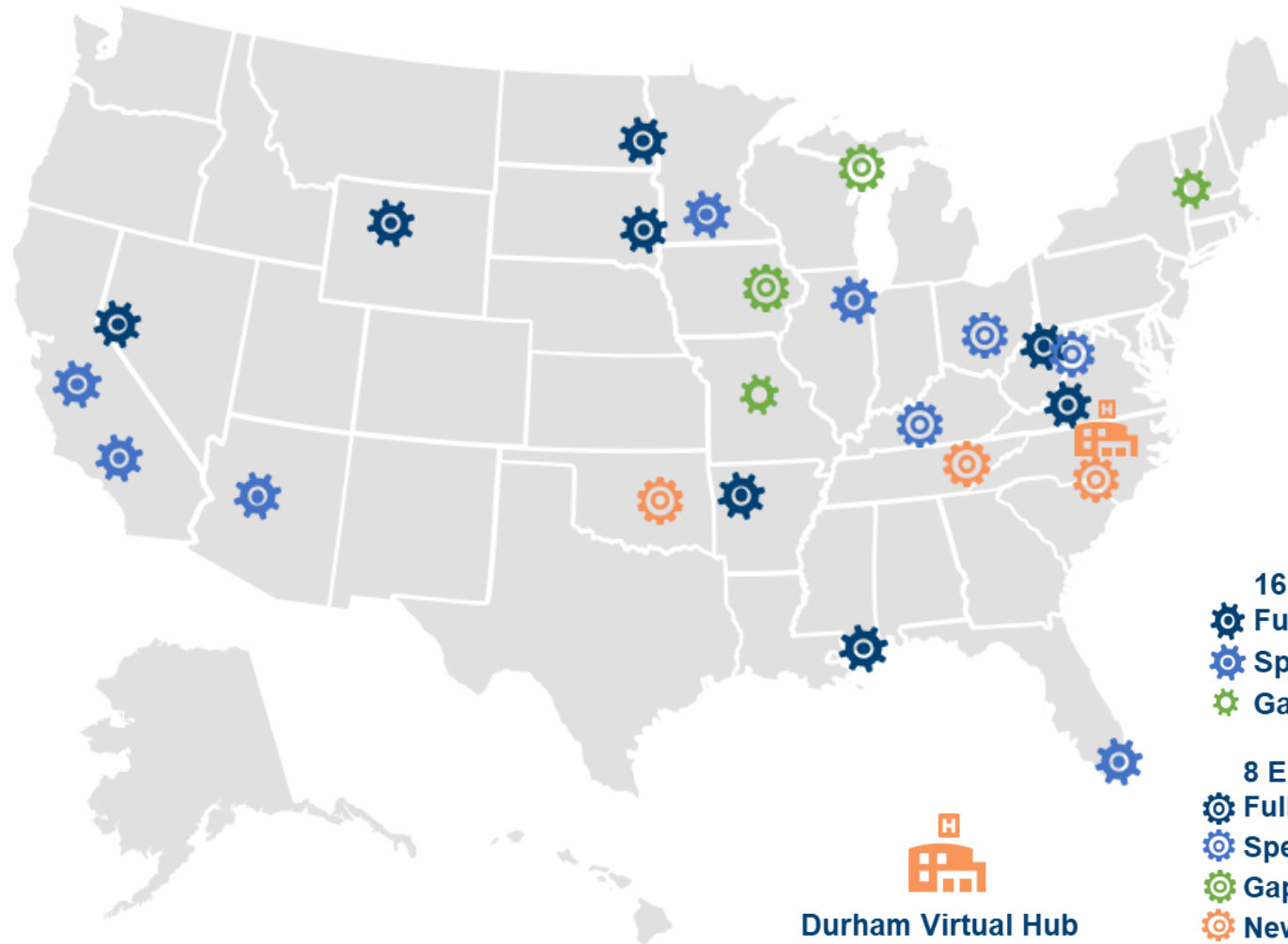
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# National TeleOncology Service Map



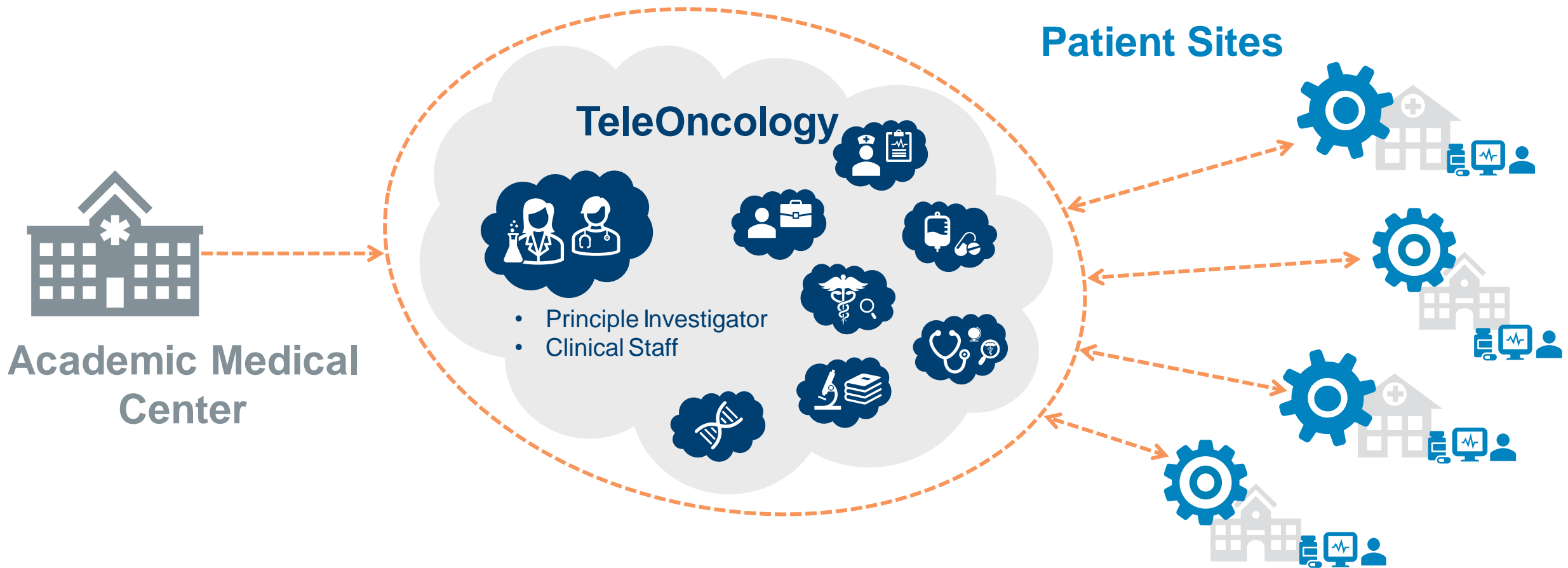
## 16 Active Sites

SITE	VISN
White River Junction, VT	V01
Clarksburg, WV	V04
Salem, VA	V06
Miami, FL	V08
North Chicago, IL	V12
Columbia, MO (Heartland)	V15
Fayetteville, AK	V16
Gulf Coast-Biloxi, MS	V16
Sheridan, WY	V19
Fresno, CA	V21
Reno, NV	V21
Loma Linda, CA	V22
Prescott, AZ	V22
Fargo, ND	V23
Minneapolis, MN	V23
Sioux Falls, SD	V23

## 8 Engaged Sites

Martinsburg, WV	V04
Louisville, KY	V09
Iron Mountain, MI	V12
Fayetteville, NC	V06
Muskogee, OK	V19
Iowa City, IA	V23
Mountain Home, TN	V09
Columbus, OH	V10

# VA Decentralized Clinical Trial Model



# Contacts

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