NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE)

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November 1, 2017

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

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Males</th>
<th>Females</th>
<th>All Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>13,438</td>
<td>30%</td>
<td>Breast</td>
</tr>
<tr>
<td>Lung &amp; bronchus</td>
<td>8,019</td>
<td>18%</td>
<td>Lung &amp; bronchus</td>
</tr>
<tr>
<td>Colon &amp; rectum</td>
<td>3,705</td>
<td>8%</td>
<td>Colon &amp; rectum</td>
</tr>
<tr>
<td>Kidney &amp; pelvis</td>
<td>1,733</td>
<td>4%</td>
<td>Uterine corpus</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1,674</td>
<td>4%</td>
<td>Melanoma</td>
</tr>
<tr>
<td>Liver</td>
<td>1,553</td>
<td>3%</td>
<td>Thyroid</td>
</tr>
<tr>
<td><strong>All Sites</strong></td>
<td>44,836</td>
<td>97%</td>
<td><strong>All Sites</strong></td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>US Region</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwestern</td>
<td>9887</td>
<td>21.4</td>
</tr>
<tr>
<td>Northeastern</td>
<td>6851</td>
<td>14.8</td>
</tr>
<tr>
<td>Southern</td>
<td>19351</td>
<td>41.9</td>
</tr>
<tr>
<td>Western</td>
<td>10080</td>
<td>21.8</td>
</tr>
</tbody>
</table>

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

*March 1, 2014 to Feb 28, 2017

Grant Year 1
2014 -15

Grant Year 2
2015 -16

Grant Year 3
2016 -17

Total

Minority Accrual
White Accrual

126
117
82
325

51 (40%)
38 (32%)
17 (21%)
106 (33%)
VA Accrual to Treatment Trials by Lead Disease (n=325) NCTN Grant Years 1 to 3 (2014 – 2017)

Prostate: 216 (7 trials)
Lung: 37 (10)
H&N: 15 (4)
CLL: 12 (2)
Colon: 12 (2)
Renal: 11 (1)
Myeloma: 9 (2)
Liver: 4 (2)
Melanoma: 3 (2)
Mesothelioma: 2 (1)
Other*: 4 (4)

*Bladder, Breast, Carcinoid, Esophagus

Ministry 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.
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.