Update from the NCI Acting Director

Douglas R. Lowy
Acting Director, National Cancer Institute
National Institutes of Health

NCAB Meeting
September 12, 2017
Hurricanes Harvey & Irma: Impact on NCI-designated Cancer Centers & NCI Grantees

• Active Monitoring
  • Thanks to Stephen White, DCB
• University of Houston, others?
Dr. Sharpless: soon
Continuing Resolution for Start of FY 2018

• Funding: October 1 - December 8
• Includes funding for Cancer Moonshot
• MK Holohan: more information
June: Grant Support Index (GSI)
September: Next Generation Research Initiative (NGRI)

- Grant Support Index
  - Focus on reducing the number of investigators with many grants, indirectly

- Next Generation Research Initiative
  - Focus on increasing support for Early State Investigators (ESI’s) and for Early Established Investigators (EEI’s)
Age of Investigators Funded by NIH

- Not solely due to Baby Boom demographics
- Multiple analyses indicate established PIs are outcompeting other groups
Funding Trends Over Time by Age: NCI RPG Investigators

Data from OER SARB
Funding Trends Over Time by Age: NCI RPG Investigators

All age groups are increasing over this period except for under 40 group

Total number of NCI-funded RPG investigators
FY 1990: 2212
FY 2003: 3671
FY 2016: 4700

Data from OER SARB
All age groups are increasing over this period except for under 40 group.
Turnover of NCI R01s is greater than non-NCI R01s

- Percent of competing R01 awards that are competing renewals is lower for NCI as compared to non-NCI
- Additionally, success rate of competing renewals at NCI is lower than non-NCI (25% vs. 36% in FY 2014)

Data Source: https://report.nih.gov/fundingfacts/fundingfacts.aspx
NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE)

Sheila A. Prindiville, MD, MPH
Presentation to CTROC
June 22, 2017
## 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
## Most Common Cancers by Sex in VA Patients, 2010

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Males n</th>
<th>Males %</th>
<th>Females n</th>
<th>Females %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>13,438</td>
<td>30%</td>
<td>Breast</td>
<td>402</td>
</tr>
<tr>
<td>Lung &amp; bronchus</td>
<td>8,019</td>
<td>18%</td>
<td>Lung &amp; bronchus</td>
<td>197</td>
</tr>
<tr>
<td>Colon &amp; rectum</td>
<td>3,705</td>
<td>8%</td>
<td>Colon &amp; rectum</td>
<td>88</td>
</tr>
<tr>
<td>Kidney &amp; pelvis</td>
<td>1,733</td>
<td>4%</td>
<td>Uterine corpus</td>
<td>75</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1,674</td>
<td>4%</td>
<td>Melanoma</td>
<td>59</td>
</tr>
<tr>
<td>Liver</td>
<td>1,553</td>
<td>3%</td>
<td>Thyroid</td>
<td>53</td>
</tr>
<tr>
<td><strong>All Sites</strong></td>
<td><strong>44,836</strong></td>
<td><strong>97%</strong></td>
<td><strong>All Sites</strong></td>
<td><strong>1,330</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 (3% of all US cancers)

### Race Distribution

<table>
<thead>
<tr>
<th>Race</th>
<th>Percent of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>79.58</td>
</tr>
<tr>
<td>Black</td>
<td>19.17</td>
</tr>
<tr>
<td>Other</td>
<td>1.25</td>
</tr>
</tbody>
</table>

### US Region

<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>

### Age-Adjusted Rates per 100k

- VA: 508.5
- US: 484

Zullig LL et al, 2016
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)
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 VA sites for enrollment of VA patients to NCTN and NCORP clinical trials.*

- Organization of an Executive Committee of NCI and VA personnel to oversee activities and help overcome barriers, particularly those at the central/national level.

*Eligible trials are those NCTN and NCORP trials on the CTSU menu
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.
Timeline for Initial Activities

- July, 2017 – Finalize, execute and fund IAA
- August - September, 2017 – Form Executive Committee (EC) and finalize VA solicitation/request for proposals
- October, 2017 – Release solicitation for NAVIGATE sites (8-10)
- Winter-Spring, 2018 – NAVIGATE kickoff meeting with sites and EC

*Start up funding in FY17; Program runs 2018-2021