NCI Director’s Update

Clinical Trials and Translational Research Advisory Committee - July 17, 2019

Douglas R. Lowy, M.D.
Acting Director

@TheNCI
@NCIDrDougLowy
In Memory of
Paul Godley, M.D., Ph.D.
National Trends in Cancer Death Rates: Annual Percent Change

**Annual Report to the Nation, 2015**

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Annual Percent Change, 2003-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver &amp; Intrahepatic Bile Duct</td>
<td>2.6*</td>
</tr>
<tr>
<td>Corpus &amp; Uterus, NOS</td>
<td>1.1*</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.9</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.3*</td>
</tr>
<tr>
<td>Testis</td>
<td>0.1</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>0.0</td>
</tr>
<tr>
<td>Melanoma of the Skin</td>
<td>0.0</td>
</tr>
<tr>
<td>Brain &amp; Other Nervous System</td>
<td>0.0</td>
</tr>
<tr>
<td>Oral Cavity &amp; Pharynx</td>
<td>-0.7*</td>
</tr>
<tr>
<td>Esophagus</td>
<td>-0.8*</td>
</tr>
<tr>
<td>Kidney &amp; Renal Pelvis</td>
<td>-0.9*</td>
</tr>
<tr>
<td>Leukemia</td>
<td>-0.9*</td>
</tr>
<tr>
<td>Cervix Uteri</td>
<td>-1.1*</td>
</tr>
<tr>
<td>Myeloma</td>
<td>-1.3*</td>
</tr>
<tr>
<td>All Sites Except Lung</td>
<td>-1.4*</td>
</tr>
<tr>
<td>Lung &amp; Bronchus (Female)</td>
<td>-1.5*</td>
</tr>
<tr>
<td>All Cancer Sites</td>
<td>-1.9*</td>
</tr>
<tr>
<td>Breast (Female)</td>
<td>-2.1*</td>
</tr>
<tr>
<td>Non-Hodgkin Lymphoma</td>
<td>-2.4*</td>
</tr>
<tr>
<td>Larynx</td>
<td>-2.5*</td>
</tr>
<tr>
<td>Stomach</td>
<td>-2.7*</td>
</tr>
<tr>
<td>Colon &amp; Rectum</td>
<td>-2.7*</td>
</tr>
<tr>
<td>Lung &amp; Bronchus (Male)</td>
<td>-2.8*</td>
</tr>
<tr>
<td>Hodgkin Lymphoma</td>
<td>-3.0*</td>
</tr>
<tr>
<td>Prostate</td>
<td>-3.4*</td>
</tr>
</tbody>
</table>

**Annual Report to the Nation, 2019**

**MEN**

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Annual Percent Change, 2003-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Melanoma Skin</td>
<td>2.8*</td>
</tr>
<tr>
<td>Liver &amp; Intrahepatic Bile Duct</td>
<td>1.1*</td>
</tr>
<tr>
<td>Oral Cavity &amp; Pharynx</td>
<td>1.0*</td>
</tr>
<tr>
<td>Soft Tissue incl. Heart</td>
<td>0.7*</td>
</tr>
<tr>
<td>Brain &amp; Other Nervous System</td>
<td>0.6*</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.2*</td>
</tr>
<tr>
<td>Bones and Joints</td>
<td>0.1</td>
</tr>
<tr>
<td>Bladder</td>
<td>-0.1</td>
</tr>
<tr>
<td>Kidney &amp; Renal Pelvis</td>
<td>-0.3*</td>
</tr>
<tr>
<td>Prostate</td>
<td>-0.9*</td>
</tr>
<tr>
<td>Myeloma</td>
<td>-1.1*</td>
</tr>
<tr>
<td>Esophagus</td>
<td>-1.4*</td>
</tr>
<tr>
<td>All Sites</td>
<td>-1.5*</td>
</tr>
<tr>
<td>Colon &amp; Rectum</td>
<td>-1.6*</td>
</tr>
<tr>
<td>Non-Hodgkin Lymphoma</td>
<td>-1.7*</td>
</tr>
<tr>
<td>Stomach</td>
<td>-1.8*</td>
</tr>
<tr>
<td>Larynx</td>
<td>-2.1*</td>
</tr>
<tr>
<td>Leukemia</td>
<td>-2.5*</td>
</tr>
<tr>
<td>Lung &amp; Branches</td>
<td>-2.6*</td>
</tr>
<tr>
<td>Melanoma of the Skin</td>
<td>-5.0*</td>
</tr>
</tbody>
</table>

**WOMEN**

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Annual Percent Change, 2003-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corpus &amp; Uterus</td>
<td>2.3*</td>
</tr>
<tr>
<td>Oral Cavity &amp; Pharynx</td>
<td>1.9*</td>
</tr>
<tr>
<td>Liver &amp; Intrahepatic Bile Duct</td>
<td>0.5*</td>
</tr>
<tr>
<td>Soft Tissue incl. Heart</td>
<td>0.2*</td>
</tr>
<tr>
<td>Brain &amp; Other Nervous System</td>
<td>0.2*</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.0</td>
</tr>
<tr>
<td>Bones and Joints</td>
<td>0.0</td>
</tr>
<tr>
<td>Bladder</td>
<td>-0.3*</td>
</tr>
<tr>
<td>Leukemia</td>
<td>-1.3*</td>
</tr>
<tr>
<td>Gallbladder</td>
<td>-1.3*</td>
</tr>
<tr>
<td>Kidney &amp; Renal Pelvis</td>
<td>-1.4*</td>
</tr>
<tr>
<td>All Sites</td>
<td>-1.5*</td>
</tr>
<tr>
<td>Breast</td>
<td>-1.5*</td>
</tr>
<tr>
<td>Non-Hodgkin Lymphoma</td>
<td>-1.6*</td>
</tr>
<tr>
<td>Stomach</td>
<td>-1.6*</td>
</tr>
<tr>
<td>Myeloma</td>
<td>-1.8*</td>
</tr>
<tr>
<td>Esophagus</td>
<td>-2.3*</td>
</tr>
<tr>
<td>Colon &amp; Rectum</td>
<td>-3.1*</td>
</tr>
</tbody>
</table>

**AVERAGE ANNUAL PERCENT CHANGE (AAPC) 2012-2016**

- **MEN**: Melanoma of the Skin: -5.0%
- **WOMEN**: Melanoma of the Skin: -4.9%

*AAPC is significantly different from zero (p<.05).

*Men & Women. For sex-specific cancer sites, the population was limited to the population of the appropriate sex.*
NCI Appropriations FY 2015 – 2020 (in millions)

21st Century Cures Act - orange
Childhood Cancer Cancer Initiative - green

--- | --- | --- | --- | --- | --- | ---
$4,950 | $5,215 | $5,389 | $5,665 | $5,744 | $5,002 | $6,199
$5,689 | $6,144 | $5,965 | $6,144 | $5,965 | $6,144 | $5,965
$400 | $400 | $300 | $300 | $300 | $300 | $300
$5,247 | $6,444 | $5,247 | $6,444 | $5,247 | $6,444 | $5,247
$195 | $195 | $195 | $195 | $195 | $195 | $195
$50 | $50 | $50 | $50 | $50 | $50 | $50

The diagram shows the appropriations for the National Cancer Institute (NCI) from FY 2015 to FY 2020, highlighting the changes in funding levels over the years. The 21st Century Cures Act and the Childhood Cancer Initiative are marked with different colors for easy comparison.
NCI/NIH BUDGET PROCESS FOR REGULAR APPROPRIATION

STEP 1
White House OMB coordinates with federal agencies to formulate the President’s budget proposal

STEP 2
Congressional appropriations committees consider President’s proposal & prepare legislation

STEP 3
Congress reconciles & finalizes appropriations legislation & sends to the President

STEP 4
President signs the appropriations bill into law making funds available for NIH & NCI

FY 2019
FY 2020
Select Working Group Updates

**Small Cell Lung Cancer (SCLC)**
Co-Chairs:
Alex Adjei, M.D., Ph.D.
Laurie Gaspar, M.D., M.B.A., F.A.S.T.R.O.

**Glioblastoma (GBM)**
Co-Chairs:
Walter J. Curran, Jr. M.D., F.A.C.R.
Chi V. Dang, M.D., Ph.D.
Four Areas of Added Emphasis

- Childhood Cancers
- Investigator-Initiated Research
- Health Disparities
- Drug Resistance
Four Areas of Added Emphasis

- Childhood Cancers
- Investigator-Initiated Research
- Health Disparities
- Drug Resistance
Updates on NCI-COG Pediatric MATCH

Study activated July 2017

• As of July 2019:
  • 645 patients enrolled
  • Monthly accrual average: 27
  • 10 treatment arms, with at least one patient enrolled on each one
  • Approximately 25% of study patients with tumor submitted have been assigned to a treatment arm
  • 10% enrolled on treatment to date

NCI-COG Pediatric MATCH has created a collaborative framework for efficient collection, processing, and sequencing of refractory pediatric cancers.
NCI-COG Pediatric MATCH Accrual

Average 27

Number of Patients Enrolled

NIH NATIONAL CANCER INSTITUTE
Pediatric cancer research conducted or supported by NCI/NIH: 2014 - 2018

Number of Awards

2014 2015 2016 2017 2018
Childhood Cancer Research Presidential Initiative

• President’s FY 2020 budget proposal includes $50M
• White House has convened several stakeholder events
Childhood Cancer Data Initiative (CCDI)

Facilitate the sharing of childhood cancer data from multiple sources through a connected data infrastructure

Identify opportunities to align and integrate multiple data sources to make data work better for patients, clinicians, and researchers

Maximize every opportunity to improve treatments and outcomes for children with cancer
Childhood Cancer Data Initiative – Next Steps

Scientific Planning Meeting
July 29-31, 2019
Washington, D.C.

For more information and to register for the videocast, visit
Cancer.gov > search > CCDI
Four Areas of Added Emphasis

- Childhood Cancers
- Investigator-Initiated Research
- Health Disparities
- Drug Resistance

- Non-Hispanic Black
- Non-Hispanic White
- American Indian/Alaska Native
- Hispanic
- Asian/Pacific Islander

Cervical cancer incidence in the U. S.

- **Incidence** in black women is now similar to white women.

- **Mortality** disparity remains.

Current mortality rates
ASR* 2012-2016
Black women: 3.5
White women: 2.2

*ASR=Annual Standardized Rate
Heart disease and cancer mortality rates, age adjusted

**Heart Disease**
- **Non-metropolitan**
- **Metropolitan**

**Cancer**
- **Non-metropolitan**
- **Metropolitan**

Moy et al, MMWR Surveil Summ, 2017
NCI Activities in Rural Cancer Control

• 21 Cancer Centers received supplements in FY18 to focus on rural populations.

• RFA-CA-18-026 (R01) Improving the Reach and Quality of Cancer Care in Rural Populations (Closed)

Additional relevant FOAs

| Collaborative Minority Health and Health Disparities Research with Tribal Epidemiology Centers | R21 PAR-17-483 R01 PAR-17-484 | 12/5/2019 |
| Research to Improve Native American Health | R01 PAR-17-496 R21 PAR-17-464 | 5/14/2020 |
| Administrative Supplements to Support Cancer Disparity Collaborative Research | P30 PA-18-842 | 9/10/2019, 9/10/2020 |
Four Areas of Added Emphasis

- **Childhood Cancers**
- **Investigator-Initiated Research**
- **Health Disparities**
- **Drug Resistance**
NCI Drug Resistance & Sensitivity Network

Steering Committee

Mayo AZ/Roch-U Minn
Multiple Myeloma

OHSU
AML

UCSF-Stanford
Lung

MGH-Broad-MIT/Koch
CRC/Melanoma/Lung

MSK/UW-Fred Hutch
Prostate

Huntsman
Martin McMahon
Lung

Roswell Park
David Goodrich
Prostate
NCI Drug Resistance & Sensitivity Network

Collaboration with other NCI & Cancer Moonshot Programs

• **ETCTN** - Experimental Therapeutics Clinical Trials Network
• **PDXNet/PDMR** - PDX Dev & Trial Ctrs Res Network/Patient-Der Models Rep
• **CHTN** – Cooperative Human Tissue Network
• **PADIS** – Pharmacodynamic Assay Development & Implementation Section

• **Moonshot Biobank**
• **HTAN/MCL** - Human Tumor Atlas Network & Mol & Cell Characterization of Screen-Detected Lesions Consortium
• **IOTN** – Immuno-Oncology Translational Network
• **CSBC** – Cancer Systems Biology Consortium

**Administrative Supplement Goal:**

*to promote collaborations between DRSN & non-DRSN investigators.*
Antiandrogen response…
…then RESISTANCE:

Activity of Clinical Grade Inhibitors in PDX Models of Castration Resistant Prostate Cancer in combination with enzalutamide
Next Steps

Present Status
• Preference given to DRSN studies involving NCI CTEP IND agents
• NCI-IND agents (n= >60) include a wide variety of small molecule and antibody inhibitors that impact classic oncogenic signaling & checkpoint targets

Future Directions
• Encourage collaborations with associate/non-DRSN members
• Promote the interface of Trans-NCI Moonshot Networks
  • PaCMEN
  • HTAN
  • PDXNet
  • IOTN
  • PI-DDN
  • CIMACs/CIDC
  • FusOnC2
Recent Leadership Appointments

• Deputy Director for Scientific Strategy and Development - Dinah Singer
• Chief of Staff - Anne Lubenow
• Deputy Executive Officer - Eric Cole
• Director, CBIIT - Tony Kerlavage
• Chief Information Officer - Jeff Shilling
• Chief Data Scientist, DCEG - Jonas Almeida
• Budget Director - Weston Ricks
Leadership Vacancies

Director, Center for Global Health (CGH)
Bob Croyle, Acting

Associate Director, Cancer Therapy Evaluation Program (CTEP)
Meg Mooney, Acting

Director, Division of Cancer Prevention (DCP)
Debbie Winn, Acting