NCI Director’s Report
Norman E. Sharpless, M.D.

Clinical Trials and Translational Research Advisory Committee
March 12, 2020

Today

• More Evidence of Progress Against Cancer
• NCI Budget
• Leadership Updates
• CTAC Working Groups
• Clinical Trials Results Reporting
• Undisclosed Support
• Discussion
Evidence of Progress Against Cancer

Facts & Figures 2020 Reports Largest One-year Drop in Cancer Mortality

• Cancer death rate declined 29% from 1991 to 2017
• 2.2% drop from 2016 to 2017
• Most rapid declines in mortality: Melanoma, NSCLC
**Status Quo:** Lung cancer mortality rates are projected to decrease by ~50% between 2020 and 2040

Projected lung cancer mortality until 2065 – ages 30-84
Means across for CISNET models

<table>
<thead>
<tr>
<th>Year</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>64</td>
<td>47</td>
</tr>
<tr>
<td>2040</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

Lung cancer mortality is decreasing faster than lung cancer incidence

<table>
<thead>
<tr>
<th>Gender</th>
<th>Incidence (2011-15)</th>
<th>Mortality (2012-16)</th>
<th>Average annual percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-2.6</td>
<td>-4.3</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-1.2</td>
<td>-3.1</td>
<td></td>
</tr>
</tbody>
</table>

Incidence: age standardized, delay-adjusted rate
Mortality: age-standardized rate

Survival Trends in NSCLC & SCLC (Women)
SEER-18, 2001-2016

NON-SMALL CELL

SMALL CELL

2-Year Small Cell Lung Cancer Survival (%)

2-Year Non-Small Cell Lung Cancer Survival (%)


35 44

14 17

Courtesy of Nadia Howlader, Ph.D., Data Analytics Branch, DCCPS, NCI

NCI Appropriations FY 2015 – 2020 (in millions)

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

$6,000

$5,000

$4,000

$3,000

$2,000

$1,000

$0

$4,950

$5,215

$5,389

$5,665

$6,144

$6,245

FY 2015
FY 2016
FY 2017
FY 2018
FY 2019
FY 2020

$195

$50
White House OMB coordinates with federal agencies to formulate the President's budget proposal.

Congressional appropriations committees consider President's proposal & prepare legislation.

Congress reconciles & finalizes appropriations legislation & sends to the President.

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

House Appropriations Labor-HHS Subcommittee Hearing: FY 2021 NIH Budget Request

- Participated alongside Dr. Collins and IC Directors from NIAID, NHLBI, NIDA, and NICHD
- 8 questions including from the Chair and Ranking Member
- Topics included NCI’s increase in applications, CCDI update, clinical trials, and kidney cancer
- Senate budget hearing is TBD

FY 2021
More than $210 Million Increase for Cancer Research and Training Across the U.S.

- **Prioritize Competing Grants** - Increase payline for most grants from the 8th percentile to the 10th
- **Sustain Commitments** - Restore 2019’s 3% cut to continuing grants

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DIVISION A—DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2020

**NCI Paylines.**—Grant applications to NCI have increased by approximately 50 percent since 2013, outpacing available funding, with requests for cancer research ten-fold greater than other Institutes. With such a high demand for NCI grants, only a fraction of this research is funded. To support more awards and improve success rates, the agreement provides $212,500,000 to prioritize competing grants and sustain commitments to continuing grants.

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**NCI RPG Pool and R01 Payline – FY 2016-20**

- R01 Payline
- Competing RPG Pool $
- Non-competing RPG Pool $

In addition to these RPGs, in FY19 NCI supported over $1.1B of extramural research grants through non-RPG mechanisms, e.g.,
- Clinical trials (U10)
- Cancer Centers (P30)
- SPORES (U54)
- Training (F, K, T)

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*Does not include SBIR/STTR or Admin Supplements

*FY 2017 includes competing first-year costs and awards from Cancer Moonshot fully funded awards.
NCI Bottom Line: A Blog About Grants & More

New blog featuring 1-2 posts per month addressing:

• budget- and funding-related milestones
• funding trends and patterns
• emerging policy or fiscal issues
• analyses of NCI’s grants portfolio

Subscribe at cancer.gov.

New Leadership

Oliver Bogler, Ph.D.
Director
Center for Cancer Training

Satish Gopal, MD, MPH
Director
Center for Global Health
Leadership Vacancies

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

Director, Division of Cancer Biology
Daniel Gallahan, Acting

CTAC Working Group Updates

- **GBM**
  Report accepted by CTAC July 17, 2019
  New concept to enhance GBM therapeutics incorporating some of the group’s recommendations will be presented at the next BSA meeting.

- **Radiation Oncology**
  Report will likely be presented at the July 22 CTAC meeting.
Clinical Trials Results Reporting

NCI-Sponsored Trials Results Reporting Over Time
Interventional Other than Phase I, PCD 12/2007 to 12/2018, as of 2/26/2020

Within 1 year of PCD
Results to be Entered

Results Overdue

Results Not Yet Due
PCD Not Yet Reached

Results Entered

PCD = Primary Completion Date. Source: NCI CCCT.
Status of NCI-Sponsored Trials Requiring* Results
As of 2/26/2020 (n=820)

<table>
<thead>
<tr>
<th>NCI-Sponsored Reporting: Based on Date Results Submitted to ClinicalTrials.gov</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 820</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results Reported</td>
<td>801</td>
<td>98%</td>
</tr>
<tr>
<td>&lt; 12 months</td>
<td>187</td>
<td>23%</td>
</tr>
<tr>
<td>&lt; 24 months</td>
<td>341</td>
<td>42%</td>
</tr>
<tr>
<td>Results Overdue – Not Reported**</td>
<td>19</td>
<td>2%</td>
</tr>
</tbody>
</table>

* Interventional Other than Phase 1 Trials with a PCD from 12/28/2007 - 12/31/2018

** Includes 6 Behavioral Interventional trials

Timeliness of Reporting for Trials
NCI-Sponsored trials for which results are Due*

*Interventional Other than Phase 1 trials with a Primary Completion Date 12/28/2007 – 12/31/2017
Undisclosed Support

Financial Conflicts of Interest
Undisclosed payments or arrangements that can lead to the perception of biased research

Foreign influence
• Shadow laboratories
• Misbehavior in peer review
• Ghost-written applications
• Transfer of IP

UNDISCLOSED SUPPORT
Erosion of public trust in cancer research
Scrutiny from media, Congress, taxpayers

Collaboration is a good thing…with transparency.
How NCI plans to help

- We recognize that the vast majority of grantees want to comply and are fine with reporting **but it is confusing**.
  - Reporting similar but not identical information to multiple institutions and journals
  - Circumstances and policies may change over time
  - Reporting forms and systems have different requirements, timelines, platforms, passwords…
  
- We are having discussions with journals, AACR, ASCO, AACI and AAMC to identify options for a database that makes it easier to do the right thing.

**More to come**
- Ongoing reviews: 180 individuals at 70+ institutions

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@TheNCI