Potential Change in NCI Policy Regarding the Submission of Grant Applications that Request Support for Phase III Clinical Trials

Roy S. Wu, Ph.D., Chief
William C. Timmer, Ph.D., Program Director, Clinical Grants and Contracts Branch / CTEP
Phase III clinical trials can be proposed: for investigator-initiated research applications (R01, P01) subject to the >$500K direct cost approval requirement.
• **Purpose:**
  – Develop and publish revised NCI policy removing Phase III clinical trials involving therapeutic interventions from the grants portfolio (R01 and P01)

• **Rationale:**
  – Phase III trials: multi-center, cost > $500,000/yr more than 5 years duration in most cases
  – duplication of NCTN and CCOP infrastructure at a time of resource constraints

• **Goal:**
  – formalize policy change with specific exceptions
Policy Revision Process

- Met with NCI Division stakeholders
- Conducted portfolio analysis
- Drafted a revised policy
- Presented policy revision to SPL
- Solicited input from the community via RFI
- Presentation to CTAC
### Portfolio Analysis

#### Proposed Phase III Trials in Grant Portfolio

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>R01</th>
<th>P01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted</td>
<td>102</td>
<td>20</td>
</tr>
<tr>
<td>Funded</td>
<td>28</td>
<td>11</td>
</tr>
</tbody>
</table>

QVR Search Terms: Phase III clinical trial; R01 or P01 grant mechanism, Type 1, 2 and 5; submitted and funded;
NCAB: May 2003 (2003/05) to Jan 2013 (2013/01)
## Portfolio Analysis

### Types of Phase III Trials in Grant Portfolio

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>R01</th>
<th>P01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Prevention</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Behavioral</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Total Funded</td>
<td>28</td>
<td>11</td>
</tr>
</tbody>
</table>
NOT CA-12-013 Request for Information (RFI)

Input on a Potential Change in NCI Policy Regarding the Submission of Grant Applications that Request Support for Phase III Clinical Trials/Therapeutic Interventions

Question to extramural researchers:
Should applications proposing Phase III clinical trials be allowed for under R01 and/or P01 funding mechanisms?

• Publicized via NIH OER Listserv & CGCB distribution list (~ 300 current and former grantees)

• Thirty day comment period
Conclusions

• Majority of extramural investigators do not propose therapeutic or imaging Phase III trials in the grants portfolio
• Over a 10 year period, change in policy would have affected less than 150 investigators
• Response to RFI was poor (N = 19 - very small)
• Split opinions even from same institution/organization
• Rare disease clinical trials are a concern
• Need to exclude behavioral research from policy
Proposed Policy Change

- No Phase III (efficacy) trials in the grants portfolio with exception of behavioral or public health intervention studies and cost effectiveness research provided they can be completed entirely within the 5 year grant cycle.
- NCTN has incentivized trials in rare diseases via revised review criteria and the development of a common menu for the entire Network.