HPTN/IMPAACT Annual Meeting 2015

NIAID CTU Recompetition Lessons Learned

Manizhe Payton, MPH
Director, DAIDS Office of Clinical Site Oversight
NIH/NIAID/DAIDS/OCSO

June 18, 2015
Overview

Changes in New CTU Grant Cycle

- CTU/CRS Landscape
- Timing of Grant Start
- CRS Performance Standards
- Funding
CTU/CRS Landscape

Changes

- Reduced number of CTUs, resulting in fewer, larger CTUs
- Promoted opportunities for consolidation
- Landscape shifted internationally
- Promoted efficiencies
- No single CRS/Network CTUs
  - Costly to operate a CTU with one CRS/one Network
## 2015 CTU/CRS Landscape

<table>
<thead>
<tr>
<th>CTU Location</th>
<th>New CTU Grant Cycle</th>
<th>Prior CTU Grant Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>26</td>
<td>55</td>
</tr>
<tr>
<td>International</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
<td><strong>72</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CRS Location</th>
<th>New CTU Grant Cycle</th>
<th>Prior CTU Grant Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>53</td>
<td>83</td>
</tr>
<tr>
<td>International</td>
<td>57</td>
<td>78</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110</strong></td>
<td><strong>161</strong></td>
</tr>
</tbody>
</table>
#CRSs by Network: New and Prior CTU Grant Cycles

- **MTN**: New: 25, Prior: 29
- **IMPAACT**: New: 16, Prior: 39
- **HVTN**: New: 23, Prior: 30
- **HPTN**: New: 23, Prior: 38
- **ACTG**: New: 59, Prior: 76

New Grant Cycle vs Prior Grant Cycle
# Networks by CTU:
New and Prior CTU Grant Cycles

<table>
<thead>
<tr>
<th>Networks</th>
<th>New Grant Cycle</th>
<th>Prior Grant Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>37</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

#CRSs
# Networks by CRS: New and Prior CTU Grant Cycle

![Bar chart showing the comparison between Prior Grant Cycle and New Grant Cycle for different numbers of networks.]

- **1 Network:** 123 in Prior, 83 in New
- **2 Networks:** 28 in Prior, 19 in New
- **3 Networks:** 7 in Prior, 7 in New
- **4 Networks:** 3 in Prior, 1 in New
- **5 Networks:** 0 in Prior, 0 in New
Lessons Learned

- As compared to single Network CRSs, multi-scope CRSs are better positioned to withstand the ‘ebbs and flows’ of the Network research agendas by participating in protocols across Networks, aiding PF flow in general, and sharing resources.
- Based on the current Networks’ scientific agendas, we believe the reduction of CRSs was appropriate.
Timing of Grant Start

Changes

- Aligned start of CTU and Network grant cycles
- Both start in December

Lessons Learned

- Synchronization of these awards facilitates efficient planning
- Improves HIV/AIDS Networks’ ability to forecast entire funding needs (including site PF) within the same grant year as the Networks
Funding

Changes

- More constrained funding environment
- Networks offered option to provide PF directly to sites in this grant cycle vs NIAID distributing PF
  - All Networks opted to distribute PF directly
  - Allows Network the flexibility to reallocate PF resources to reflect current Network needs
Funding

Lessons Learned

- CRSs have been challenged in managing multiple funding processes with resultant need for additional administrative staff to learn new fiscal systems and oversee funding.

- Network mentoring of CRS staff to support invoicing, address fiscal questions, and explain fiscal processes greatly assists site staff in successfully invoicing and working with Networks on new systems.

- Consistent interpretation of PF vs Core funding is critical across Networks.

- CRSs with efficient models of operation including sharing of resources and multiple funding streams are poised for success.
Changes

- Removal of the requirement of n=20 (NIAID driven annual accrual requirement)

- Each Network to define performance standards

- NIAID is critically evaluating CRS level of activity in partnership with Network during this grant cycle

- CTUs have a role to play in evaluating CRS performance
Lessons Learned

- Positive shift of site oversight so that it is shared cooperatively between Networks and NIAID

- Provides opportunity for Networks to determine individual performance standards based on nature and complexity of protocols

- NIAID will coordinate closely with each Network’s leadership or performance evaluation committees, as NIAID evaluates the performance of sites in the grant cycle
Thank you for your attendance and additions to the Lessons Learned from the current CTU Grant Cycle