Overview of CAB
Demographics and
Restructuring the Clinical Trials Units

HPTN Annual Meeting
June 9, 2011

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Office of Clinical Site Oversight
DAIDS, NIAID
Agenda

- Current CTU Structures

- Some results from recent OCSO CTU Surveys with respect to CAB activities and structure

- CTU Restructuring Efforts
Per the 2006 CTU RFA, “Each CTU is required to establish a productive partnership in the community in which they propose to conduct research, including the development and ongoing support of a Community Advisory Board (CAB)”.
I. CTU Core Funding (determined by NIAID)

- Includes (but not limited to) support for the following “administrative” CTU responsibilities:
  - Key personnel salaries
  - Regulatory fees
  - Lab and pharmacy
  - Equipment
  - Office supplies
  - CAB activities

- Formula Core funding based on size of CTU and number of Network affiliations
- Provided on an annual basis.
II. Protocol Implementation funds (PIF) *(determined by Network)*

- Includes (but not limited to) support for the following protocol related activities
  - Participant care related costs
  - Participant stipends
  - Staff salaries
  - Community outreach, recruitment, and retention activities

- Distributed by NIAID to CTU/sites on an annual basis, along with CORE, via the “annual award” for all Networks except HVTN.

- Determination of PIF varies by Network
  - Formula based
  - Need based
Community Related Support

General Rules

- Although the expectation is that each CTU PI will provide support for CAB related activities and community outreach, DAIDS does not specify how much financial support must be provided.

- The amount of support is based on input from CAB members.

- For the current year and perhaps going forward, itemized CAB budgets are requested from CTU’s in their annual reports.

- Budget amounts for both CAB and community outreach activities vary greatly between Networks. *(in general prevention > treatment)*
Example of CAB Expenses

- CAB workshop costs.
- Meals/refreshments for CAB meetings.
- Speaker fees for meetings.
- Transportation reimbursement for CAB members when attending meetings and workshops.
Steps Moving Forward

If you are interested in developing a budget proposal to your site:

- Identify a “point person” within your CTU you are comfortable approaching, works closely with the PI, and has some knowledge of site budgets i.e., site coordinator or administrative officer

- Offer to work with this individual or site “financial person” to determine an annual budget for community outreach

- If there is a specific need requiring “additional” funding, develop and submit a written proposal with budget to the PI via the “point person”

- Ultimately, the PI will decide if and what funds are available for request
Tips for Budget Proposals

1. State purpose and justification for request.

2. Provide specific line items with amount and cost for each.

3. Include “must have” items rather than “nice to have.”

4. Provide supporting documentation or “estimates” when available.
OCSO
Clinical Trials Network Survey Results
Community Advisory Boards
Current CTU Statistics
Number of CTUs by Geographic Location

Total CTUs = 72, Total CRSs=153
Number of CABs by Geographic Location

Total CABs is 138 across the 72 CTUs
Number of CRSs and CABs by CTU
Geographic Location

Total CRSs = 153, Total CABs = 138
<table>
<thead>
<tr>
<th>GEOGRAPHIC LOCATION</th>
<th>RANGE OF CABs, RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>1 - 10</td>
</tr>
<tr>
<td>International</td>
<td>1 - 7</td>
</tr>
<tr>
<td>Dom. CTU with all Int’l. CRSs</td>
<td>1 - 5</td>
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<tr>
<td>Dom. CTU with mix of Domestic and International</td>
<td>2 - 3</td>
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CAB Staffing
Proportion of CTUs with dedicated CAB Staff by Geographic Location

- Domestic: 57% (N=36)
- International: 59% (N=17)
- Dom. CTU, all Intl. CRSs: 70% (N=10)
- Dom. CTU, mix CRSs: 67% (N=6)
<table>
<thead>
<tr>
<th>GEOGRAPHIC LOCATION</th>
<th>STAFF LEVEL OF EFFORT, RANGE CAL. MONTHS</th>
</tr>
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<tbody>
<tr>
<td>Domestic</td>
<td>0.6 – 10.8</td>
</tr>
<tr>
<td>International</td>
<td>3.6 – 16.6</td>
</tr>
<tr>
<td>Dom. CTU with all Int’l. CRSs</td>
<td>4.8 – 24.0</td>
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</tbody>
</table>
Average CAB Level of Effort in Cal. Months, by CTU Geographic Location, for CABs with Dedicated Staff

N=19  N=10  N=6  N=4

*For the Domestic and Dom. CTU, mix CRSs one record for each geographic classification has been omitted from the analysis as the level of effort was not available
Conclusions

- CAB sharing occurs more often among CRSs with International CTUs and CTUs which are Domestic with all International CRSs

- The Domestic and International CTUs have a larger range of CABs (1-10 and 1-7, respectively) as compared to the Domestic CTUs with all International CRSs and Domestic CTUs with a mix of domestic and international CRSs

- The Domestic and International CTUs support less CAB staff level of effort as compared to the Domestic CTUs with all International CRSs and Domestic CTUs with a mix of domestic and international CRSs
HIV/AIDS Clinical Trials Networks

Background

- Awards for the current HIV/AIDS Leadership Groups will expire in 2013
  - AIDS Clinical Trials Group
  - HIV Prevention Trials Network
  - HIV Vaccine Trials Network
  - International Maternal Pediatric Adolescent AIDS Clinical Trials Group
  - International Network for Strategic Initiatives in Global HIV Trials
  - Microbicides Trials Network

- Awards for the clinical trial units (CTUs) and clinical research sites (CRS) are scheduled to expire in 2014
Goals for CTUs

- Robust, flexible clinical research site capacity to respond quickly to NIAID and Network research priorities

- Multi-scope CTUs (across networks, diseases, and populations)
  - Collaborate with other partners

- Efficient and effective utilization of resources with emphasis on cost containment
  - More tightly link site capacity to trials

- Evaluate domestic and international balance
  - Promote expansion of site capabilities
  - Optimize and achieve consistency in approval timelines
The Future CTUs

- Fewer CTUs with an overall increase in the number of Clinical Research Sites (CRS) per CTU
  - Goal of minimum of 25 CTUs
  - Efficient configuration of CTU/CRS to support multiple Networks simultaneously

- Multi-scope activities achieved across CTU
  - All CTUs will be able to perform HIV/AIDS research
  - Some CTUs will also be able to perform non HIV/AIDS research

- Increased flexibility
  - Comprised of 2 types of sites:
    - CRS (stable) and protocol-specific sites (surge capacity)
  - Streamlined procedures for adding/subtracting sites
The Future CTUs

- **Preserve community education and engagement**
  - CAB configuration based on local needs and priorities

- **Increased authority and accountability**
  - Performance and capacity management
  - Resource sharing, utilization and cost containment
  - Requires significant commitment from grantee institution

- **Increased contribution to the scientific agenda**
  - Opportunity for multiple PIs
  - Assess local needs, priorities, protocol feasibility
  - Participation in non-Network research
CTU Requirements

- What is the appropriate scope for individual CTUs?
  - Individual CTUs must affiliate with a minimum of **two** HIV/AIDS Networks
  - Non-AIDS infectious diseases Network capability statement is an option
  - Each CRS affiliated with only **one** CTU

- Is there an upper limit on the number of CRS in a single CTU?
  - The upper limit in the RFA will be **eight** CRS per CTU

- How many CRS per CTU are required to efficiently support multiple Networks?
  - Each CRS can affiliate with one-to-many Networks
CTU Funding Model

- Core Funding
  - Maintain infrastructure
  - Based on geographic location, size, and scope

- Protocol Implementation Funds
  - Costs that can be attributed to specific protocols
  - Amounts to be estimated by Networks
  - Provided through CTU awards or directly by Networks
CTUs Evolved

CTU
- Expanded responsibilities
- Shared resources
- Increased administrative capacity

Clinical Research Sites (CRS)
Scientific Contributors & Trial Implementers

Protocol-Specific Sites
PS 1
PS 2
Consultations on Scientific Priorities, Site, Unit and Network Structure

- **Individual and Group Consultations**
  - HIV/AIDS Community groups (e.g. Community Partners, Project Inform, Global Advocacy for HIV Prevention, etc.)
  - NIH Institutes and Centers
  - HIV/AIDS Investigators

- **Network Meetings**

- **NIAID Town Hall Meetings**

- **NIAID Website**

  [http://blog.aids.gov](http://blog.aids.gov)
Timeline for the Leadership Awards

Leadership Group awards in 2013-2014

- Planning and Consultations
- Develop and Release FOA
- Period to Respond and Submit
- Review Period & Awards Process
Timeline for the CTU/CRS Awards

- Planning and Consultations
- Develop and Release FOA
- Period to Respond and Submit
- Review Period & Awards Process

We are here

Middle CY 2012

CTU/CRS awards in 2014

CY 2014

CTU/CRS awards in 2014
Questions???

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