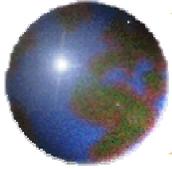


# AIDS Research Advisory Committee

## *Draft Concepts for DAIDS Clinical Research Networks*

*January 26, 2004*

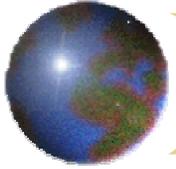




## *Guiding principles to evolve the networks*

- ✦ Address domestic and international clinical research questions of highest priority
- ✦ Integrate HIV/AIDS prevention and treatment research for the best clinical science
- ✦ Maximize scientific opportunities through coordinated research
- ✦ Increase efficiency through resource sharing
- ✦ Build and sustain clinical research capacity in resource poor settings
- ✦ Partner with organizations with complementary strengths



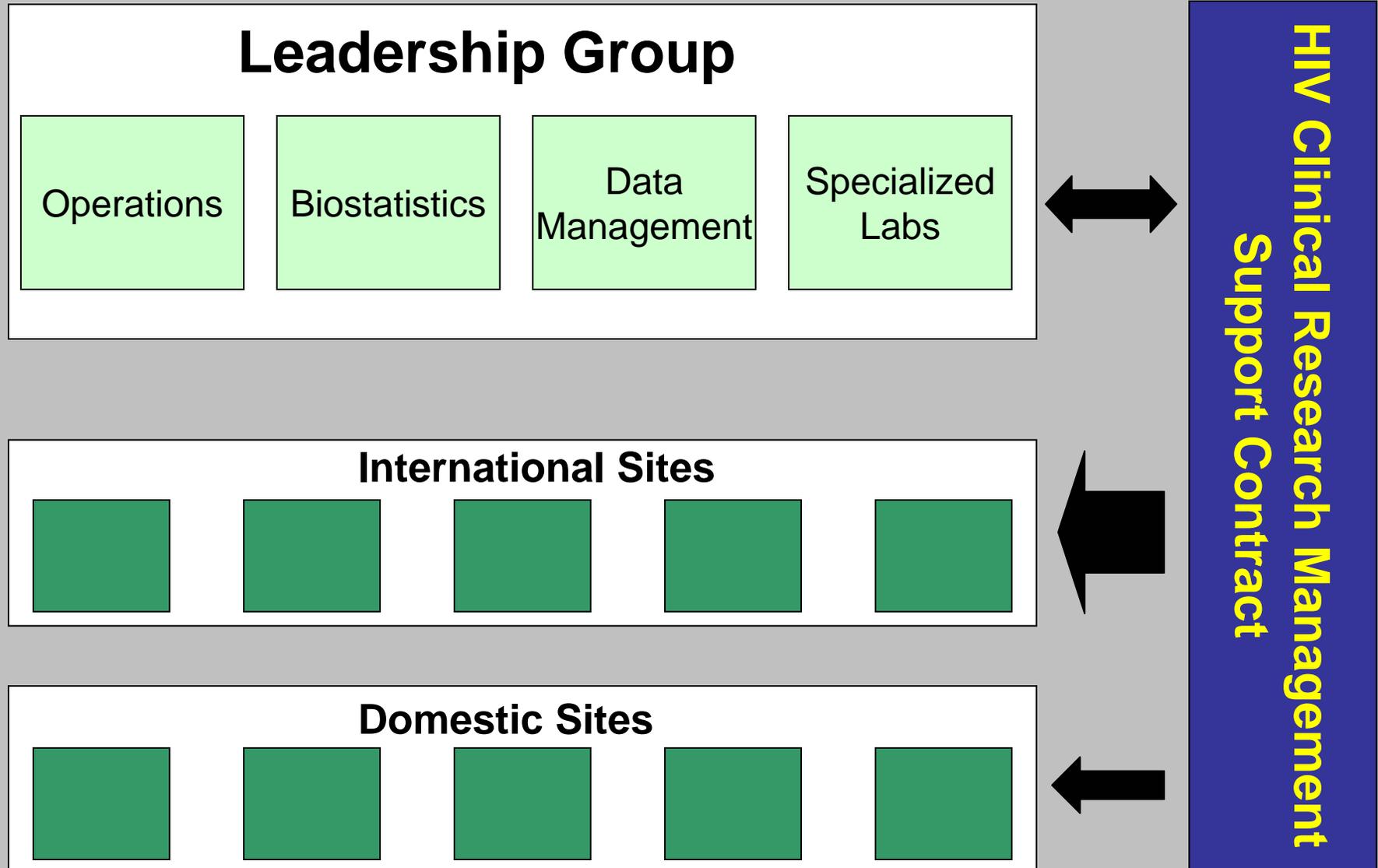


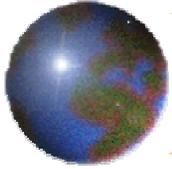
## *From 'principles' to requirements*

- ✦ Cross-Group leadership, increased accountability & greater scientific coordination
- ✦ Coordinated development of pluripotent international clinical research sites
- ✦ Sharing of laboratory resources and protocols
- ✦ Common data entry interfaces and data elements
- ✦ Coordinated specimen management guidelines
- ✦ Shared/standardized training for common needs
- ✦ Meet with one another!
- ✦ Coordinated approach to clinical research product acquisition, distribution and provision
- ✦ Become more efficient with all resources, including \$\$



# Prototype Network Structure





# *Draft Concepts*



# Draft Concept Plan

**HIV Clinical Sciences  
Coordinating Committee**

**Support Office  
(RFP or BAA)**

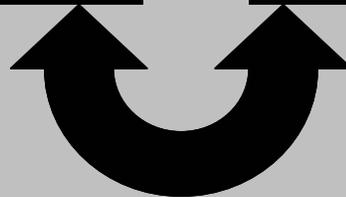
**Therapeutics Research  
Leadership Groups (RFA)**

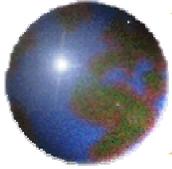
**Vaccine & Prevention  
Research Leadership Groups  
(RFA)**

**Domestic Therapeutic  
Sites (RFA)**

**International Sites (RFA)**

**Domestic  
Vaccine & Prevention  
Sites (RFA)**





# *HIV Therapeutics Leadership Group(s)*

## Objective:

- Fund experts in family-focused HIV treatment research to lead domestic and international programs evaluating innovative, multi-pronged approaches to managing HIV and its complications (e.g. co-infections, malignancies, oral health) in adults, adolescents, children, women, minorities, IDU's, the indigent and other affected and/or disenfranchised populations

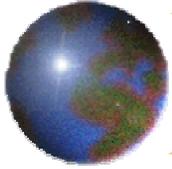
## Mechanism: RFA

- Linked U01s to support:  
leadership group, operations office, biostatistical and data management unit(s), and specialized lab(s)

## Number of Awards: 2-5

## Duration: 5 years





## *HIV Vaccine and Prevention Leadership Group(s)*

### Objective:

- ▣ Fund experts to lead domestic and international programs in testing innovative, multi-pronged approaches to HIV vaccine & prevention research

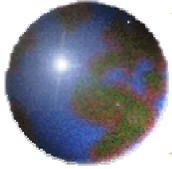
### Mechanism: RFA

- ▣ Linked U01s to support:  
leadership group, operations office, biostatistical and data management unit(s), and specialized lab(s)

Number of Awards: 2 - 4

Duration: 5 years





## *Domestic Sites for HIV Therapeutic Clinical Trials*

### ✦ Objective:

- ✦ Fund investigator-based clinical research sites to conduct therapeutics clinical trials for HIV and its complications (e.g. co-infections, malignancies, oral health) in adults, adolescents, children, women, minorities, IDU's, the indigent and other affected and/or disenfranchised populations in the United States
- ✦ Enhance and enrich the international clinical research effort through peer-to-peer collaboration, institutional partnering, scientific training, etc.

### ✦ Mechanism: RFA

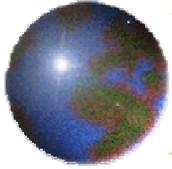
- ✦ U01s to provide core support

### ✦ Number of Awards:

- ✦ Based on research goals and needs of network(s)

### ✦ Duration: 5 years





## *Domestic Sites for HIV Vaccine and Prevention Clinical Trials*

### Objective:

- ❑ Fund investigator-based clinical research sites to conduct HIV vaccine and prevention clinical trials in the United States
- ❑ Enhance and enrich the international clinical research effort through peer-to-peer collaboration, institutional partnering, scientific training, etc.

### Mechanism: RFA

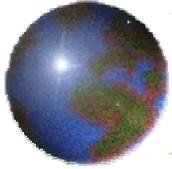
- ❑ U01s to provide core support

### Number of Awards:

- ❑ Based on research goals and needs of network(s)

### Duration: 5 years





## *International Sites for HIV Vaccine, Prevention and Therapeutic Clinical Trials*

### ✦ Objectives:

- ✦ Promote scientific autonomy and enhance contributions to scientific agenda
- ✦ Enhance clinical research capacity; address in-country needs
- ✦ Link HIV vaccine, prevention and treatment research in resource poor countries

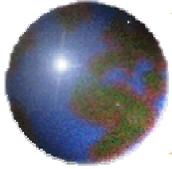
### ✦ Mechanism: RFA

- ✦ U01 awarded directly to foreign institution for core activities
- ✦ Opportunities to affiliate with multiple networks
- ✦ Additional resources for common needs, e.g. training, capacity building, infrastructure development, through DAIDS HIV Clinical Research Management Support contract

### ✦ Site selection and award process:

- ✦ Evaluation criteria that acknowledge site capabilities and development needs
- ✦ Expand number of sites with repeat solicitation(s) if needed





## *Support Office for HIV Clinical Science Coordination*

### Objective:

- Support HIV Clinical Science Coordinating Committee:
  - Manages inter-network coordination activities
  - Arranges meetings and conference calls
  - Generates summaries; documents Committee deliberations

Mechanism: RFP or BAA

New/Renewal/Expansion: New

Number of Awards: 1

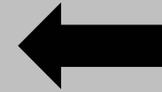
Duration: 5 years



# DAIDS Global Clinical Research Matrix

**HIV Clinical Sciences  
Coordinating Committee**

**Support  
Office**



**Network  
A**

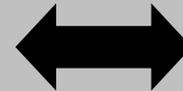
**Network  
B**

**Network  
C**

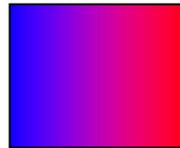
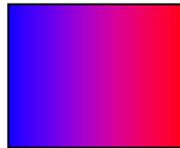
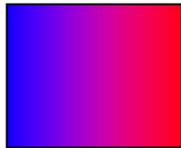
**Network  
D**

**Network  
E**

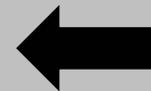
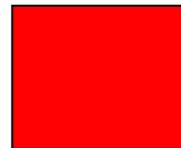
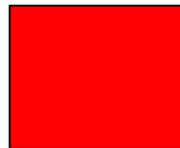
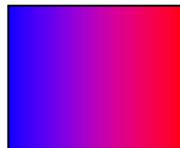
**HIV Clinical Research  
Management Support  
Contract**

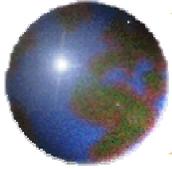


**International Sites**



**Domestic Sites**





## *Keeping things in perspective*

- ✦ RFAs are important because they establish requirements and provide structure
- ✦ Investigator response and peer-review also figure prominently
- ✦ Post-award, RFAs are history
- ✦ Cooperative agreement is the durable instrument of change & program management

