

NIAID HIV/AIDS and Infectious Diseases Clinical Trials Networks

The HIV/AIDS Perspective

Carl W. Dieffenbach, Ph.D.

Director, Division of AIDS

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“I am in the process of exploring the possibility... of utilizing our HIV/AIDS clinical trials networks for the implementation of similar clinical trials capacities for TB as well as other infectious diseases.”

Pacific Health Summit, June 17, 2009

Expanding the Research Foci of NIAID Clinical Trials Networks – DAIDS' Role

- **HIV/AIDS – Current AIDS Clinical Trials Networks**
- **AIDS Co-Morbidities (TB, Hepatitis B and C) –Modified AIDS Clinical Trials Networks**
- **Non-AIDS Infectious Diseases – Expanded Scope of Current NIAID Clinical Trials Capacity**

Background

- **Awards for the current HIV/AIDS Leadership Groups will expire in 2013**
 - AIDS Clinical Trials Group
 - International Maternal Pediatric Adolescent AIDS Clinical Trials Group
 - HIV Vaccine Trials Network
 - HIV Prevention Trials Network
 - Microbicides Trials Network
 - International Network for Strategic Initiatives in Global HIV Trials
- **Awards for the clinical trial units and clinical research sites are scheduled to expire in 2014**

Goals

- **Establish multi-disease research capacity by capitalizing on the infrastructure of the HIV/AIDS clinical trials networks**
 - Tuberculosis and hepatitis
 - Emerging scientific questions of HIV+ and at-risk populations
- **Address targeted scientific priorities**
- **Maintain community involvement**
- **Increase flexibility of the network infrastructure**

Goals

- **Ensure that a transparent mechanism is in place for meritorious ideas to be considered, reviewed and supported**
 - External investigators
 - Site investigators
- **Site capacity more tightly linked to trials**
- **Work with host countries to improve the efficiency and timeliness of the research approval process**

Priority Areas for HIV/AIDS and AIDS-related Research

HIV Vaccines

Therapeutics

**Pediatrics and Maternal &
Child Health**

HIV Prevention

A Request for Applications (RFA) will be released for each of these scientific priority areas

Vaccine Priorities

- **Design and conduct of clinical trials**
- **Advance concepts to elicit and assess mucosal, innate immune responses**
- **Perform extensive analysis of potential correlates of protection**
- **Incorporate and foster research on behavioral & social aspects in the prevention and transmission of HIV**
- **Integrate clinical and basic/non-human primate research agendas**

Prevention Priorities

- **Clinical product development for pre-exposure prophylaxis, microbicides, and emerging products**
- **Integrated prevention strategies**

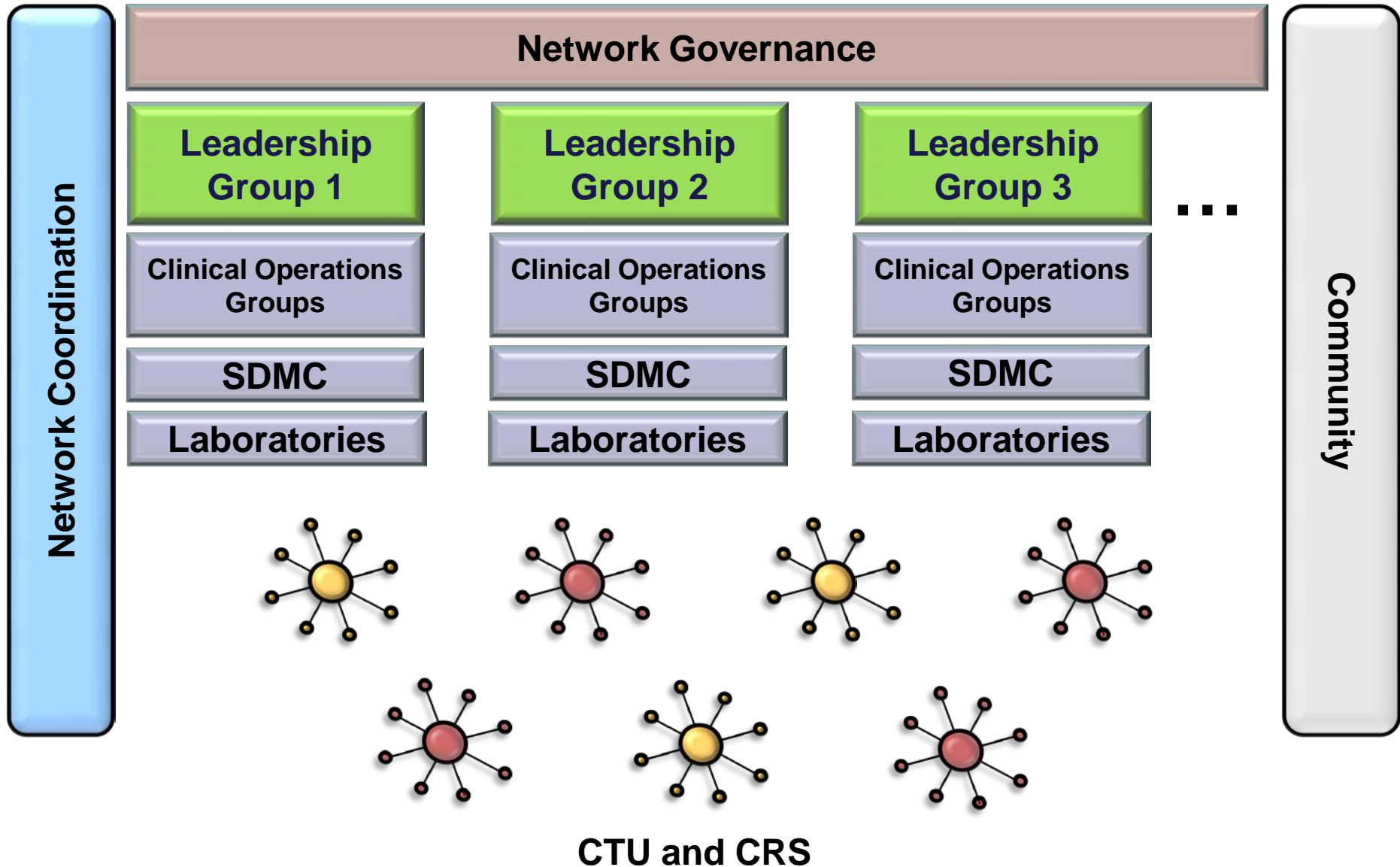
Therapeutic Priorities

- **Non-infectious co-morbidities and novel interventions**
- **Cure and/or functional cure**
- **Therapeutic strategies for TB**
- **Therapeutic strategies for hepatitis**

Pediatrics and Maternal & Child Health Research Priorities

- **Vaccines**
- **Cure**
- **Co-infections, co-morbidities and consequences of ART**
- **Pharmacology and drug formulation**
- **Prevention**

2013 Network Structure



Governance and Coordination

- **Strategic Working Group (SWG)**

- Scientific vision and priorities
- High resource trials
- Network strategic plans

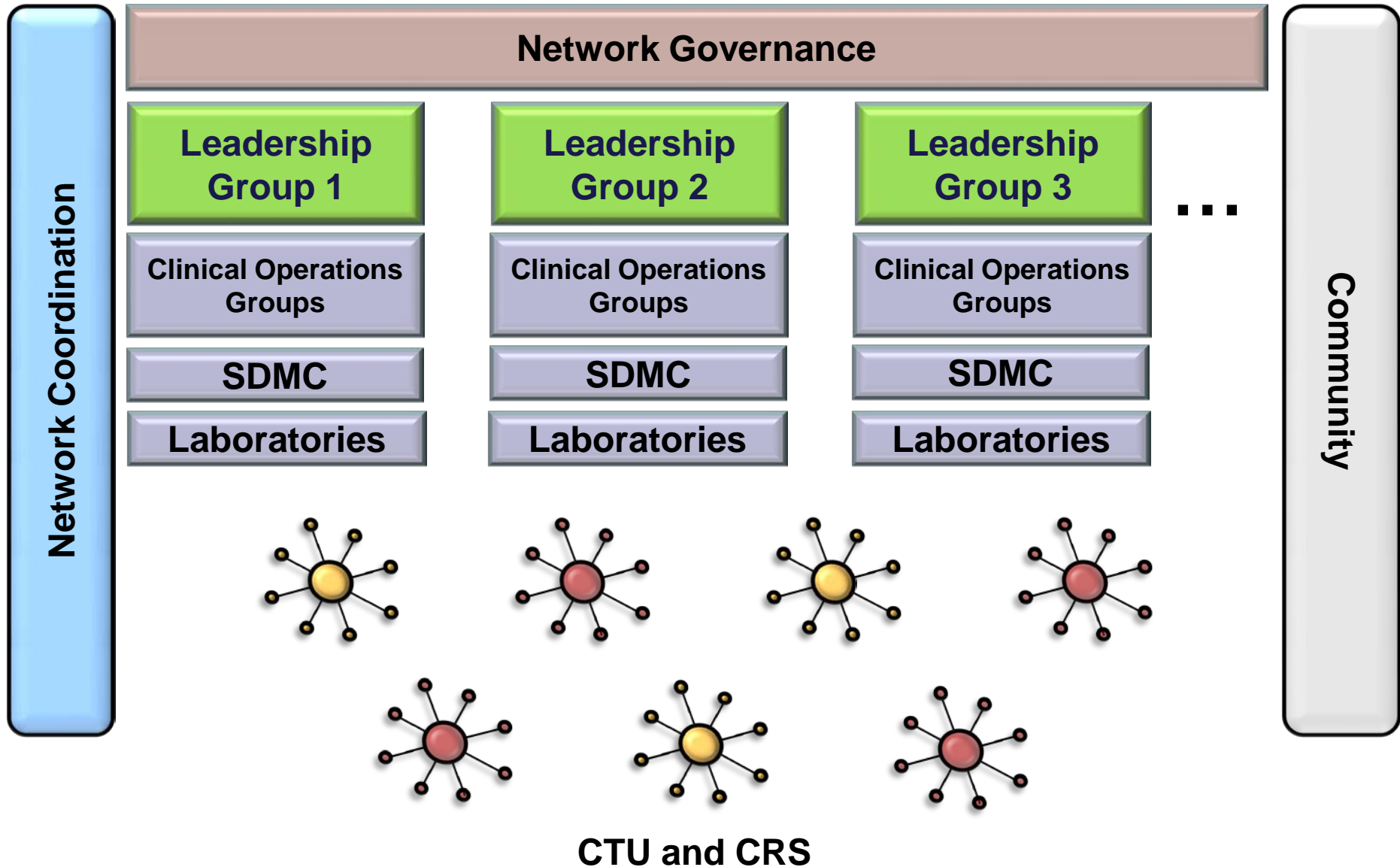
- **Operational Working Group**

- Capacity and resources

- **The Office of HIV/AIDS Network Coordination**

- Network supported
- Cross network issues

2013 Network Structure



2013 Network Structure

Network Governance

Strategic Working Group

Purview:

- 1) Strategic Scientific Vision
- 2) High Resource CT's
- 3) Cross-Cutting Issues
- 4) Review Network Strategic Plans
- 5) Trans-Agency Collaborations

Membership:

- 1) External Advisors/SME's
- 2) Network PI's
- 3) Community Partners Reps
- 4) NIAID Leadership
- 5) Federal Agencies

Operational Working Group

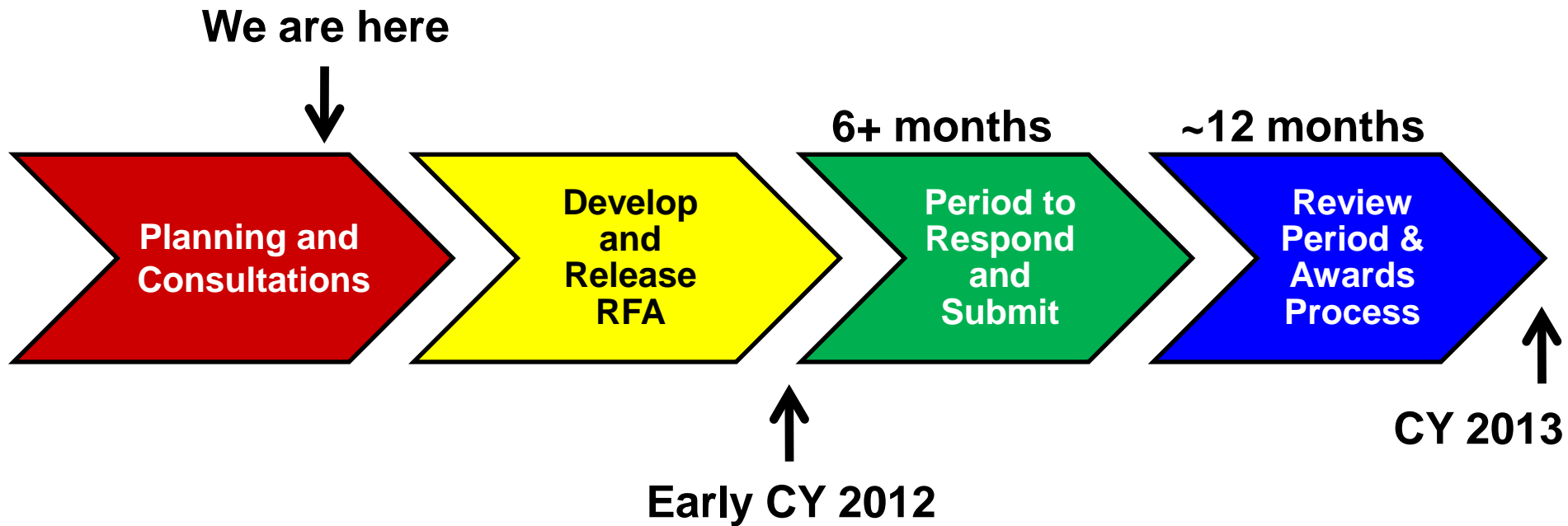
Purview:

- 1) Implementation
- 2) Resource Utilization
- 3) Access to Outside Network
- 4) Prioritization Between Resources
- 5) Other IC's (w/\$) Input

Membership:

- 1) Largely Federal
- 2) Invited Guests

Process for the Leadership Group Awards



Leadership Group awards in 2013-2014

What is Different This Time with Respect to the HIV/AIDS Leadership Groups?

- **Four RFAs vs. one RFA**
- **Scientific priorities have evolved**

Providing Input

- <http://blog.aids.gov>
- **Network Meetings**
- **Ad hoc Consultations**

Additional information is available on the NIAID website at: www.niaid.nih.gov