

# Role of the Microbicide Trials Network (MTN) in the DAIDS HIV Prevention Landscape



## MTN Regional Meeting

Carl W. Dieffenbach, Ph.D.  
Director

Division of AIDS, NIAID, NIH

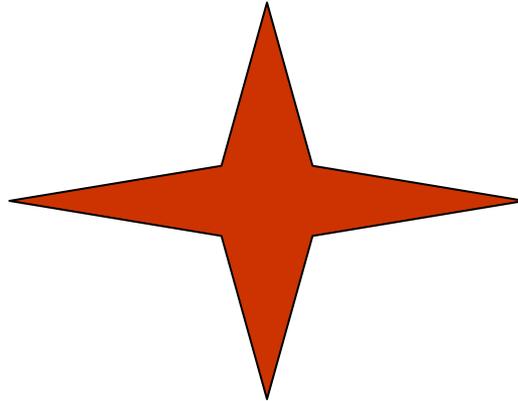
*September 9, 2008*



# Vision for DAIDS

---

**Support the best peer reviewed science; focus on the highest priority science; maintain flexibility**



**Accelerate the pace of discovery**

**Team work & partnership**

**Culture of openness, transparency and information sharing**

# Clinical Research Priorities

**Microbicides**

**Prevention of  
HIV  
Infection**

**Translational  
Research /  
Drug  
Development**

**HIV  
Vaccines**

**Mother to Child  
Transmission**

**Optimization of  
Clinical  
Management  
including  
Co-Morbidities**

**Populations**

# Division of AIDS Office of the Director

Science Planning & Operations Branch

Scientific Communications & Information Branch

Office of Clinical Site Oversight

Office for Policy in Clinical Research Operations

Pharmaceutical Affairs Branch

Human Subjects Protection Branch

Regulatory Affairs Branch

Policy, Training & QA Branch

Clinical Research Resources Branch

Basic Sciences Program

Pathogenesis & Basic Research Branch

Targeted Interventions Branch

Epidemiology Branch

Prevention Sciences Program

Microbicide Research Branch

Prevention Research Branch

Therapeutics Research Program

HIV Research Branch

Complications & Co-infections Research Branch

Drug Development & Clinical Sciences Branch

International Maternal Adolescent Pediatric Branch

Vaccine Research Program

Preclinical Research & Development Branch

Vaccine Discovery Branch

Vaccine Clinical Research Branch



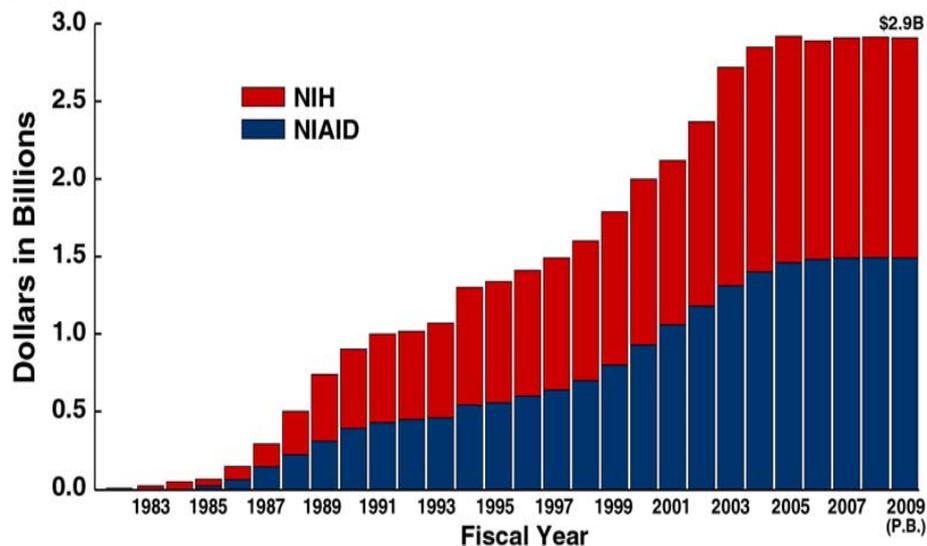
# Challenges Ahead

---

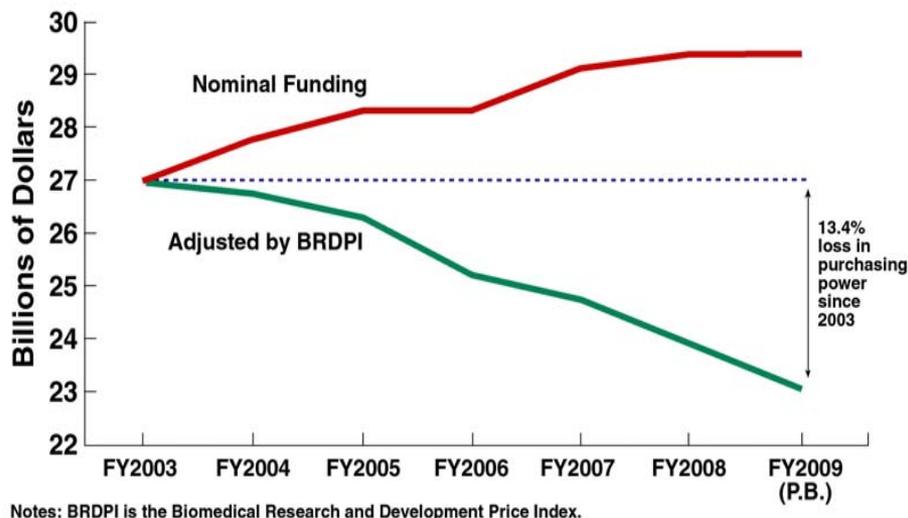
- We are facing major challenges in HIV prevention, treatment and care.
- A robust research agenda is essential to address these challenges. The MTN, the other clinical trial networks, community groups and other stakeholders are integral to conceiving and successfully executing this agenda.
- We are confronting these challenges in a time of budgetary constraint.

# Amount of Funding and the Impact of Inflation on Purchasing Power

## NIH and NIAID AIDS Research Funding FY 1982-2009 (PB)



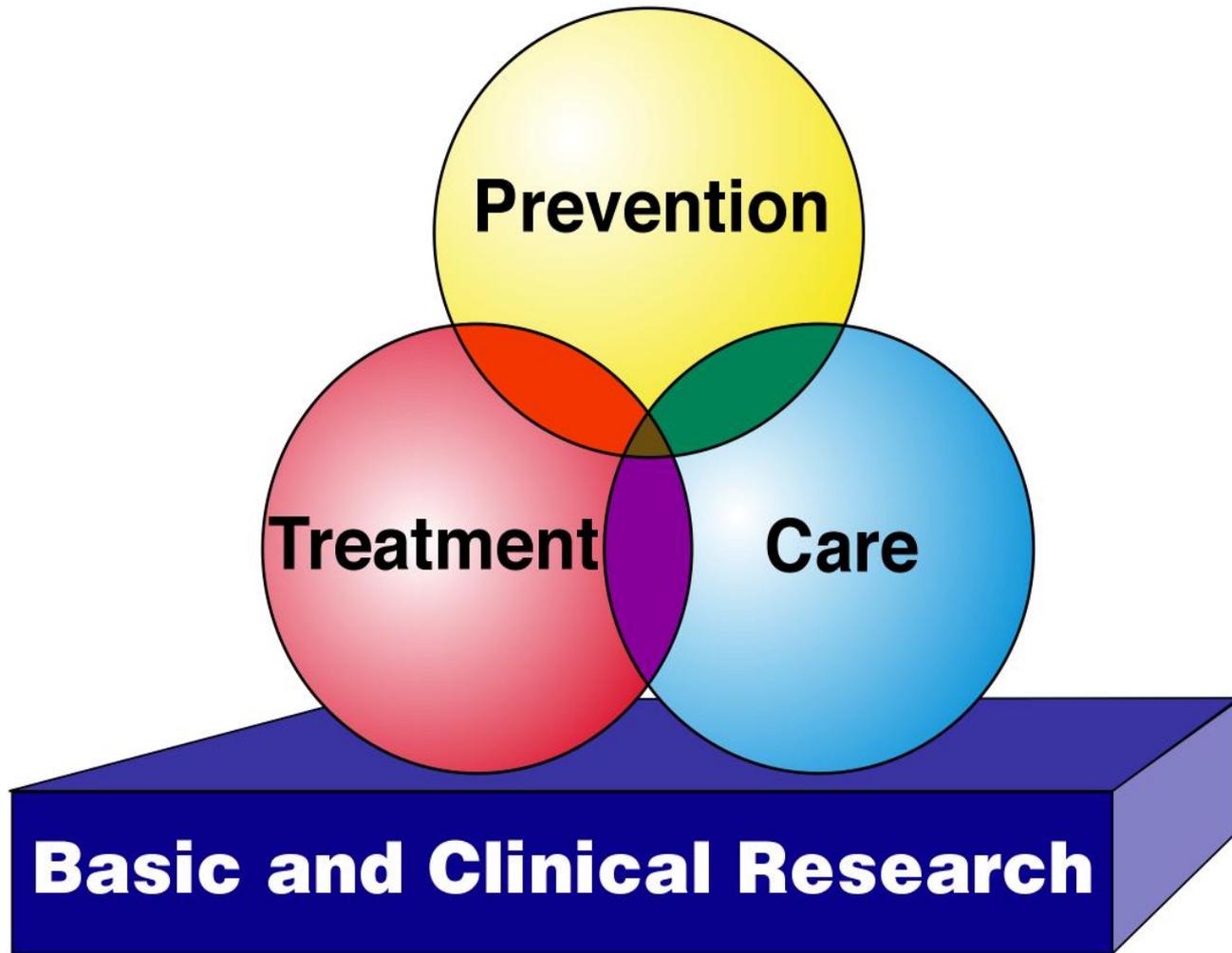
## Inflation Eroded Gains in NIH Funding Real and Nominal NIH Funding Levels Since 2003



When combined with devaluation of the dollar against other currencies, this impact is magnified

# **Confronting AIDS in the 21st Century**

---



# Approaches to HIV Prevention

---

- Education and behavior modification
- Condoms, and other barrier methods
- Treatment/prevention of drug/alcohol abuse
- Clean syringes (i.e. needle exchange programs)
- **HIV/STI testing and counseling**
- **Interruption of mother-to-child transmission**
- **Circumcision**
- **Topical microbicides**
- **Pre-exposure prophylaxis**
- **Vaccination**

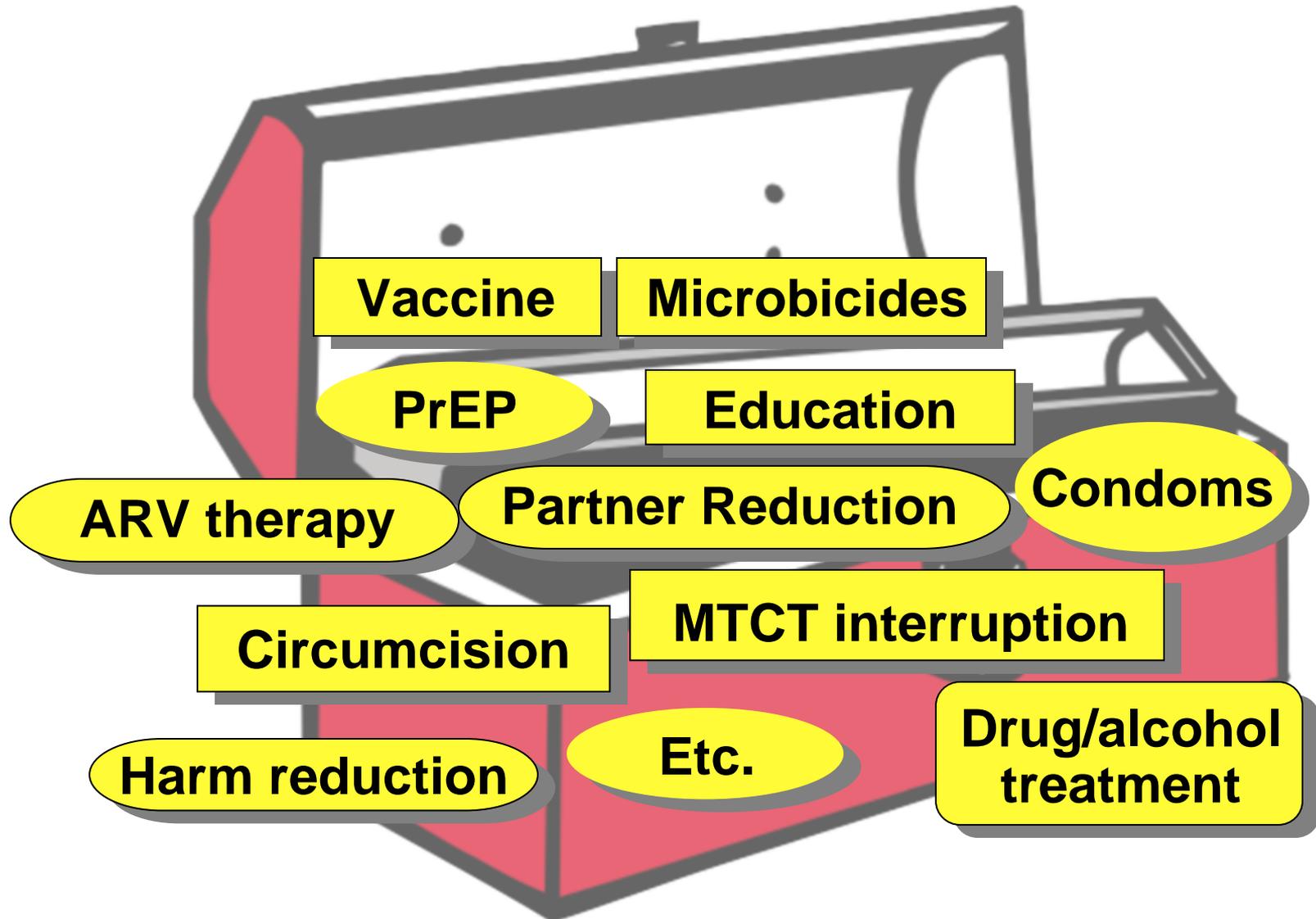
# **HIV Prevention Research: Guiding Principles**

---

- **Multiple strategies needed to assemble a well-rounded “prevention toolkit.”**
- **No one prevention strategy will be 100% effective, appropriate to or accepted by everyone.**
- **Multiple prevention strategies must be evaluated in different populations, domestically and globally, to determine the best combinations for a given population.**

# A Comprehensive HIV Prevention “Toolkit”

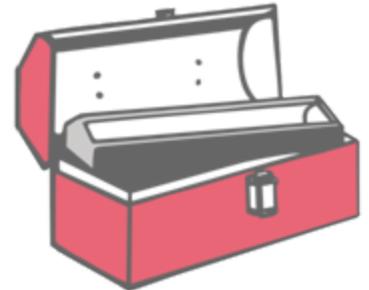
---



# Role of the MTN

---

- Prove the concept
  - Show that a topically applied product can substantially reduce HIV transmission
- Maximize the effectiveness
  - Adherence
  - Route of administration
  - Safety
- Integrate into combination prevention strategies and programs



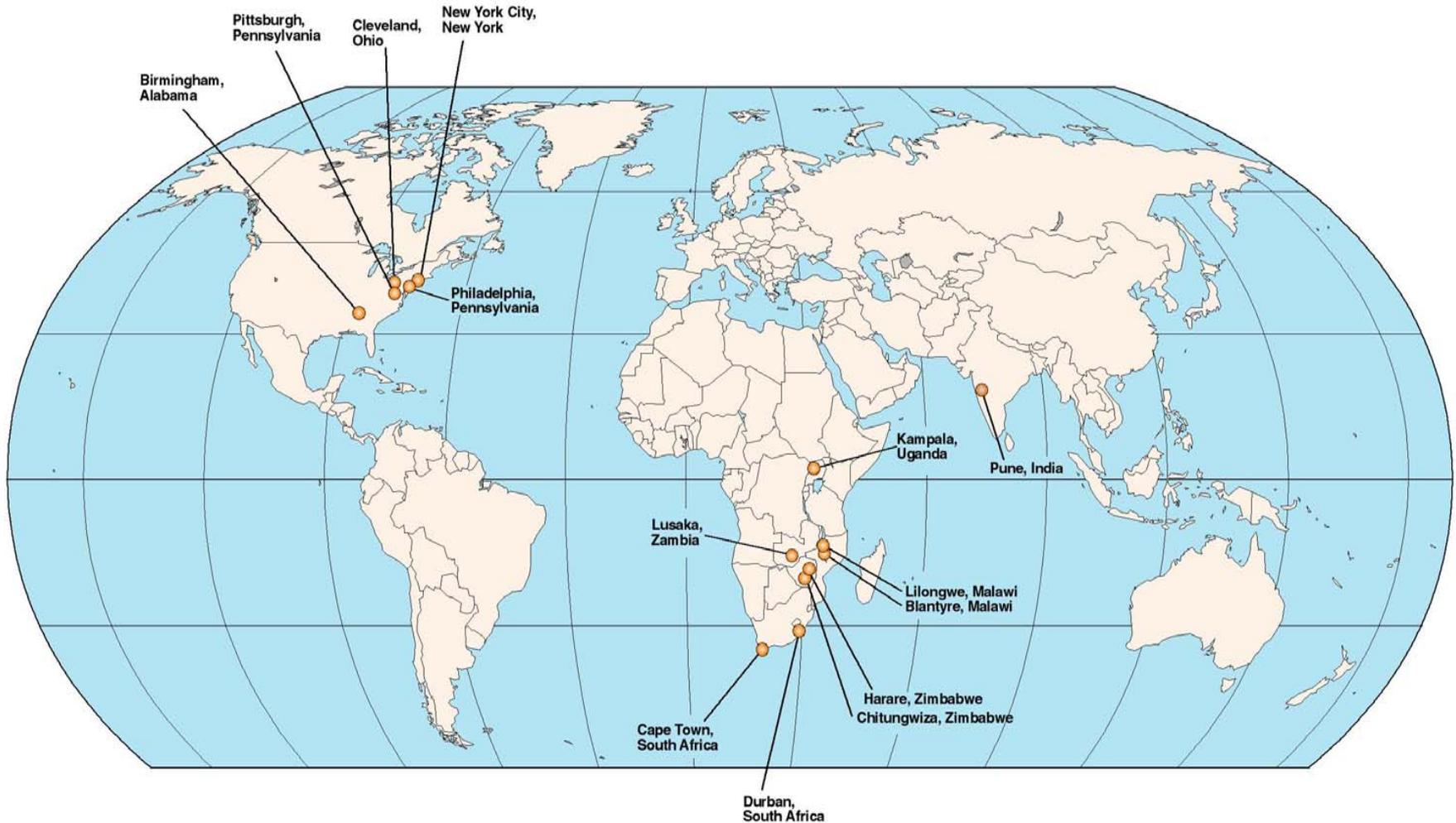
# Much Accomplished, Much to Do

---

- The first two years as a new network have been amazing
  - HPTN 035
    - Target accrual met
    - High retention rate
    - Quality and timely data
    - On schedule
  - MTN 003/VOICE
    - Unique, innovative study design
    - Addresses critical questions in prevention research

# Clinical Research Sites Affiliated with MTN by City

---



# Looking Forward

---

- The NIH and NIAID top HIV research priority is prevention
- We must develop combination prevention methods that can be programmatically implemented to reduce new infections worldwide
- A cornerstone of the NIH agenda is the identification of a safe, acceptable and effective topical microbicide that prevents HIV infection

Thank you!

Questions