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OFFICE OF THE DIRECTOR  
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES  
NATIONAL INSTITUTES OF HEALTH  
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DATE: July 28, 2000  
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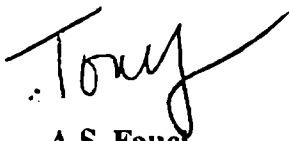
OUR FAX #: 301 496-4409

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REMARKS:

Dear Sandy:

As per our recent conversation, please use this proposal for your own internal purposes and do not distribute since it is merely a draft that has not been cleared through any of the participating groups. Thank you.

Sincerely,

  
A.S. Fauci

**JUL 27 2000**

**Durban Initiative on AIDS Control  
National Institute of Health Proposal**

**Durban Initiative on AIDS Control  
NIH Proposal  
July 27, 2000**

**Introduction.**

The Impact of HIV/AIDS on Sub-Saharan Africa can only be described as devastating. It is an infectious disease disaster that has already killed millions of people in the prime of their lives and left in its wake a horrific toll of shattered families, crowded orphanages, economic deterioration and social disintegration. Unless dramatic and drastic actions are taken this unacceptable toll of disease and death will inexorably continue and expand. Moreover, families, communities and societies worldwide are affected, but nowhere is the effect more pronounced and the need to intervene greater than in Sub-Saharan Africa where nearly 25 million individuals are currently living with HIV/AIDS.

"The persistent infectious disease burden is likely to aggravate, and in some cases may even provoke economic decay, social fragmentation, and political destabilization in the hardest hit countries..." (NIE 99-17D "The Global Infectious Disease Threat and Its Implications for the United States")

The impact on Sub-Saharan Africa, where 71% of the world's HIV-infected individuals reside, has been particularly hard hit and remains the most vulnerable region.

South Africa, with a population of nearly 42 million, now has the largest number of people living with HIV/AIDS in the world – 4.2 million adults, most of whom are 15-49 years of age. The health care delivery system is overburdened and decaying. Existing prevention programs are clearly not working as the epidemic in South Africa continues to grow rapidly. Young women are particularly vulnerable. The annual survey of women attending public health antenatal clinics showed that almost 23% were HIV positive by the end of 1998, a 33.8% increase over the previous year. Some provinces are more affected than others, with the highest increase in KwaZulu-Natal.

There is an urgency to reduce the impact of HIV on individuals, communities, and societies, and to reduce the number of new HIV infections. This urgency requires that action at an unprecedented scale be undertaken.

The purpose of this document is to outline a specific plan of action, with an initial focus on what we know works, with the goal of assisting South Africa in establishing comprehensive programs and national guidelines for HIV/AIDS surveillance, care and prevention of HIV/AIDS that reaches both urban and rural settings. This plan is proposed to stimulate discussion. To be successful in the implementation of this plan it will be essential for the agencies of the U.S. Government most concerned with this problem: USAID, Department of State, FDA, CDC, NIH and other agencies work closely on the implementation of this coordinated effort. It is also key that effective working relationships are developed with the South African Government, the World Health Organization, UNAIDS and other UN agencies or the implementation of this program will be compromised.

## **Components of the action plan**

The proposed plan is designed to achieve two immediate 5-year goals – to improve care and treatment of HIV infected persons, and to strengthen HIV/AIDS prevention programs. In addition, we propose to engage South Africa in a longer-term program to identify approaches that will effectively halt the spread of HIV, although these programs are not considered in the initial five-year costs. The highlights of this plan include the following elements:

- Provision of medical care and treatment, including provision of anti-retrovirals and drugs to treat HIV infection and its complications in adults and children, with the goal of raising the level of care and treatment to that which is the highest attainable and sustainable within 5 years.
- Expanding prevention programs and integrating them with provision of care, focusing initially on areas of highest impact, with the goal of halving the number of new infections yearly within 5 years. This will include:
  - Expansion of voluntary counseling and testing programs (VCT)
  - Expansion of education and behavioral interventions at the individual/family/community level with an emphasis on safe sex, condom use and abstinence and targeted the most vulnerable populations
  - More effective diagnosis and aggressive treatment of sexually transmitted diseases (STDs), particularly ulcerative STDs
  - Provision of drugs to prevent maternal-infant transmission
- Long-term research to develop additional interventions, especially vaccines and topical microbicides that could completely halt the spread of HIV/AIDS

## **Building Capacity and Capabilities to Implement the Action Plan**

The capacity and expertise to provide basic medical care at clinics, hospitals, schools, and research institutions would need to be vastly strengthened in order to implement even a basic program of HIV/AIDS prevention and care in South Africa. Substantial initial focus in three general areas will be required: improving the health care delivery system; strengthening core capabilities; and provision of adequate operational resources.

- **Health Care Delivery.** South Africa has a well-organized health care delivery system. However, this system lacks critical features necessary to deliver the highest level of care and treatment for HIV-infected persons. We propose a program that would, in the next 3 years, upgrade or build health care centers capable of delivery the highest quality comprehensive HIV/AIDS care and prevention programs. The dimensions of this phase remain crude estimates, but we believe that the establishment of 40 HIV/AIDS Clinical Care Center throughout South Africa would be a reasonable place to start. Most of these center would need to be located in regions of high transmission (KwaZulu Natal, Guateng, Durban and Capetown). The immediate goal of these centers would be to implement an integrated care and prevention program for their target population; and to conduct demonstration projects

to delineate the highest level of care and treatment attainable and sustainable in South Africa.

To be successful, these centers will have to provide:

- Basic services and infrastructure for labs, clinics and hospitals (clean water, dependable electricity, transportation services, etc)
  - Equipment for the conduct of basic lab and diagnostic procedures
    - Basic clinical laboratory testing (e.g., blood tests, radiology, etc)
    - Standard serological and microbiological assessment for HIV, TB, STDs, opportunistic infections (OIs).
    - Rapid screen for HIV infection
    - PCR capabilities in sites of demonstration projects and clinical research
    - HIV Viral load capabilities
    - CD4+ counting
    - Standard diagnostic tests for toxicity evaluation
  - A cold chain
  - Data management and data transmission capabilities; information systems
  - Pharmaceutical programs to manage provision and supply of therapeutic agents
  - Possible delivery of antituberculosis drugs through DOTS and/or STD treatment
- 
- **Strengthening core capabilities.** The most important need is to have enough trained people on site to deliver the level and type of health care needed. This need includes not only physicians skilled in the use of antiretroviral therapy and HIV/AIDS, but also nurses, counselors, paramedical personnel, community health workers, pharmacists and other health care personnel. These enhanced capabilities are required to conduct feasibility research and implement a comprehensive HIV/AIDS care and prevention program that is considerably improved over what is currently available. This includes, but may not be limited to:
    - Trained medical care providers and associated personnel: doctors, nurses, counselors, outreach workers, pharmacists, phlebotomists, blood bank specialists, medical technicians, medical record experts, etc
    - Data management and data transmission capabilities; information systems
    - Project management capabilities
    - Community liaisons and communication capabilities to the general population

To assist South Africa in this endeavor, we recommend:

- Creation of an HIV/AIDS Corp of Health Care Educators and Providers, including but not limited to physicians, nurses, counselors/trainers, managers, medical technicians, pharmacists, information/data base/computer specialists, who will provide support and assistance in implementing prevention and care initiatives; and train local health care providers, managers and HIV/AIDS educators and leaders. This could be part of an international Corp coordinated by an organization such as WHO/UNAIDS.
- Incentives to join the Corp could be educational loan paybacks; additional credits toward retirement within PHS/Civil Service/DOD; overseas deployment bonuses

- **Provision of basic tools for care and research.** To dramatically improve the level of care and prevention services in South Africa will require provision of the necessary lab and diagnostic tests, therapies, equipment, computers, and supplies as generally outlined above under general needs. We recommend creation of an innovative public-private partnership council at the highest level of the South African and U.S. governments to
  - Identify needs;
  - Create plans for provision of the necessary tools through donations, low-cost bulk purchases, technology transfer for in-country production, development of less expensive, field-ready alternatives where such are necessary, and other creative options

### **General principles for program implementation**

- The program must clearly be a South African Program with contribution and participation from the United States and other developed countries, UNAIDS, the World Bank and the World Health Organization.
- All stakeholders should be actively involved in the planning and implementation of national and local programs; this includes the valuable contribution of community leaders/representatives and traditional healers
- Initiatives must build upon and utilize existing health care delivery and research capacity in South Africa
- Delivery of health care and prevention activities must be integrated. This will ensure the synergy needed to achieve the long-term public health goal of stopping the spread of HIV/AIDS.
- The activities of all U.S. agencies and other partners must be tightly coordinated; information sharing is essential.
- Public-private partnership will be critical to success and should be built or strengthened wherever feasible
- South Africa should be encouraged to consider any changes it sees fit to existing policies/laws that would facilitate this effort.
- Donor funds should be leveraged by South Africa to acquire from other public and private organizations and philanthropies the additional funds necessary to attain the stated goals.

### **Role of the National Institutes of Health**

The role of the National Institutes of Health (NIH) is envisioned to be substantial in the following areas:

- The design, implementation and conduct of clinical, preclinical and fundamental research, including feasibility research/demonstration projects
- Research training
- Research infrastructure
- Research ethics

### **Resource Requirements**

**Durban Initiative on AIDS Control  
Cost Estimates (in millions of \$)**

| Activity                                                          | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total          |
|-------------------------------------------------------------------|--------|--------|--------|--------|--------|----------------|
| <b>Human Resource Development</b>                                 |        |        |        |        |        |                |
| Basic <sup>1</sup>                                                | 125    | 200    | 300    | 350    | 420    | 1395           |
| Specialized <sup>2</sup>                                          | 25     | 35     | 50     | 75     | 100    | 285            |
| Specialized Training in HIV/AIDS Care and Prevention <sup>3</sup> | 72     | 72     | 72     | 72     | 72     | 360            |
| International HIV/AIDS Corps                                      | 125    | 132    | 150    | 165    | 180    | 752            |
| Improving Clinical Care Facilities <sup>4</sup>                   | 200    | 220    | 242    | 266    | 290    | 1218           |
| Treatment and Prevention Demonstration Projects <sup>5</sup>      | 150    | 165    | 182    | 200    | 220    | 917            |
| <b>Prevention Education and Intervention</b>                      |        |        |        |        |        |                |
| Voluntary Counseling and Testing <sup>6</sup>                     | 250    | 275    | 303    | 331    | 365    | 1524           |
| Mass Media Campaign                                               | 50     | 55     | 61     | 67     | 75     | 308            |
| Education campaigns targeted at youth and family <sup>7</sup>     | 100    | 110    | 121    | 133    | 150    | 614            |
| Cost of Antiretrovirals <sup>8</sup>                              | 2000   | 3250   | 4250   | 5000   | 6300   | 20800          |
| Antiretroviral monitoring <sup>9</sup>                            | 400    | 800    | 1400   | 1750   | 2100   | 6450           |
| OI Screening and Treatment <sup>10</sup>                          | 500    | 750    | 1000   | 1200   | 1600   | 5050           |
| STD Screening and Treatment <sup>11</sup>                         | 200    | 225    | 250    | 275    | 300    | 1250           |
| <b>Maternal-Infant Transmission</b>                               |        |        |        |        |        |                |
| Nevirapine <sup>12</sup>                                          | 1      | 1      | 1      | 1.5    | 2      | 6.5            |
| State of the Art (AZT) <sup>13</sup>                              | 14     | 15     | 16     | 17     | 18     | 80             |
| <b>Total</b>                                                      |        |        |        |        |        | <b>41009.5</b> |

<sup>1</sup> Training 42,000 new nurses, lab techs, paramedical, counselors, etc to staff clinics and associated programs. Cost estimated at \$10,000 per person per year, to be phased in over a five year period to achieve 42,000 new personnel.

<sup>2</sup> Expanding number of physicians by 1,000 by year 5 at a cost of \$100,000 per physician per year.

<sup>3</sup> Continuing medical education for physicians, counselors and other medical personnel, training goal is to have 4,200 health care providers at \$2,000 per, advanced training for 2,100 infectious disease doctors at \$10,000 per and training of general prevention counselors ~ 210,000 at \$1,000 per student.

<sup>4</sup> Establish or improve 10 tertiary care facilities at \$50 million per facility plus 50 primary care facilities at \$10 million per facility.

<sup>5</sup> Establish three demonstrations at \$50 million per project.

<sup>6</sup> Counseling and HIV testing for 5 million persons per year at \$50 per person

<sup>7</sup> Education outreach targeted at 10 million youth at \$10 per person

<sup>8</sup> Estimated at \$3000 per patient, 2.1 million patients phased in over 5 years.

<sup>9</sup> Includes costs of viral load, CD4 and ancillary testing at \$1000 per person per year for 2.1 million people phased in over five years.

<sup>10</sup> Goal is to screen 4.1 million people four times a year at \$100 per visit and provide 4.1 million treatments per year at \$100 per treatment.

<sup>11</sup> Screen and treat 1 million people twice a year at \$100 per visit.

<sup>12</sup> Screen and treat 70,000 pregnancies at \$14 per pregnancy, including the cost of drugs

<sup>13</sup> Based on the estimate of \$200 per pregnancy in 70,000 pregnancies

## Appendix

Durban Initiative on AIDS Control  
National Institutes of Health Proposal

## **Appendix I: Details of specific approaches to the HIV/AIDS problem.**

### **Voluntary Counseling and Testing (VCT)**

#### **Obstacles:**

- Fear that confidentiality won't be maintained
- Fear of discrimination/violence from community or partner/family if HIV positive
- Lack of understanding of HIV infection
- Availability of rapid testing methods and getting results on-the-spot; getting women to return to learn results; lack of clarity re: the role of the partner
- Impact of VCT delivery method on willingness of individual to learn result
- Perception that test results don't matter – i.e., that there is not any care which is available and make any difference if the result is positive

#### **Needs:**

- Infrastructure strengthening to provide appropriate facilities
- Large scale community awareness programs
- Rapid test to detect HIV infection
- Operational research to determine best practices
- National policy/laws that address confidentiality
- Community support
- Linkage to treatment intervention programs which provide care and treatment and are seen to make difference

#### **Initial plan:**

- Expand VCT programs linked to demonstration centers where care can be provided, and based in appropriate non-health care settings, such as places of employment, schools, churches
- Establish training and accreditation program for locally based counselors
- Expand evaluation and use of Abbott Determine rapid assay for HIV-1/2
  - Sensitivity 99.6%; specificity 98.0% in recent evaluation in Western Cape
  - Even better results in Kwa Zulu - Natal
  - Evaluate in 10 additional settings; 2 per province and compare with standard lab methods
  - Does not require cold storage; special training; special equipment or reagents
- Initiate clinical trials at the community level to evaluate the social impact of VCT (PTN plan)

## **Education and behavioral interventions**

### **Obstacles:**

- To be defined in local contexts

### **Needs:**

- Utilization of occupational and social settings as entry point to identify families of HIV-infected individuals
- Focus on families and communities

### **Initial plan:**

- Expand prevention programs for youth; design and conduct 20 demonstration projects on impact of education/behavioral interventions in schools using peer educators and volunteers; measure knowledge of HIV; risk taking behaviors; HIV acquisition; STD acquisition; pregnancy; attitudes about gender/sexuality; include youth-focused reproductive health services
- Expand prevention programs for other vulnerable populations
- Conduct 20 demonstration projects in collaboration with major private sector companies to reach individuals through their occupational setting; provide comprehensive prevention/care package; measure new HIV infections every 6 months over time
  - Condom promotion (male and female)
  - Social marketing
  - Mass educational activities
  - Voluntary counseling and testing
  - Peer counselors
  - OI prophylaxis
  - Syndromic treatment of STDs
- Establish a toll free national hotline or other locally defined methods of mass communication to provide referrals and information on HIV/AIDS
  - Emphasize quality of counselors, provision of support information, referral database
  - Emphasize utilization of local resources
- Initiate demonstration project in collaboration with local communities to maximize education and prevention programs
- Initiate international community level, randomized controlled trial aimed at reducing HIV incidence in adolescent women (PTN plan)

## **Prevention of Mother-infant Transmission (MIT)**

### **Obstacles:**

- Lack of access to VCT and getting results quickly
- Lack of access to proven interventions
- Lack of trained personnel to deliver education and intervention
- Difficulties in reaching women early enough to educate and plan; and to provide drug to take at home when labor starts
- Lack of affordable intervention to prevent transmission during breastfeeding
  - Cost of formula
  - Stigma if women don't breastfeed in some communities?
  - Cultural beliefs that reinforce breastfeeding?
  - Conflicting messages re: risk/benefit of breastfeeding
- Uncertainty re: long term impact of resistance to NVP
- Resolution of ethical issues of lower cost mass NVP vs. targeted approach
  - Lack of information on adherence if women don't know their status
- Lack of knowledge re: level of adherence possible

### **Needs:**

- Conduct a demonstration project to evaluate 2 dose NVP for potential impact in South Africa and that includes: training, development of communication strategies and messages for sample populations; development of breastfeeding policy; research on role of male partner; community education; measurement of adherence and outcomes, including resistance
  - Training to include background on epidemic; MIT; the proposed intervention; role of staff in counseling; conduct of rapid HIV test; recognition of side effects/drug-related rash
  - Increase in number of staff and resources required
- Research to explore practical and affordable alternatives to breastfeeding
- Research on feasibility of second line mass therapy to women who decline enrollment in targeted program

**Initial plan:** Pilot program of NVP to reduce MIT in South Africa

**Goal:** to determine feasibility, identify obstacles and methods to overcome them in nationwide program of provision of drug to prevent MIT of HIV; to conduct adjunct research to identify more effective interventions and approaches

### **Plan:**

Implement a pilot 3 months VCT program for all pregnant women in 10 health serviced (2 in each of 5 provinces), selected to be representative of the public health service in South Africa

Offer pregnant women found to be HIV+ the 2 dose NVP intervention under an approved clinical protocol

Counsel all women on advantages and risks of breastfeeding. Provide formula to women who choose it. Encourage women who elect breastfeeding to breastfeed exclusively and to wean at 6 months

Assess obstacles; reassess strategy as treatment for the general population becomes more available so that in utero exposure can also be addressed

Follow women at 10-14 weeks post partum to assess

HIV infection using PCR in infants

Level of NVP resistance in a sample of women and infants;

Offer enrollment in additional follow up protocol for those harboring resistant strains.

Adverse events

#### Additional research

- Impact of extended NVP during breastfeeding for those who elect to breastfeed
- Design and implement safety/feasibility study of mass therapy to women who decline VCT (PTN plan)
- Complete phase I/II of safety and pharmacokinetics of NVP given daily, twice a week, or weekly in breastfeeding infants from birth to 6 months of age (PTN)
- Conduct phase II study of chlorhexidine wash to prevent MIT
- Design and implement study to evaluate drug intervention (NVP) in newborns only, for use when it is not possible to treat the mother (PTN plan)

## Effective treatment of STDs

### Obstacles:

- Lack of epidemiological data on prevalence/incidence of STDs
- Cost of and access to good medical care and to drugs
- Stigma; Unwillingness to attend clinics
- Extensive migrant labor patterns which foster spread of STDs and HIV through commercial sex

### Needs:

- Research to document prevalence/incidence of STDs
  - Carletonville: syphilis 5-23%; gonorrhoea 3-16%; chlamydia 4-9%
  - Horizon's project now doing presumptive STD treatment of sex workers
- Behavioral intervention to increase willingness to seek treatment for STDs
- Access to drugs
- Clearer paradigm for STD treatment strategies for different populations

### Initial plan:

- Strengthen STD education, surveillance and syndromic management at public health centers
  - Initiate and evaluate outreach and counseling programs for their success in increasing the number of women who seek and complete treatment for STDs
  - Provide all necessary diagnostic testing, care, and drugs for STD treatment
- Conduct demonstration project in multiple representative sites to evaluate and compare different algorithms for more effectively diagnosing STDs
  - determine the feasibility and cost of utilizing only advanced technologies (PCR) relative to existing methods (syndromic and/or culture) or a mixture of approaches
- Include South Africa in 3 year study of hybrid syndromic/mass STD treatment (PTN plan)
  - Core transmitters given periodic presumptive STD treatment in addition to syndromic treatment and standard of care
  - Bridge transmitters given syndromic STD treatment and standard of care
  - General population given national standard of care
- Integrate new information into demonstration projects as necessary

## Provision of care for HIV Infection and its complications

### Obstacles:

- Lack of epidemiological data on prevalence/incidence/impact of OIs
- Widespread inadequacy of access to basic health care and trained medical personnel to administer it
- Cost of and access to drugs
- Inadequate monitoring to avoid for emergence and spread of resistant strains
- Other Infrastructure and training as outlined above

### Needs:

- Nationwide guidelines and programs to provide potent therapeutic regimens to treat HIV infected children and adults, and to treat and prevent the complications associated with HIV/AIDS
- Research to establish best practices on use of ARV drugs in infected adults and children
- Research to document prevalence/incidence/impact of OIs in adults and children

### Initial plan:

- Design and implement 20 demonstration projects (4 each in 5 provinces) at representative centers in urban and rural areas with the goals of (a) optimizing clinical management of HIV infection in adults and children, (b) development of national clinical guidelines for care of infected adults and children
  - Evaluate potent antiretroviral regimens for impact on disease in adults and children; safety/toxicity; acceptability; compliance; emergence of resistance and its impact
  - Evaluate the effect of endemic infections (malaria, TB) on HIV disease; evaluate the impact of treating endemic infections on HIV disease; evaluate safety, acceptability, compliance, emergence of resistance; clinical outcome
  - Initiate pilot studies to define the most practical prophylaxis regimens (TB, Bactrim 2x weekly, fluconazole weekly) and monitor the impact on resistance patterns of endemic pathogens; monitor safety, acceptability, compliance, emergence of resistance, outcomes.
  - Evaluate the effect of nutritional supplementation on HIV associated weight loss; evaluate nutrition as an adjunct to drug therapy/prophylaxis
- Establish national cohorts to define concomitant complications, risk factors, and incidence.
- Evaluate anti-retroviral therapy (ART) in HIV positive persons with goal of preventing HIV transmission to uninfected sexual contacts, specifically, in South Africa, discordant couples (PTN plan)
- Evaluate ART as pre-exposure prophylaxis (PTN plan)
- Evaluate ART as post-exposure prophylaxis in sexual assault victims (PTN plan)

## **Development of microbicides**

### **Obstacles:**

- Minimal experience in conducting microbicide HIV vaccine trials
- Difficulty in explaining purpose of research to women; lack of understanding that efficacy is not determined in early trials
- Requirement of partner consent or use of condoms to participate in early trials
- Lack of precedent or policy re: how effective a microbicide would have to be for licensure
- Lack of definition of target population
- Distribution/access issues

### **Needs:**

- Additional information on factors influencing participation in trials

### **Initial plan:**

- Launch phase IIb trial of carrageenan microbicide (R01)
- Complete phase I trial of PRO2000/5 gel microbicide in 2 South African sites (PTN)
- Consider additional trials as products become available (PTN plan)

## **Development of vaccines**

### **Obstacles:**

- Few candidates being developed based on subtype C; lack of knowledge of relevance of vaccine subtypes
- Time frame in obtaining US IND to allow export of US-produced candidate vaccines for testing elsewhere
- Lack of experience in conducting HIV vaccine trials
- Lack of clear pathway for getting approval for HIV vaccine trials in South Africa
- Lack of policy re: how effective a vaccine would have to be, and for how long to justify implementation
- Lack of definition of target population

### **Needs:**

- Additional candidate vaccines suitable for testing in South Africa
- Broader community understanding of vaccine clinical research to manage expectations and increase acceptance and participation
- Improved understanding of the virological and immunological characteristics of HIV infected persons and of the epidemiology of HIV in specific groups
- Knowledge of potentially protective epitopes in this population

### **Initial plan:**

- Continue and expand epidemiological, virological and immunological studies to prepare for vaccine trials
  - MHC characterization; HIV characterization; CTL epitope identification, particularly in acutely infected individuals; evaluation of highly exposed, uninfected individuals; determination of incidence of infection in target groups
- Continue and expand community outreach at potential trial sites
  - Develop and initiate program to train community leaders through exchange program with US-based community educators
- Support development of VEE replicon candidates based on clade C
  - Initiate interagency agreement between NIAID and DOD to expedite development of second generation VEE replicon for testing in South Africa
- Support collaborations with Chiron corporation to product clade C based candidate vaccine for testing in South Africa
- Fund additional awards whose goal is to advance development of HIV vaccines for Africa
- Provide additional infrastructure support for existing VTN and PTN trial sites
- Expand training of South African researchers in good clinical practice in general and vaccine trials specifically
- Involve US FDA representatives in meetings and discussions about products being developed for South Africa
- Support modeling studies on public health impact of vaccines with different efficacy characteristics and different target populations
- Provide funding to WHO/UNAIDS and IAVI to specifically address and solve access issues