

**Turning the Corner on the  
AIDS Pandemic:  
Focusing the Science-Driven HIV  
Research Enterprise**

**October 2017**

# Setting the 2027 Research Agenda

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- **Every 7 years, NIH competitively reviews its HIV network funding, addressing significant changes in research priorities that have occurred since the last competition**
- **By establishing a forward-looking agenda now, NIH will determine the focus and structure of its HIV clinical trial networks through 2027**



# **We Stand on the Shoulders of Past Successes**

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- **Therapeutics**
- **Development of PrEP**
- **Sex-specific protection**
- **Virtual elimination of perinatal and breastfeeding transmission**
- **Building on RV144**
- **Development of long-acting technologies**

## **Statement on NIH Efforts to Focus Research to End the AIDS Pandemic**

**August 12, 2015**

### **High priority areas of HIV/AIDS research are those that:**

- Reduce incidence of HIV/AIDS through the development of better PrEP and safe and effective vaccines
- Develop the next generation of HIV therapies with improved safety and ease of use
- Discover and develop a cure for HIV/AIDS
- Improve prevention and treatment of HIV-associated co-morbidities and co-infections
- Foster cross-cutting areas of basic research, health disparities research, and training

# Goals for 2027

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- **Ten years from now, imagine that we have:**
  - Long-acting and durable prevention and treatment strategies effective for at least 6 months
  - HIV vaccines with an efficacy greater than 50 percent
  - Cure or ART-free remission in large subsets of HIV-positive people of all ages
  - Normalized life expectancy for HIV-positive people
  - Reduced the burden of infectious and non-infectious co-morbidities, including TB co-infection

**To achieve these goals in  
2027, how should we refine  
the clinical trials networks  
today?**

# What Levers Can NIH Pull?

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- **Biomedical innovation**
- **Identify behavioral patterns and interventions**
- **Forge and nurture partnerships to extend reach**
- **Facilitate hand-off to implementers**
  - **PEPFAR, health systems, Ryan White, HRSA, CDC, foreign governments**

# Science Levers

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- **Biomedical innovation**
- **Identify behavioral patterns and interventions**
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# Fostering Biomedical Innovation

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- **Three key areas of research emphasis will be driven by intervention, covering all target populations:**
  - Prevention
  - HIV vaccines
  - Therapeutics
  
- **Form follows function. NIH will move to a triad of clinical trial networks:**
  - Prevention
  - HIV vaccines
  - Therapeutics

# Prevention Scientific Foci

**Novel biomedical methods  
of HIV prevention**

**Behavioral and social  
science partnerships**

**Protection in populations  
most at risk, including  
adolescents, young adults,  
and U.S. minorities**

# Prevention

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- **Develop tools that are:**
  - Safe
  - Acceptable
  - Desired
  - Highly effective in preventing HIV acquisition
  - Protective system-wide
  - Next generation, where appropriate (e.g., PEP)
- **Define the needs of vulnerable populations and tailor-fit prevention strategies**
  - Interventions will focus on populations most at risk including adolescents, young adults, and U.S. minorities

# Vaccine Scientific Foci

**Establish efficacy**

**Define correlates  
of protection**

- **What will be the criteria to move a vaccine concept forward for licensure?**

# Vaccines

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- **Evaluate vaccines to prevent HIV acquisition**
  - Once reasonable safety is determined, initiate studies in adolescents and younger children
- **Define correlates of HIV risk and protection**
- **Bridge from phase 2b/3 studies to licensure and market**
  - Partnerships required

# Therapeutic Scientific Foci

**Novel and durable  
therapy**

**Cure**

**Tuberculosis**

**Complications and  
coinfections**

# Therapeutics

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- **Novel and durable therapy for HIV**

- Establish efficacy of long-acting formulations that are fully suppressive and dosed infrequently
- Newer ART during pregnancy, at birth, through childhood and adolescence

- **Cure or ART-free remission from infancy through adulthood**

- Immune-based interventions, including therapeutic vaccines
- Immune activation as a driver of persistence
- Gene/cell therapies

- **Novel and durable therapy for TB**

- Define new TB treatment and prevention strategies across the lifespan, including a vaccine
- Newer TB medications during pregnancy, at birth, through childhood and adolescence

- **Complications and co-infections in adults**

- Define and address mechanisms
- Partner to prevent and treat end organ disease
- Define curative strategies for Hepatitis B co-infection

# **Future Pediatric and Maternal Health Research Agenda**

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- **Prevention of sexual transmission in adolescents**
- **HIV vaccine evaluation in pediatrics**
- **License newer ART during pregnancy, at birth, through childhood and adolescence**
- **Establish ART-free remission from infancy through adulthood**
- **License the newer TB medications during pregnancy, at birth, through childhood and adolescence**
- **Define new TB treatment and prevention strategies across the lifespan, including a vaccine**
- **Limited studies on co-morbidities, specifically neurologic and cognitive issues**
- **Evaluation of vaccines for other infectious diseases (RSV, flu) in HIV exposed and HIV+ children**

# Leveraging Partnerships

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- **Biomedical innovation**
- **Identify behavioral patterns and interventions**
- **Forge and nurture partnerships to extend reach**
- **Facilitate hand-off to implementers**
  - **PEPFAR, health systems, Ryan White, HRSA, CDC, foreign governments**

# Partnerships: The Next Required Step

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- **NIH's role is innovation, moving from bench to bedside, with the goal of public health impact**
- **Maintain existing and foster new collaborations and partnerships**
  - Within NIH, HHS and the Federal Government
  - Foundations and NGOs
  - Private sector
- **Partnering with implementers, facilitating the hand off**
- **Team approach required for partnership formation**

# **Partnerships for Implementation Research**

**Develop combination prevention and treatment strategies**

**Prevent and treat infectious and non-infectious co-morbidities**

**Improve initiation and adherence to prevention and treatment**

**Address cross-cutting issues in infants, children, adolescents and young adults**

# What to Expect

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- **Requesting feedback by November 30, 2017**
- **January 2018: Formal presentation to AIDS Research Advisory Committee**
- **2018: Begin Funding Opportunity Announcement (FOA) authorship**
- **2019: FOAs issued, peer review**
- **2020: Awards made (FY 2021)**



# We Want to Hear from You

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- **Tell us what you think. Share a big vision or a specific note.**
- **Input deadline: November 30, 2017**
- **[NIADnetworkrefinement@mail.nih.gov](mailto:NIADnetworkrefinement@mail.nih.gov)**
- **<https://www.niaid.nih.gov/research/HIV-Research-Enterprise>**