



NIAID: State of the Institute and Priorities in HIV/AIDS Research

Anthony S. Fauci, M.D.

Director

**National Institute of Allergy and
Infectious Diseases**

National Institutes of Health

May 17, 2018



Azar Confirmed as HHS Secretary, Hargan as Deputy HHS Secretary



Alex M. Azar II, JD



Eric D. Hargan, JD

Adams Confirmed as 20th U.S. Surgeon General



Jerome M. Adams, MD, MPH

Jan. 16: U.S. Surgeon-General Adams Visits NIH



Redfield Named CDC Director



Robert R. Redfield Jr., MD

The New York Times

May 23, 2017

W.H.O. Elects Ethiopia's Tedros as New Director General



Tedros Adhanom Ghebreyesus, Ph.D.

April 20, 2018: Dr. Tedros Visit to NIH and Signing of WHO-NIAID MOU



Budget Update

March 23, 2018: FY 2018 Spending Bill Signed into Law

- **Total U.S. budget: \$4.4 trillion**
 - Discretionary budget: \$1.3 trillion
- **NIH receives \$37.3 billion for FY 2018**
 - \$3 billion (9 percent) increase over FY 2017



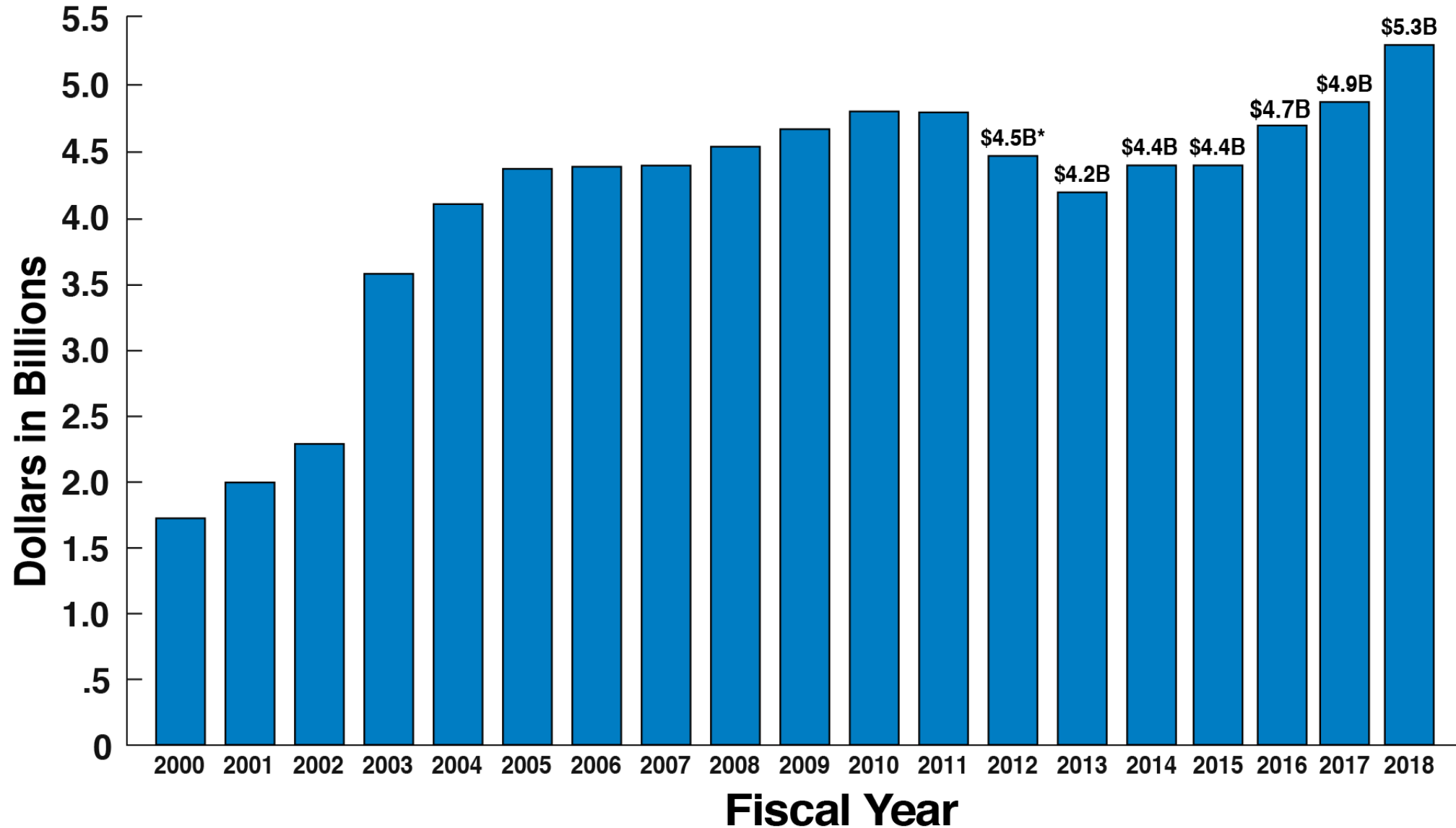
National Institutes of Health

Budget Comparison by Institute/Center

(Dollars in Thousands)

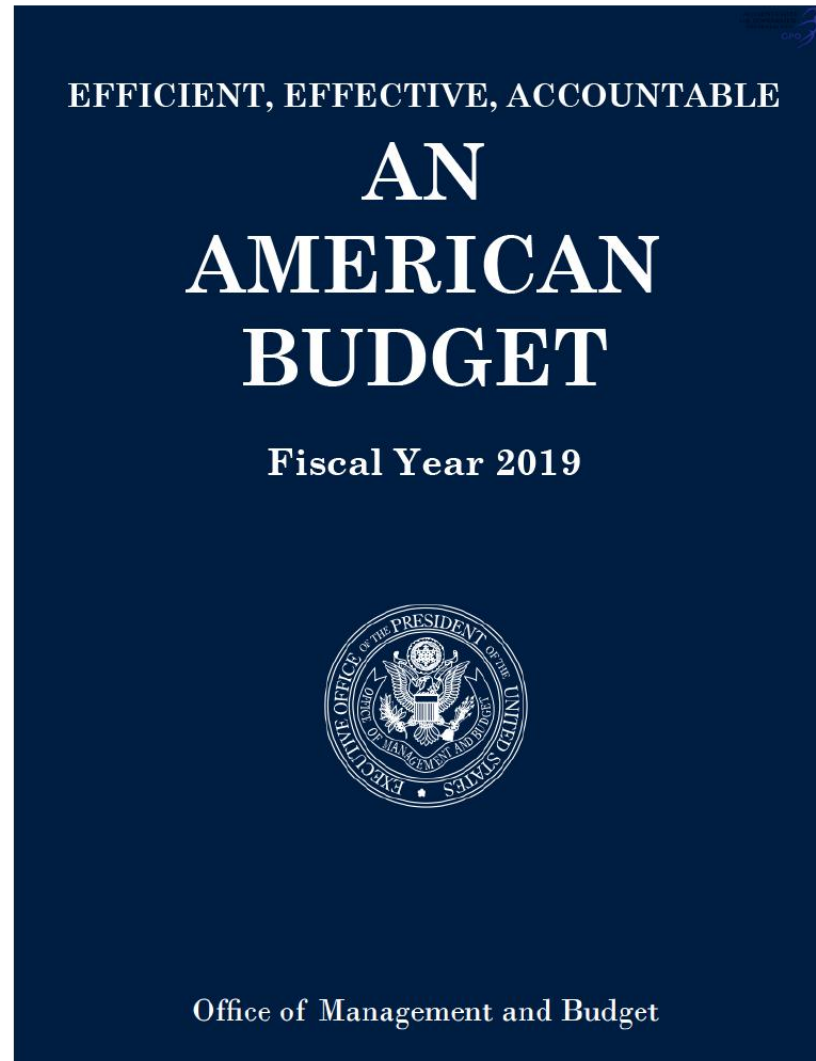
IC	FY 2017 Operating	FY 2018 Omnibus	Percent Change
NCI	\$ 5,659,955	\$ 5,634,800	-0.4%
NIAID	4,905,718	5,260,210	7.2%
NHLBI	3,209,929	3,383,201	5.4%
NHGRI	528,346	556,881	5.4%
NCATS	704,330	742,354	5.4%
NIGMS	2,646,152	2,785,400	5.3%
NIA	2,048,814	2,574,091	25.6%
NIDA	1,070,846	1,383,603	29.2%
Other ICs	11,597,879	12,936,053	11.5%
Subtotal	\$ 32,371,969	\$ 35,256,593	8.9%
OD	1,728,603	1,925,893	11.4%
B&F	128,567	128,863	0.2%
Total	\$ 34,229,139	\$ 37,311,349	9.0%

NIAID Funding, FY 2000-2018



*Beginning in FY 2012, budget no longer passes through funds to the Global Fund.

FY 2019 President's Budget Request Released on February 12, 2018



National Institutes of Health

Budget Comparison by Institute/Center

(Dollars in Thousands)

IC	FY 2018 Omnibus	FY 2019 President's Budget	Percent Change
NCI	\$ 5,634,800	\$ 5,626,312	-0.2%
NIAID	5,260,210	4,761,948	-9.5%
NHLBI	3,383,201	3,112,948	-8.0%
NHGRI	556,881	512,979	-7.9%
NCATS	742,354	685,087	-7.7%
NIGMS	2,785,400	2,572,669	-7.6%
NIA	2,574,091	1,988,200	-22.8%
NIDA	1,383,603	1,137,403	-17.8%
NIRSQ, NIOSH, NIDILRR	-	730,794	-
Other ICs	12,936,053	12,936,053	-11.6%
Subtotal	\$ 35,256,593	\$ 32,562,401	-7.6%
OD	1,925,893	2,004,306	4.1%
B&F	128,863	200,000	55.2%
Total (Program Level)	\$ 37,311,349	\$ 34,766,707	-6.8%
Opioids & Serious Mental Illness	-	750,000	-
Grand Total NIH	\$ 37,311,349	\$ 35,516,707	-4.8%

**The President Proposes
a Budget**

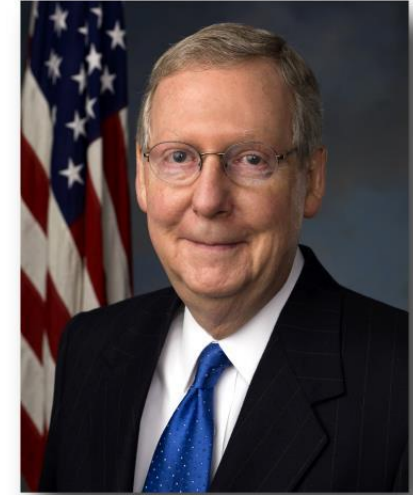


**The Congress Determines
the Budget**

Legislative Update

Senate Leadership in 115th Congress

■ **Majority Leader: Mitch McConnell
(R-KY)**



■ **Minority Leader: Chuck Schumer
(D-NY)**



House Leadership in 115th Congress

■ House Speaker: Paul Ryan
(R-WI) - **retiring**



■ Majority Leader: Kevin McCarthy
(R-CA)



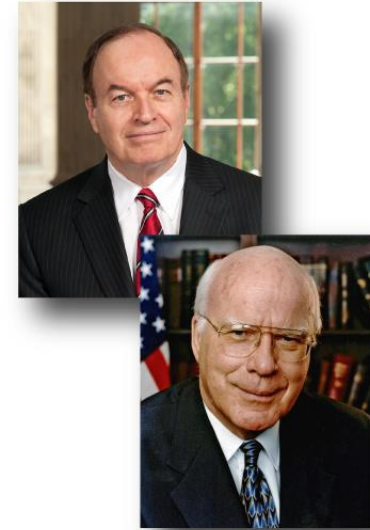
■ Minority Leader: Nancy Pelosi
(D-CA)



Senate Committee Leadership

■ Senate Appropriations Committee

- Chair: Richard Shelby (R-AL)
- Ranking Member: Patrick Leahy (D-VT)



■ Labor-HHS Appropriations Subcommittee

- Chair: Roy Blunt (R-MO)
- Ranking Member: Patty Murray (D-WA)



House Committee Leadership

■ House Appropriations Committee

- Chair: Rodney Frelinghuysen (R-NJ)*
- Ranking Member: Nita Lowey (D-NY)



■ Labor-HHS Appropriations Subcommittee

- Chair: Tom Cole (R-OK)
- Ranking Member: Rosa DeLauro (D-CT)



■ House Energy and Commerce Committee

- Chair: Greg Walden (R-OR)
- Ranking Member: Frank Pallone (D-NJ)



*retiring

Selected NIAID Legislative Activities

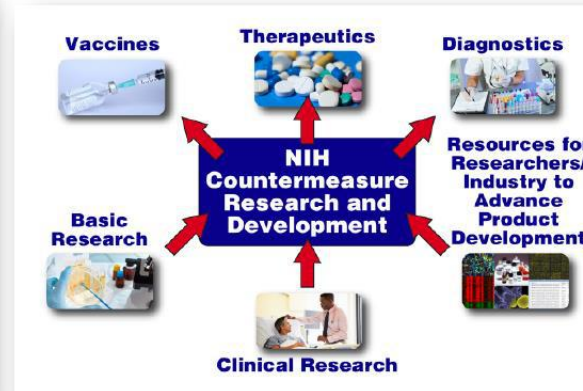
- **March 8, 2018**
- **House Energy and Commerce Subcommittee on Oversight and Investigations**



Topic: Examining U.S. Public Health Preparedness for and Response Efforts to Seasonal Influenza

Selected NIAID Legislative Activities (cont.)

- April 18, 2018
- House Appropriations Subcommittee on Labor-HHS



Topic: Biodefense and Emerging and Re-emerging Infectious Diseases

Selected NIAID Legislative Activities (cont.)

- **April 11, 2018: House Appropriations Subcommittee on Labor-HHS**
- **May 17, 2018: Senate Appropriations Subcommittee on Labor-HHS**



Topic: FY 2019 Budget Hearing - National Institutes of Health

Selected NIAID Legislative Activities (cont.)

- **April 11, 2018**
- **Congressional Meet and Greet Hosted by Rep. Pete Sessions (R-TX)**



Topic: NIH research, including NIAID Zika and Influenza Vaccine Research

■ **Antimicrobial resistance**

■ **Universal flu vaccine**

■ **Tuberculosis**

■ Antimicrobial resistance

■ Universal flu vaccine

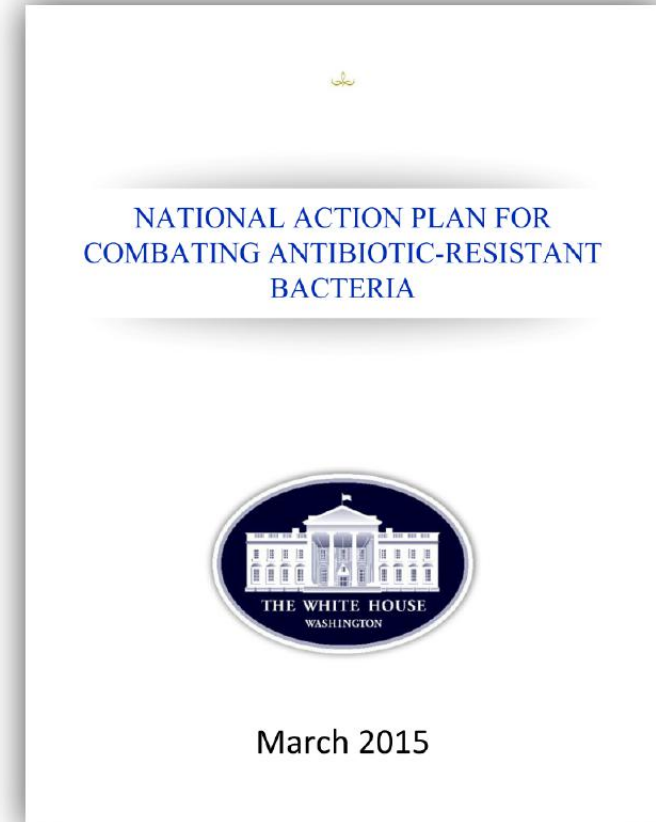
■ Tuberculosis

White House Plan for Combating Antibiotic-Resistant Bacteria (CARB) – March 2015

■ National Action Plan goals

- Stewardship
- Surveillance
- Diagnostics
- Research
- International Collaboration

Additional NIAID Funding: \$100M (FY 2016), \$50M (FY 2017), \$50M (FY 2018)



Vaccines



Therapeutics



Diagnostics



Basic Research



Resources for Researchers/ Industry to Advance Product Development



Clinical Research





Antimicrobial Resistance

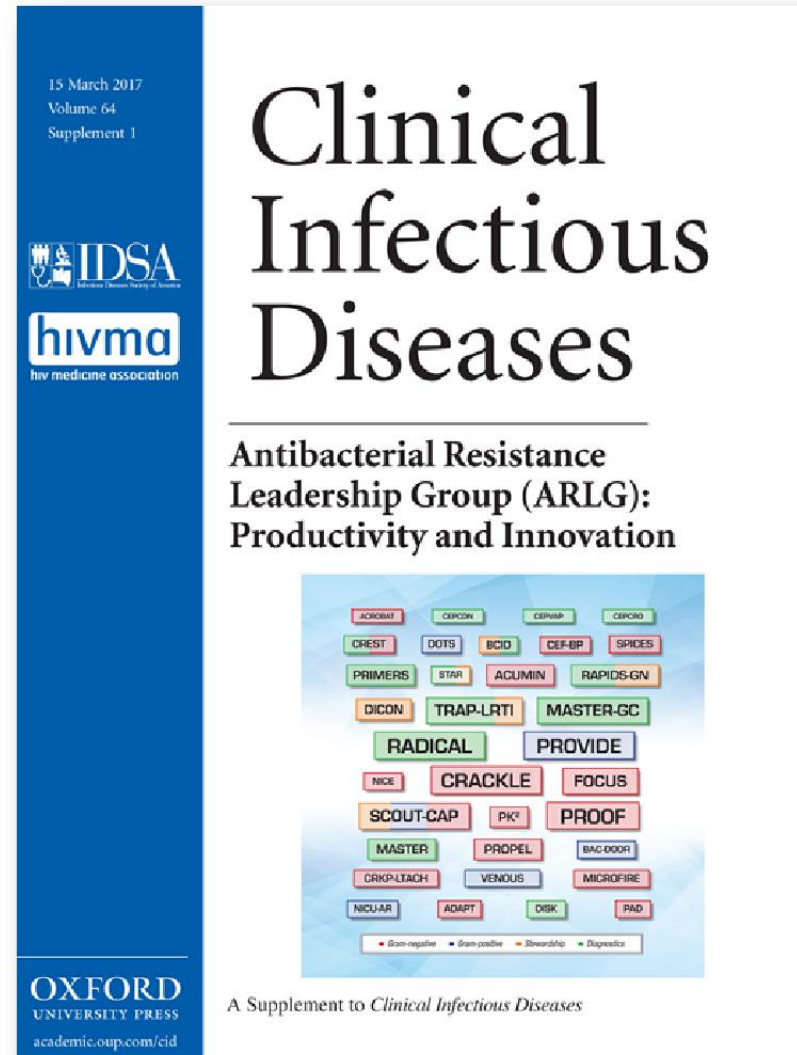
HD Marston, DM Dixon, JM Knisely,
TN Palmore, AS Fauci



Novel Approaches to Address Antimicrobial Resistance

- Antimicrobials
- Harnessing the Immune System
- Manipulating Microbial Communities
- Antivirulence Strategies
- Rapid Diagnostics

NIAID Antibacterial Resistance Leadership Group (ARLG)



- Created in June 2013 to develop, prioritize, and implement a clinical research agenda on antibacterial resistance
- To date, the ARLG has
 - reviewed >90 study proposals
 - initiated >35 studies
 - included data from >13,000 subjects
 - published >85 manuscripts

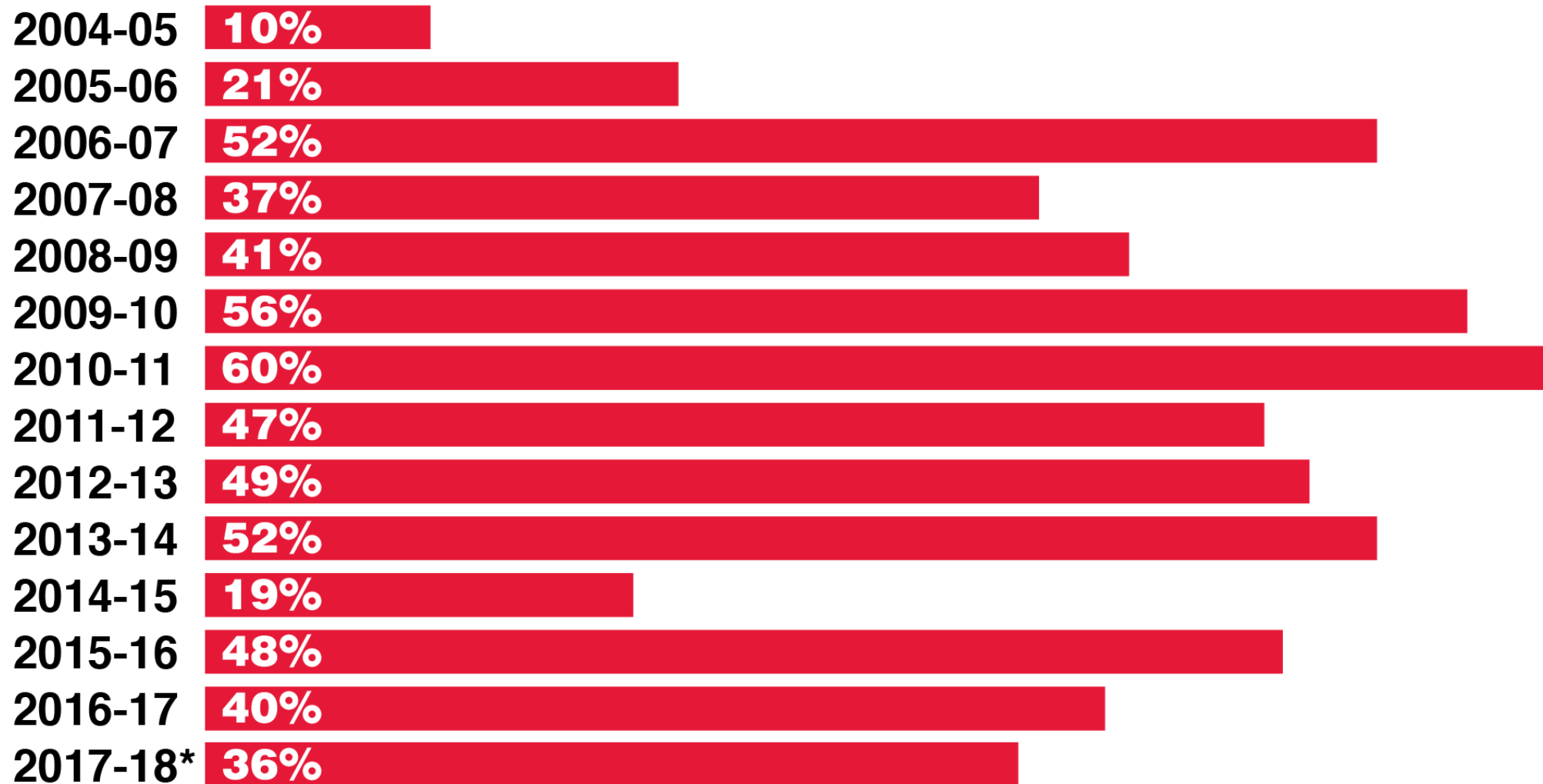
■ **Antimicrobial resistance**

■ **Universal flu vaccine**

■ **Tuberculosis**

- **Current seasonal influenza vaccines are not consistently effective**
- **Pandemics do occur and response after the fact is not effective**
- **“Chasing after” potential pandemic outbreaks (pre-pandemic viruses) is costly and ineffective**

Adjusted Influenza Vaccine Effectiveness Estimates, United States



*Interim estimate

Source: CDC





The
New England
Journal of Medicine

Established in 1812 as THE NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

Volume 378

January 4, 2018

Number 1

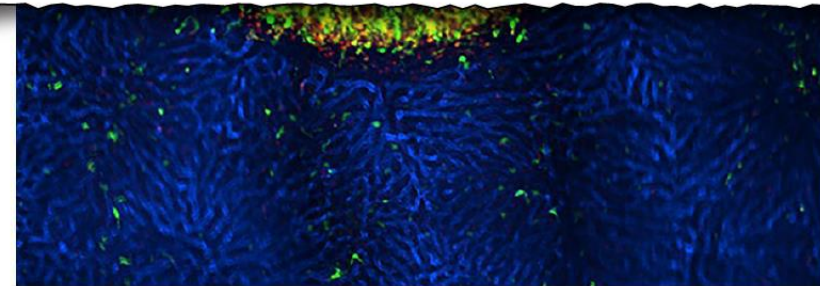
Chasing Seasonal Influenza — The Need for a Universal Influenza Vaccine

CI Paules, SG Sullivan, K Subbarao, and AS Fauci



The Pathway to a Universal Influenza Vaccine

CI Paules, HD Marston, RW Eisinger, D Baltimore,
AS Fauci



Published online
February 28, 2018

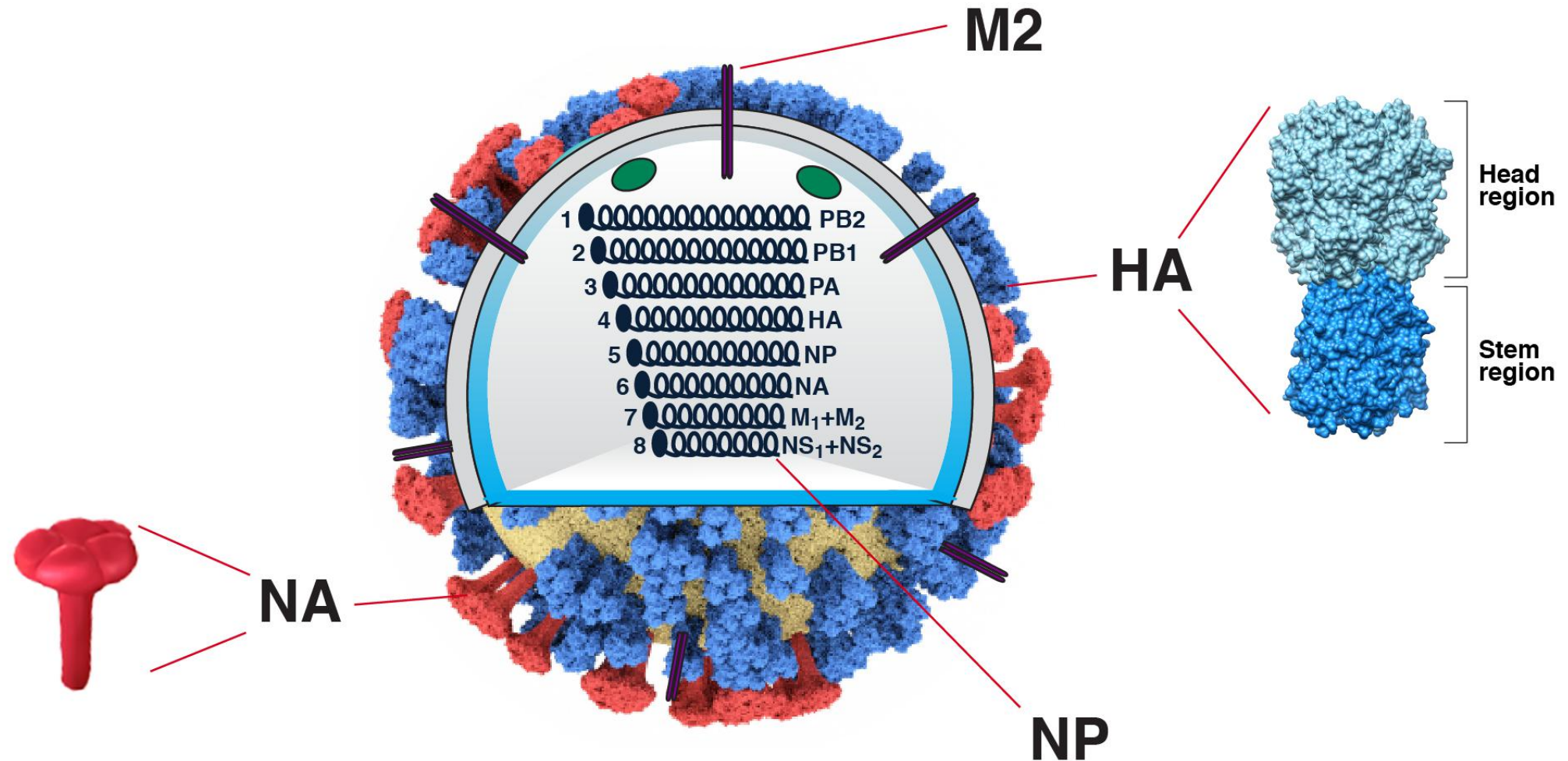


The Journal of Infectious Diseases

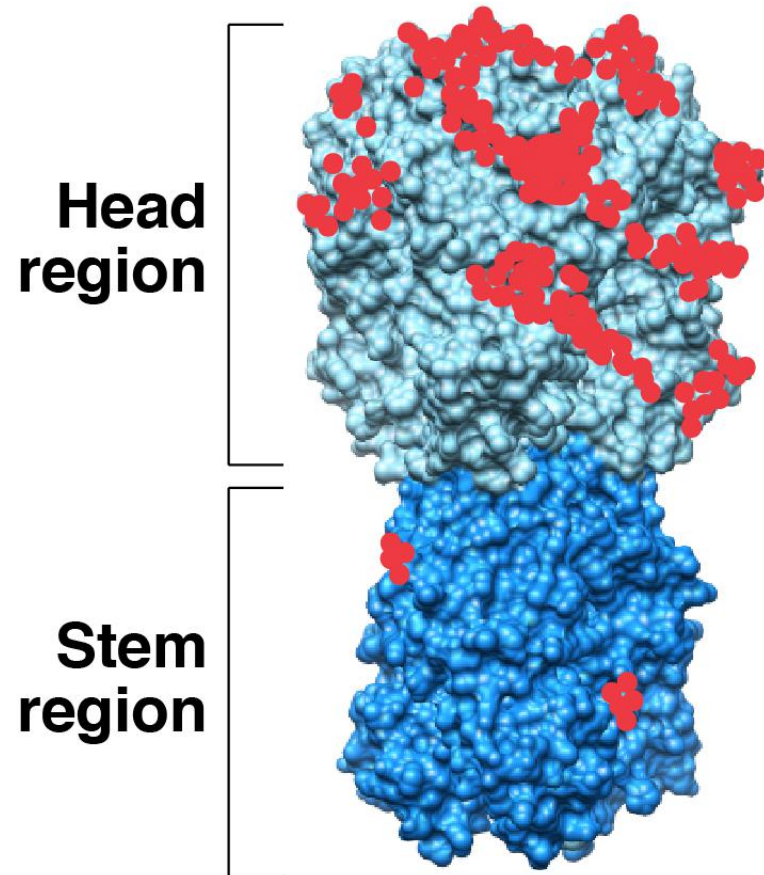
A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases

**EJ Erbeling, D Post, E Stemmy, PC Roberts, A Deckhut Augustine,
S Ferguson, CI Paules, BS Graham, AS Fauci**

Selected Targets for “Universal” Influenza Vaccines



Influenza A Hemagglutinin (HA)



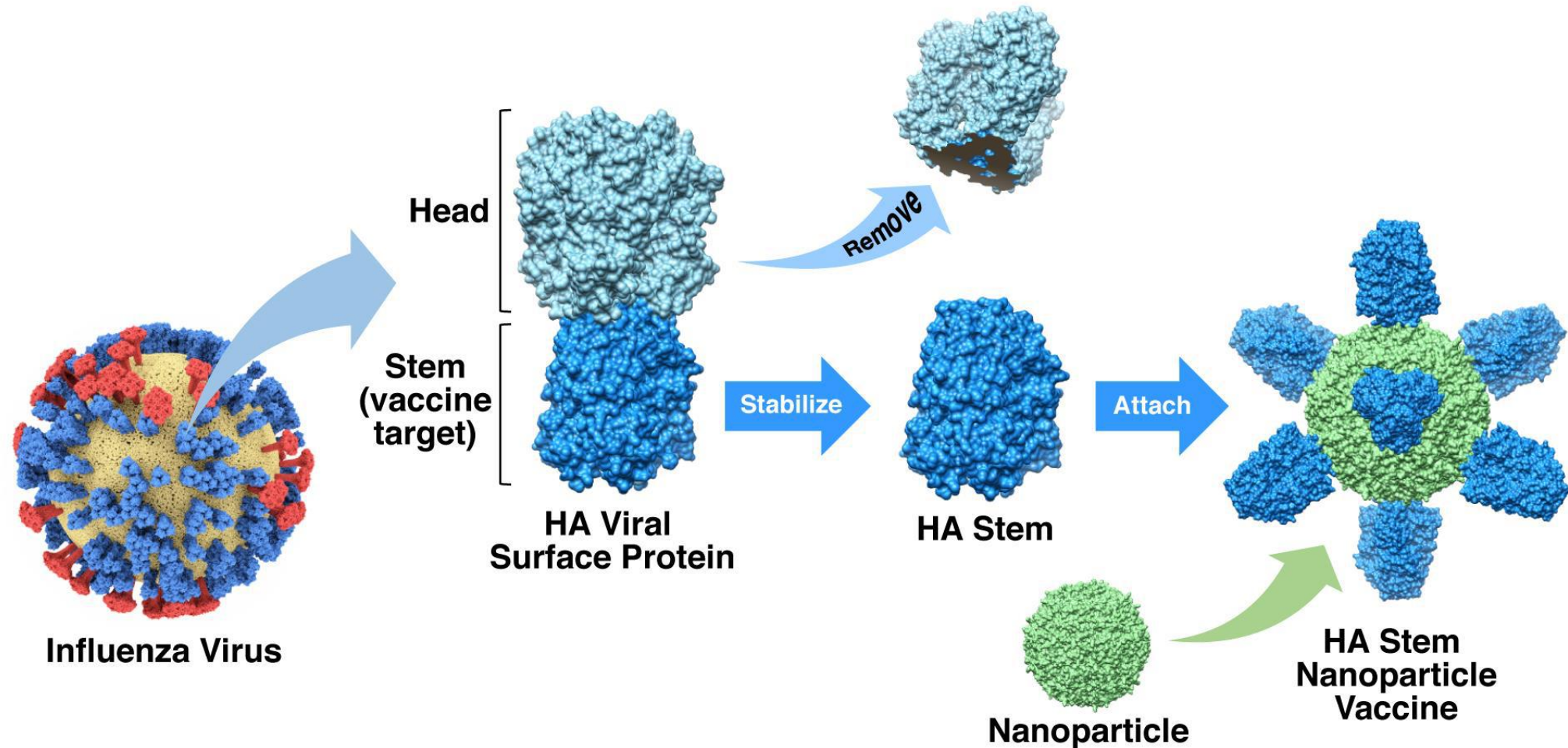
Head region

- Target of current influenza vaccines
- Differs among influenza strains
- Many mutations (●) each season

Stem region

- Target of universal influenza vaccines
- Similar among influenza strains
- Few mutations each season

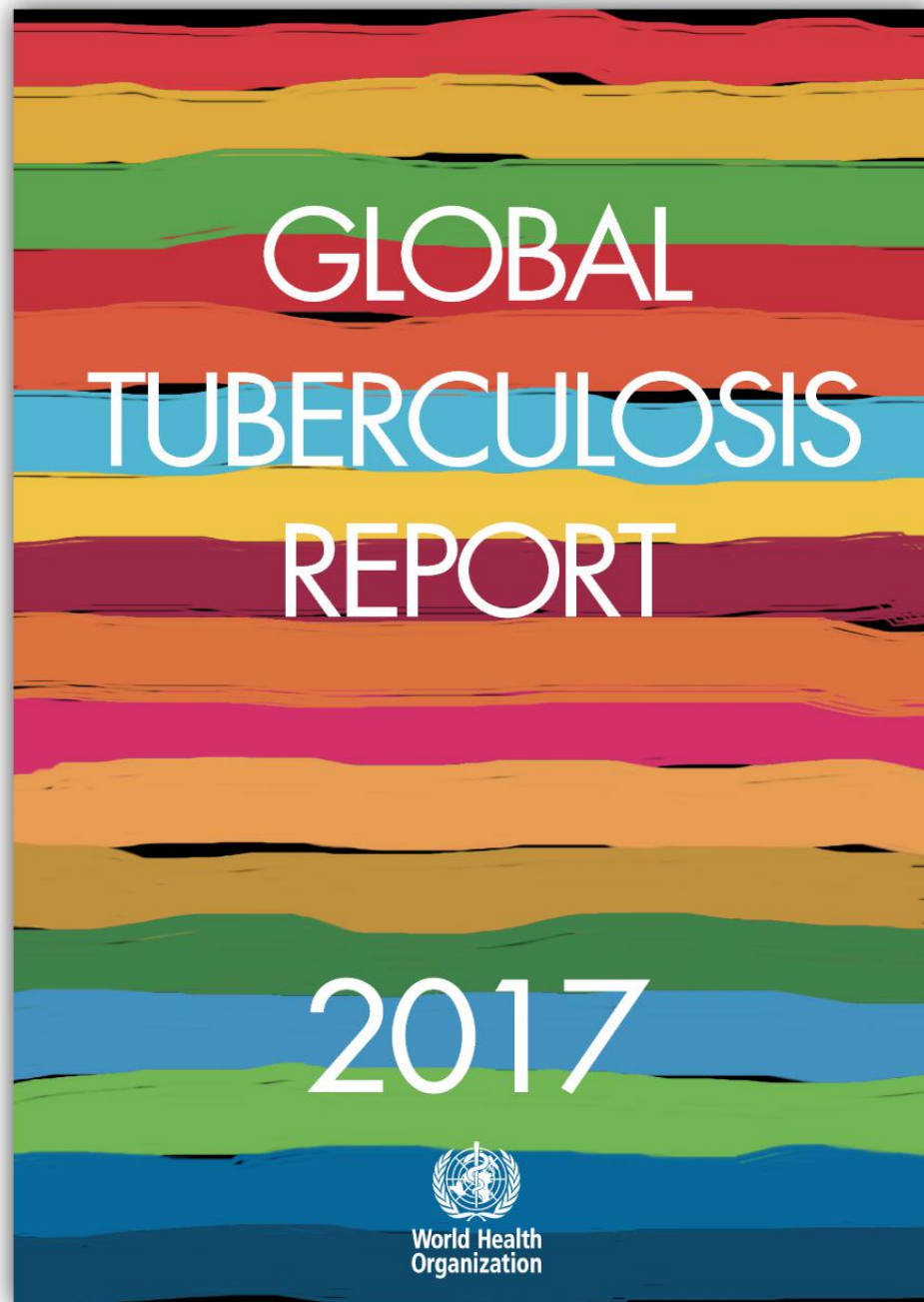
Representative Approach to the Development of a Universal Influenza Vaccine



■ **Antimicrobial resistance**

■ **Universal flu vaccine**

■ **Tuberculosis**



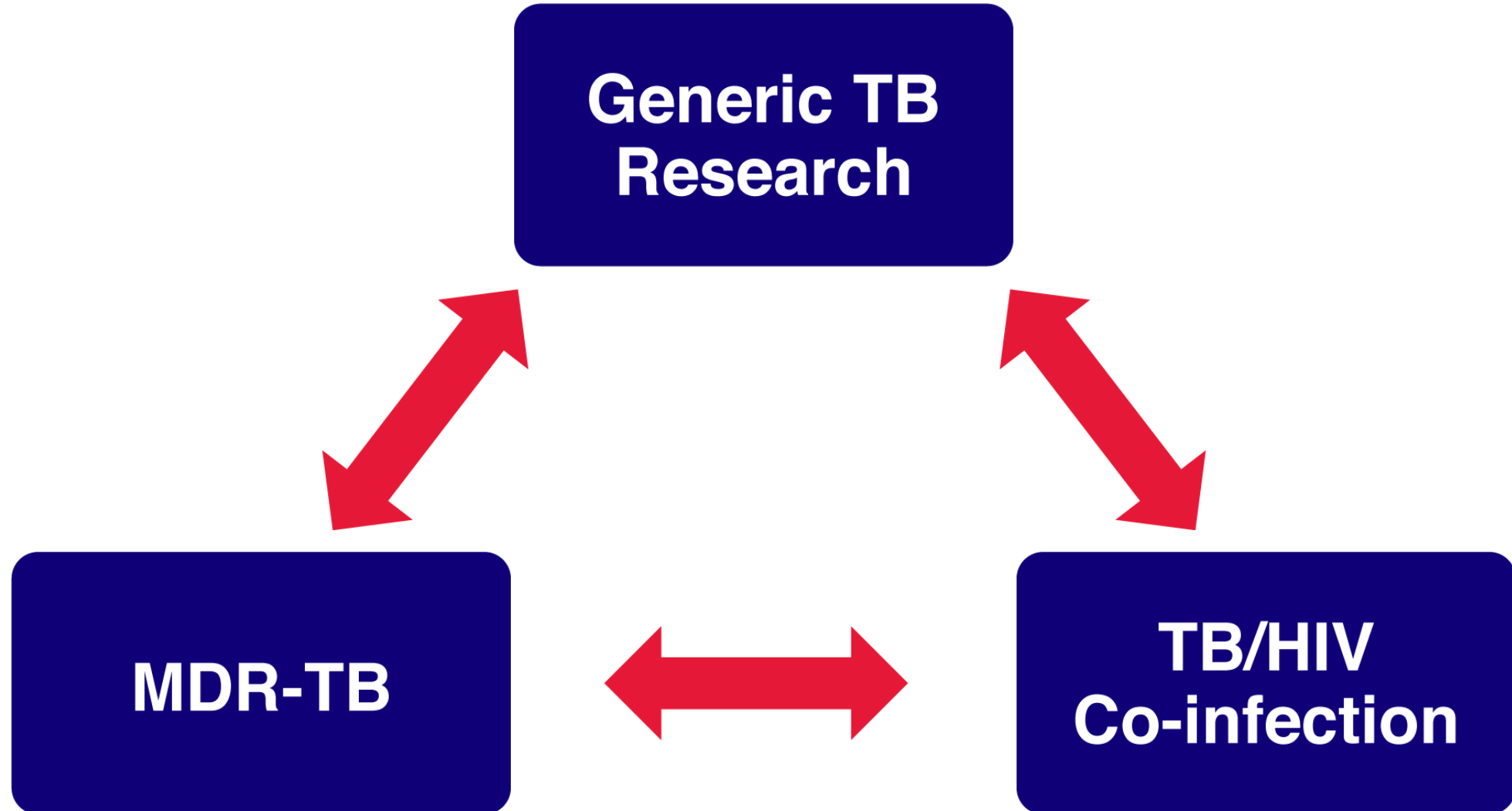
In 2016,

- **TB remains the top ID killer worldwide**
- **~10.4M new TB cases worldwide**
- **~1.7M deaths (4% drop from 2015), including 400,000 people co-infected with HIV**
- **>~600,000 new cases of drug-resistant TB, including 490,000 with MDR-TB**

Nov. 2017: WHO Global Ministerial on Ending TB in the Sustainable Development Era, Moscow



Comprehensive TB Research Portfolio



Concrete Action Now: UN High-Level Meeting on Tuberculosis

N Herbert et al.

“...a once-in-a-generation opportunity to transform the global response at the first UN General Assembly (UNGA) High-Level Meeting on Tuberculosis to be held on Sept. 26, 2018, in New York.”

THE LANCET

Vol. 391, Issue 10126

March 24, 2018

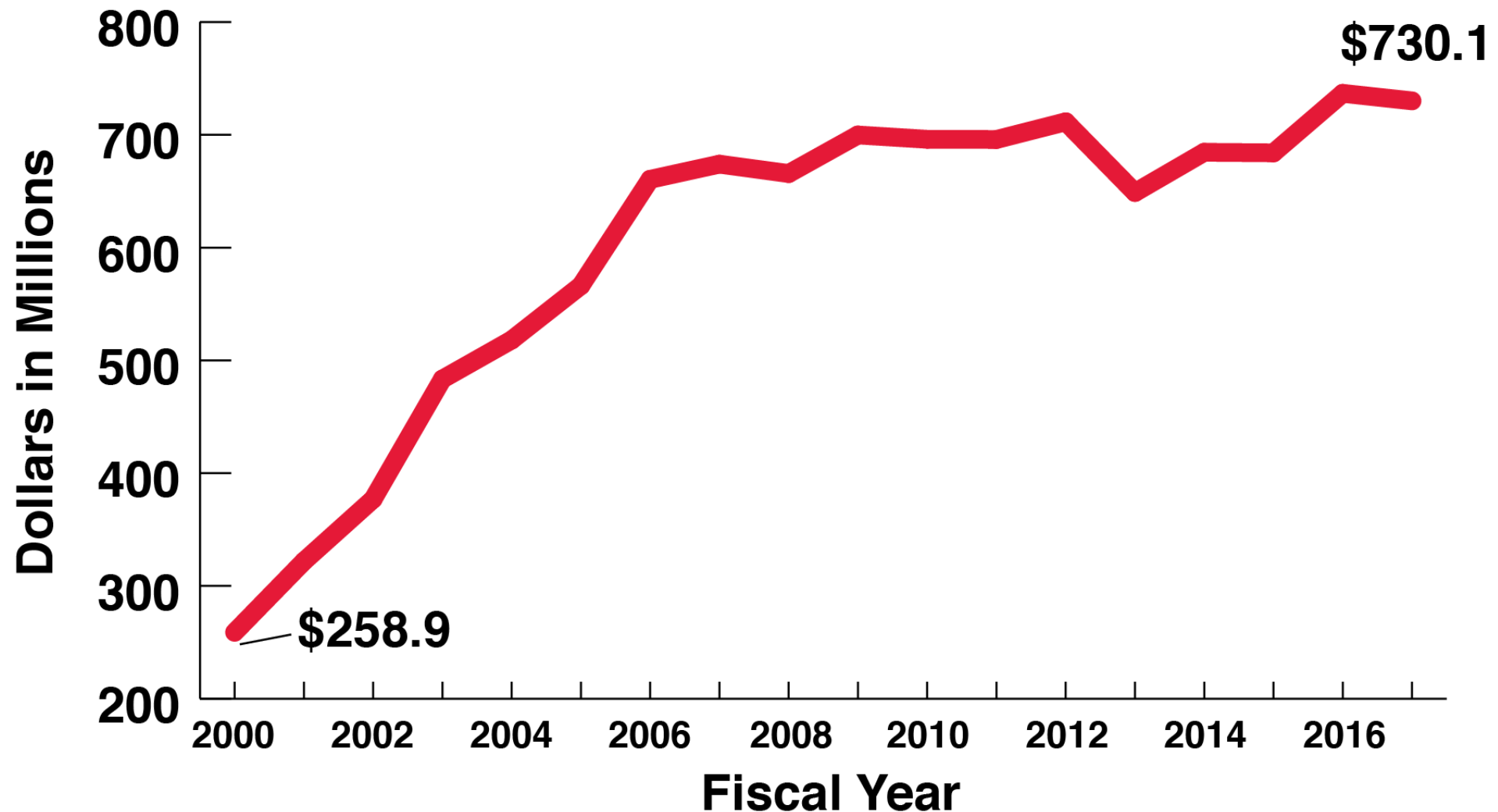
Lancet Commission on Tuberculosis: Building a Tuberculosis-free World

E Goosby et al.

- **Pivot to new strategies to address TB burden**
- **Address social, financial and clinical barriers to TB care**
- **Invest in TB research and development – global priority**
- **Need substantial dedicated resources to implement strategies to end TB**

**HIV Prevention
in
the NIH HIV Research
Agenda**

NIAID HIV Prevention Research Funding, FY 2000-2017



NIAID HIV Prevention Research Funding, FY 2017

	<u>\$(Millions)</u>
Epidemiology of Transmission	19.1
Biology of Transmission	15.5
Microbicides	86.3
Vaccines	509.1
Behavioral Prevention	37.9
Antiretrovirals as Prevention	65.5
<hr/>	
Total NIAID HIV Prevention	\$730.1
Total NIAID HIV/AIDS	\$1.67 Billion

Enrollment in HPTN 071 (PopART) Completed

- HPTN 071 (PopART), **P**opulation Effects of **A**ntiretroviral Therapy to **R**educe HIV **T**ransmission
- Launched in 2013
- Goal: Determine the impact of a package of HIV prevention interventions on community-level HIV incidence
- Enrollment: 48,541 adults in 21 communities in South Africa and Zambia



PrEP Use in the United States



- In 2016, there were 77,120 PrEP users in the U.S., up from 8,768 PrEP users in 2012

Reasons Cited for Not Using PrEP*

- **Cost**
- **Potential side effects**
- **Do not know where to access**
- **Impact on insurance**
- **Do not feel at risk**
- **Provider's reaction to request for PrEP**

***MSM PrEP-informed non-users**

Long-acting Antiretrovirals for Prevention



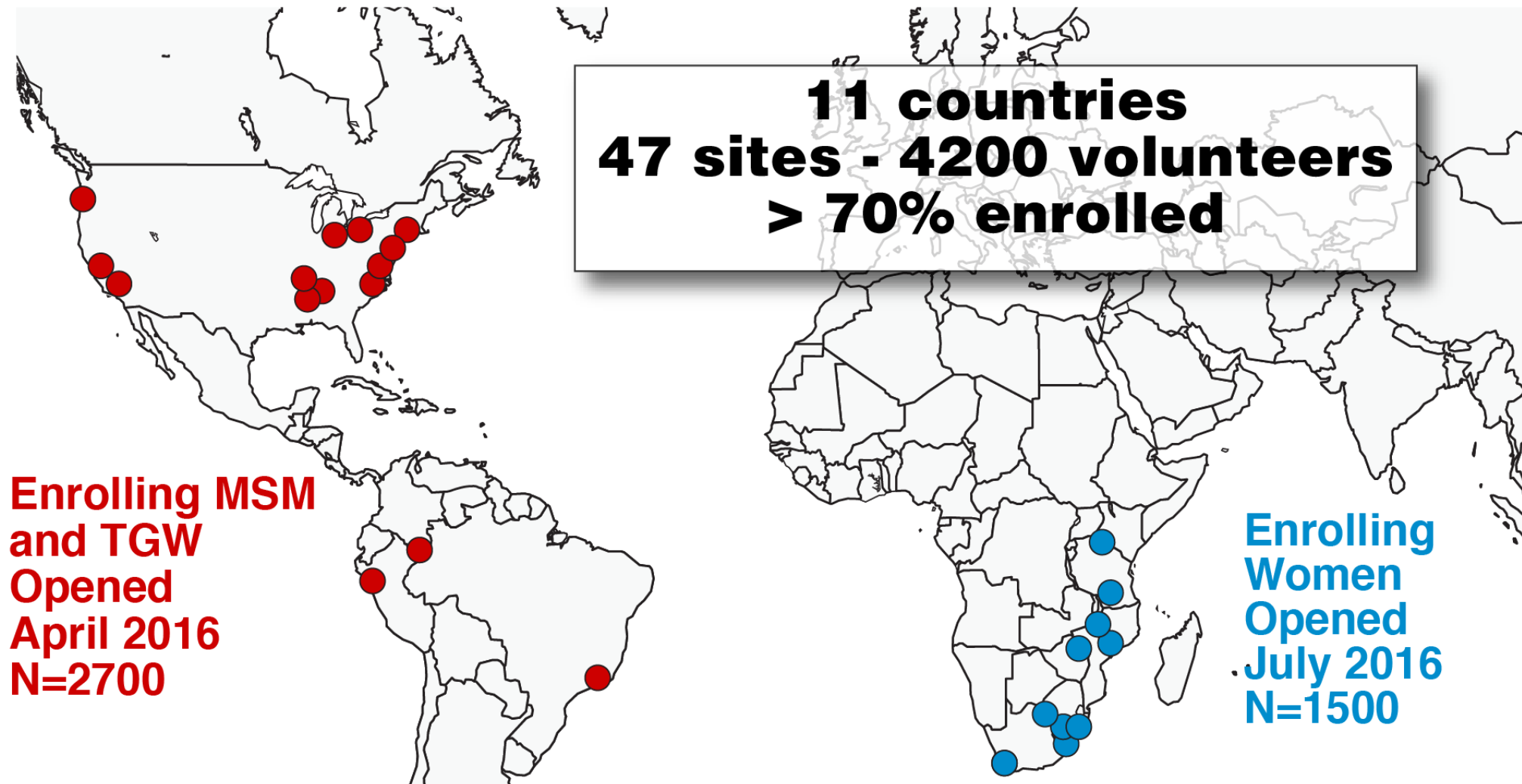
- RCT of long-acting cabotegravir vs. TDF/FTC for PrEP
- 4500 MSM and TGW in multiple countries



- RCT of long-acting cabotegravir vs. TDF/FTC for PrEP
- 3200 women in Sub-Saharan Africa

Antibody-Mediated Prevention (AMP)

VRC01 mAb Phase 2b Studies in High Risk Men and Women



Courtesy Julie Ledgerwood, DO

Long-acting bNAbs Protect NHPs Against SHIV Infection

nature
medicine

Published Online April 16, 2018

A Single Injection of Crystallizable Fragment Domain-modified Antibodies Elicits Durable Protection from SHIV Infection

R Gautam, MA Martin et al.

- Long-acting broadly neutralizing antibodies 10-1074-LS and 3BNC117-LS protect macaques against SHIV infection
- Protect for a median of 4-6 months

October 24/31, 2017
Vol 318 No 16

JAMA

The Journal of the
American Medical Association

An HIV Vaccine is Essential for Ending the HIV/AIDS Pandemic

AS Fauci

Development of a moderately effective vaccine together with optimal implementation of existing treatment and prevention modalities could end the current HIV pandemic.

Dual Pathway to Ending the HIV/AIDS Pandemic

