



National Institute of  
Allergy and  
Infectious Diseases

# The NIAID Mission

*Priorities for Research in Women & Children*

**January 13, 2025**

NICHD ADVISORY COUNCIL

JEANNE MARRAZZO, MD, MPH

DIRECTOR, NIAID



# Learning Early to Advocate for Patients & Communities

## Inspiration for Infectious Disease Focus



Early days of the HIV epidemic



Women's health



Strong educators with academic & public health commitment



Terrific role models



Frances Marrazzo, ca 1954; US Army Hospital, Livorno, Italy



Demonstrating at NIH, Bethesda, ca 1986

# My Trajectory

## Infectious Disease Career Path



STIs: chlamydia screening, diagnosis

Vaginal infections → bacterial vaginosis

Vaginal microbiome

Antiretroviral-based pre-exposure prophylaxis for HIV-1

Multi-component prevention

# Career Trajectory

## Infectious Disease Career Path



University of Washington



University of Alabama at Birmingham



National Institute of Allergy and Infectious Diseases



**Began tenure as sixth NIAID Director in Fall 2023**



# **Hugh Auchincloss, MD**

**NIAID Principal Deputy Director**  
*retired September 30, 2024*

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**Sarah W. Read, MD, MHS**  
**NIAID Principal Deputy Director**  
*effective October 2024*

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# NIAID MISSION

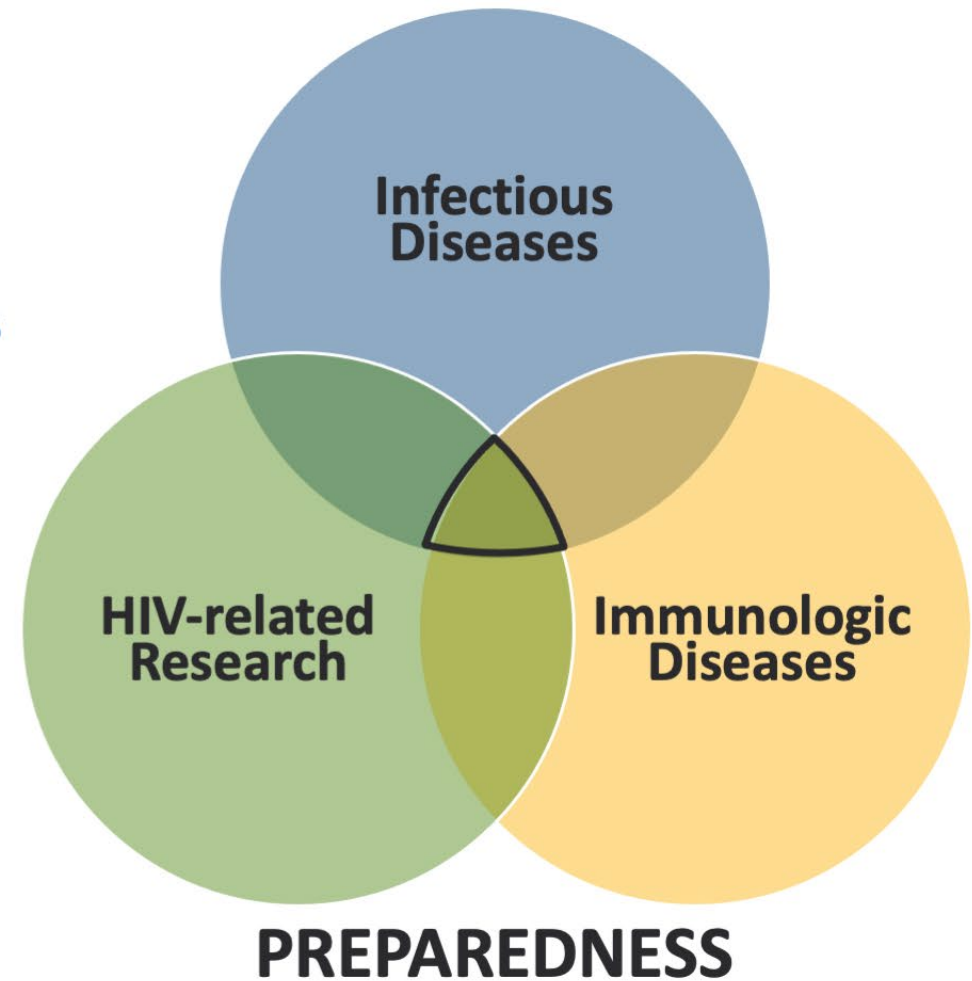
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NIAID **supports and conducts** biomedical research to better understand and treat infectious, immunologic, and allergic diseases

National Institute of Allergy and Infectious Diseases

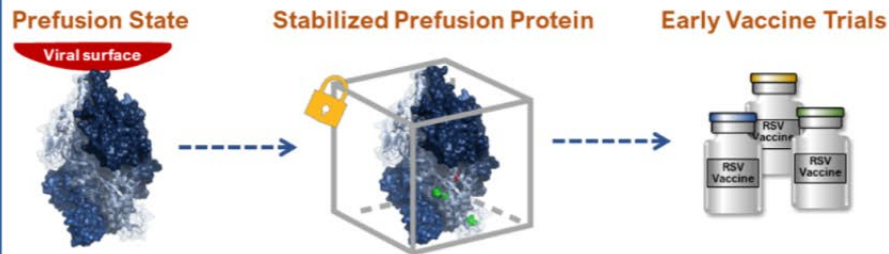
# The NIAID Research Portfolio

- **Infectious diseases**
  - Pathogen characterization
  - Model development
- **Immunology and immunologic diseases**
  - Basic immunology
  - Correlates of protection
- **HIV-related research**
  - Therapeutic and vaccine development
  - Community outreach





# NIAID Research Informs Public Health Interventions



***Locking the RSV F Protein in the Prefusion State Leads to Protective Immune Response***



***Learning Early about Peanut Allergy (LEAP) Trial Results Inform Updated Guidelines***



**HPTN**  
HIV Prevention  
Trials Network

***FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention***

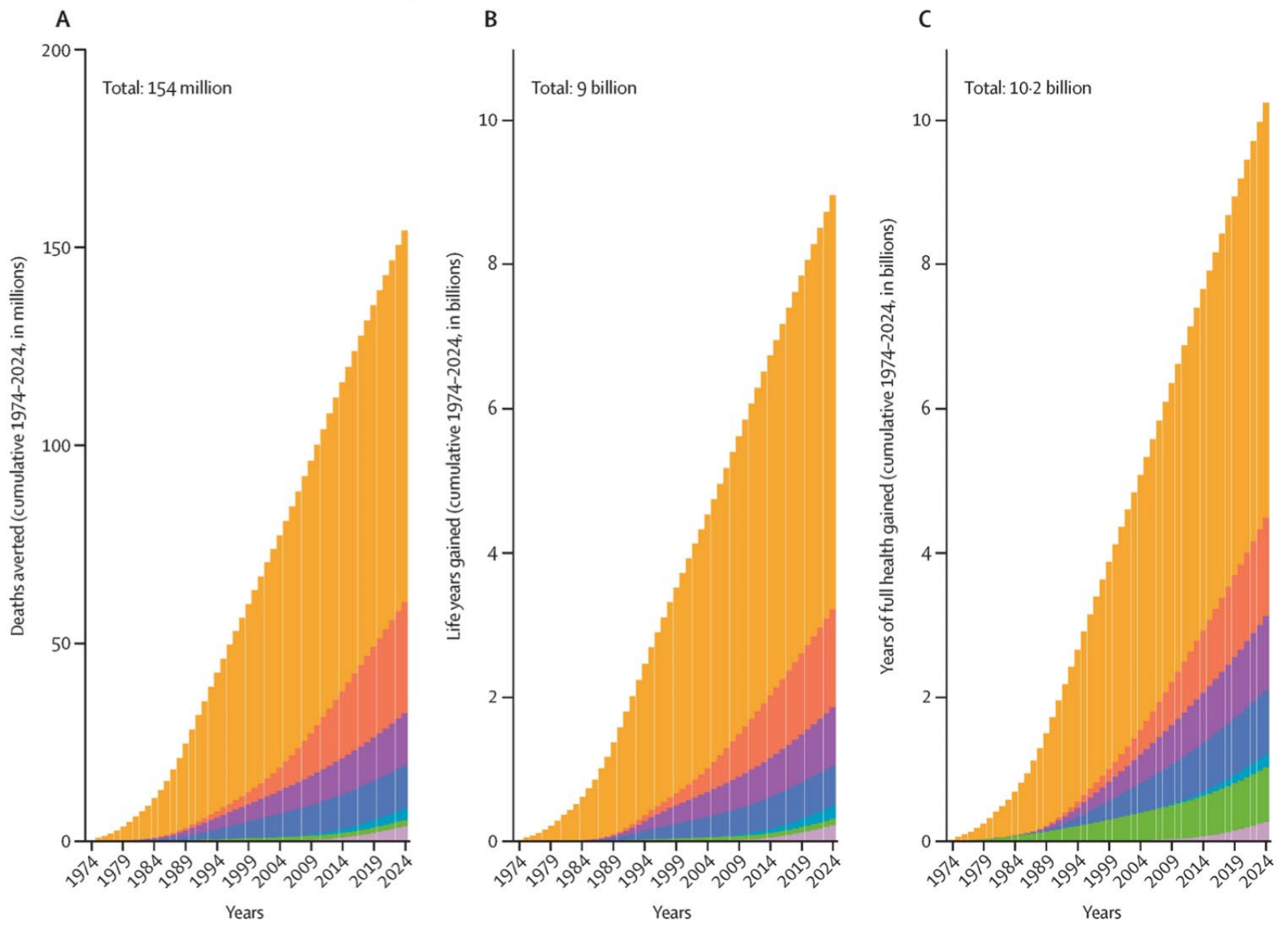


***Surgeons Transplant Pig Kidney Into a Patient, a Medical Milestone***

# World Health Organization's Expanded Programme on Immunization Celebrates 50<sup>th</sup> Anniversary

*Modeling the impact of 50 years of vaccination against 14 pathogens*

- Measles
- Pertussis
- Haemophilus influenzae type B
- Other disease
- Tetanus
- Tuberculosis
- Poliomyelitis



**Deaths averted, years of life saved, and years of full health gained by vaccination**

# NIAID

National Institute of Allergy  
and Infectious Diseases

## *Strategic Plan* 2025-2029

# SHAPING THE FUTURE

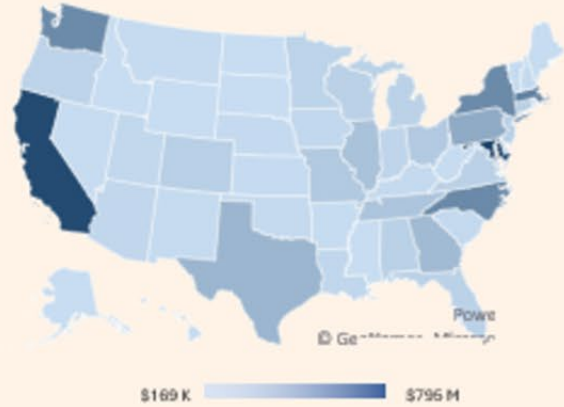


NIAID funds scientific research across the United States.

**\$5.25 billion**  
Total NIAID funding distributed across the U.S in FY 2023.

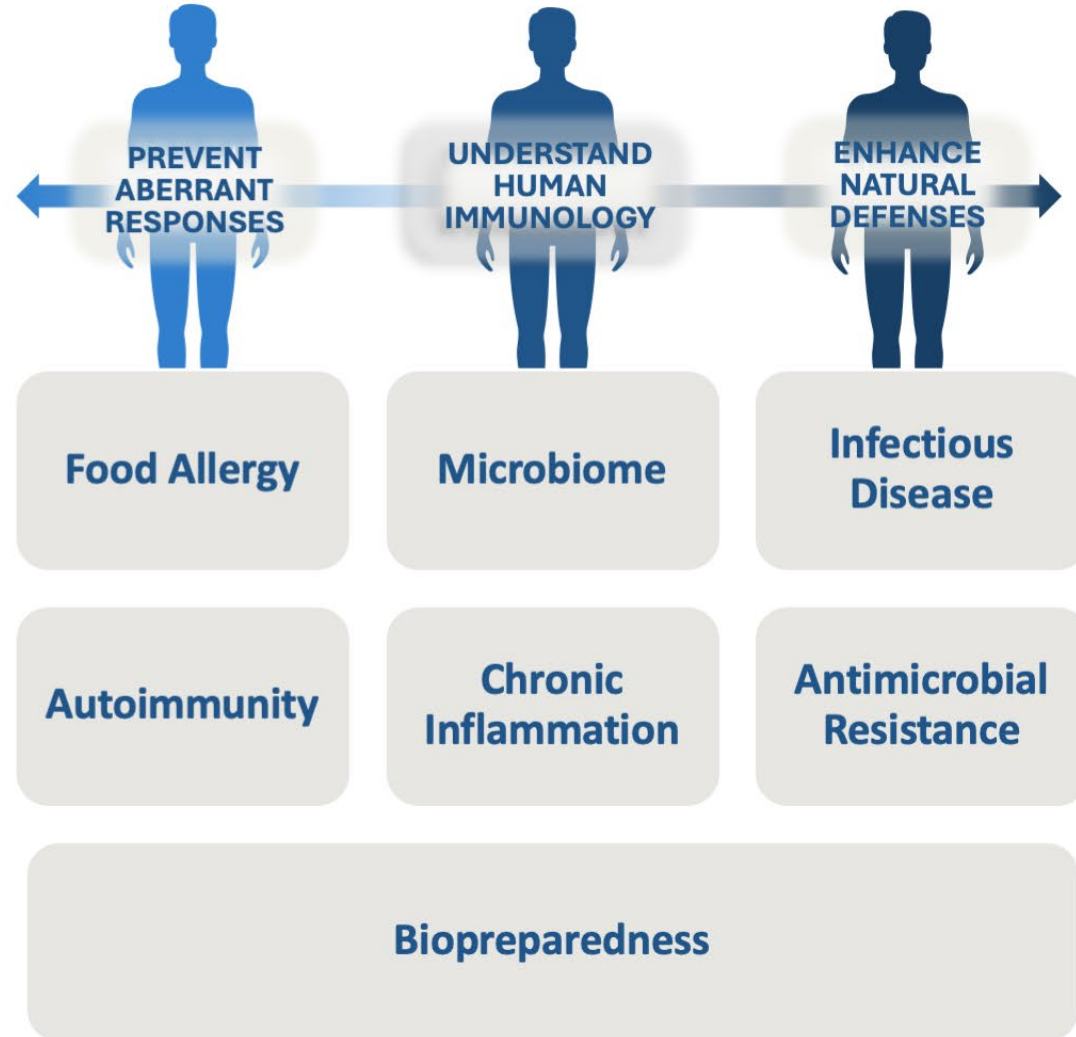
**6,680**  
NIAID funded research grants and contracts in FY 2023.

**240**  
Congressional Districts in which NIAID research grants or contracts were awarded in FY 2023.



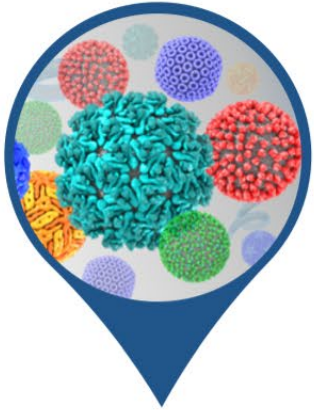
New NIAID leadership inspired an updated strategic plan that will guide NIAID-funded research for the next 5 years.

*The updated NIAID strategic plan will focus on an **integrated, holistic approach to immunologic and infectious disease research** to improve human health*



# People are the Unifying Element for Enacting NIAID's Priority Areas

**Pandemic Preparedness & Biosecurity**



**Infectious agents, including HIV**



**Research Infrastructure**



**RESEARCHERS THROUGHOUT THE CAREER SPAN**

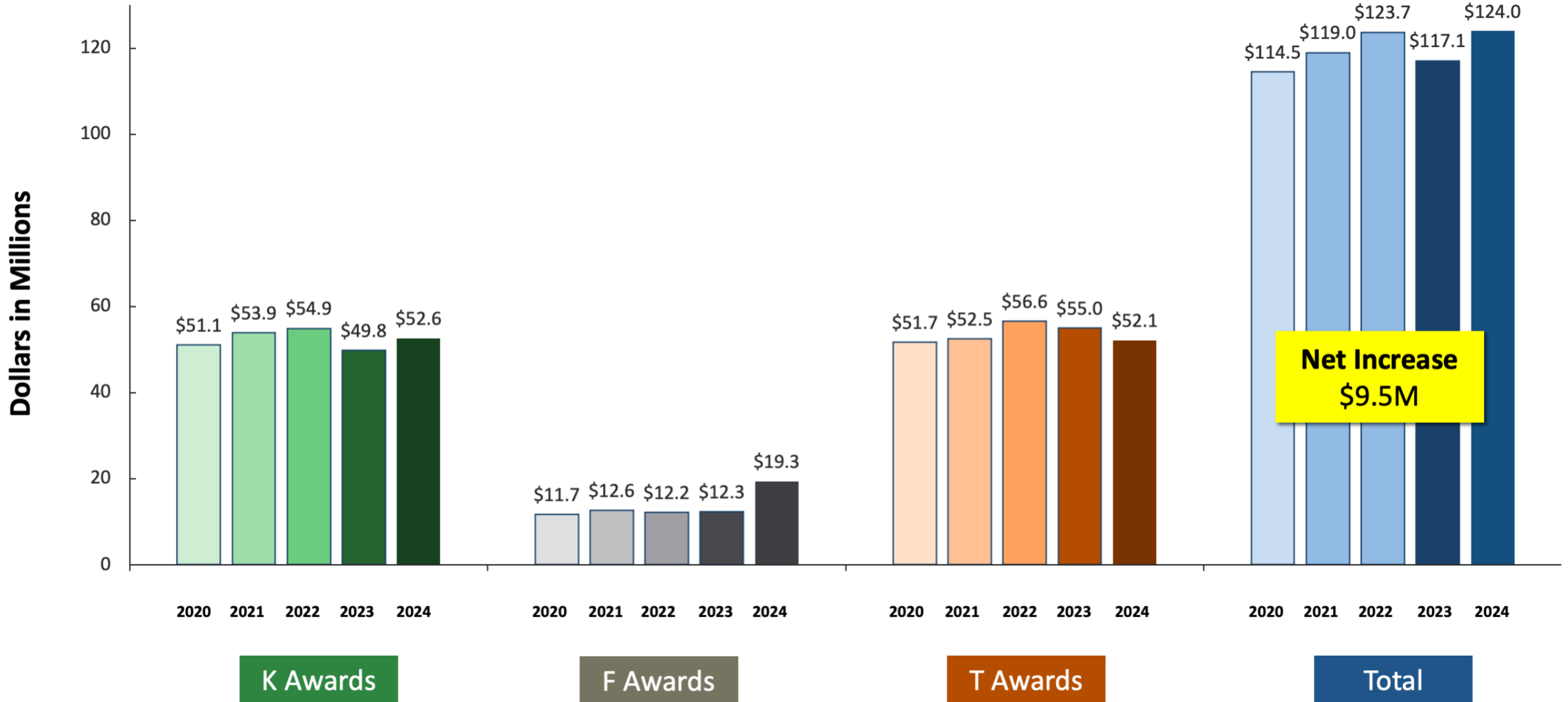
**Allergy & Immunology**



**Inclusivity & Accessibility**



# NIAID Training Budget Trends (FY 2020 – 2024)



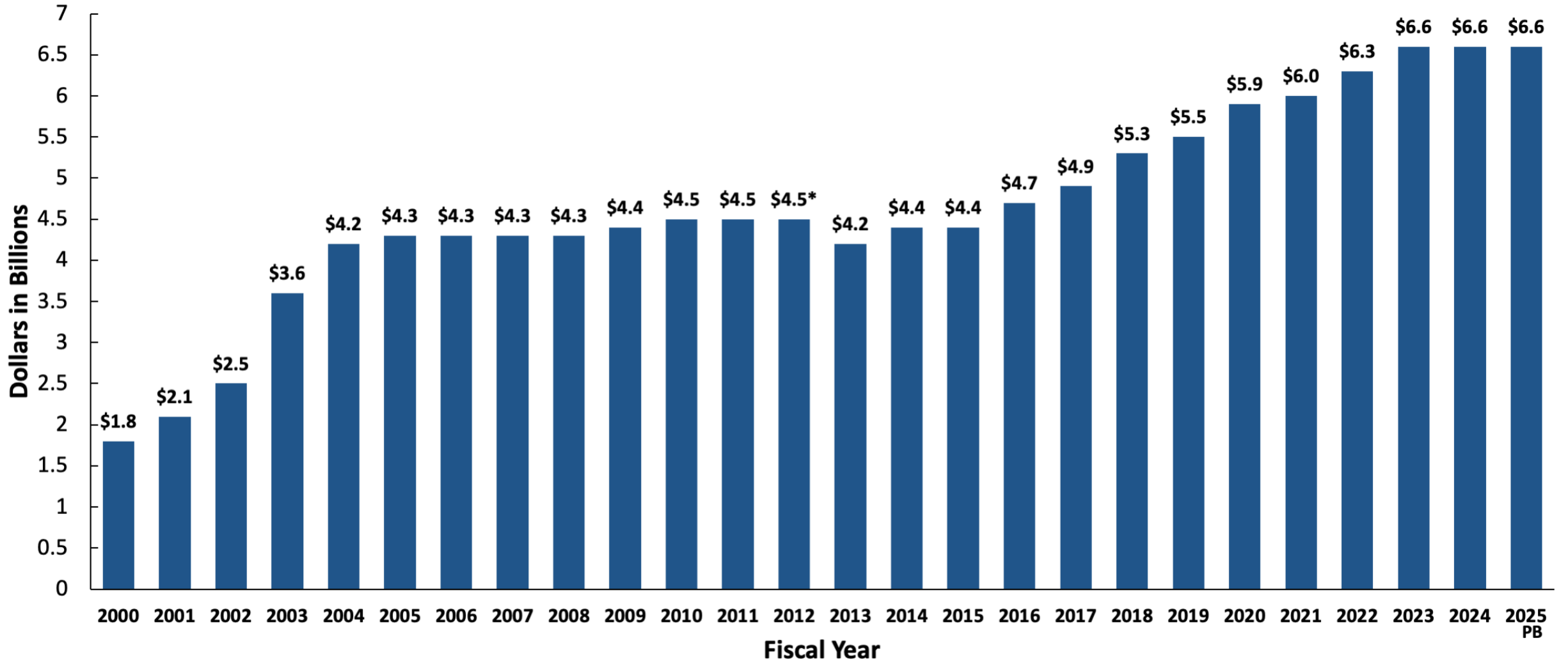
# NIAID Budget Update

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**BUDGET**



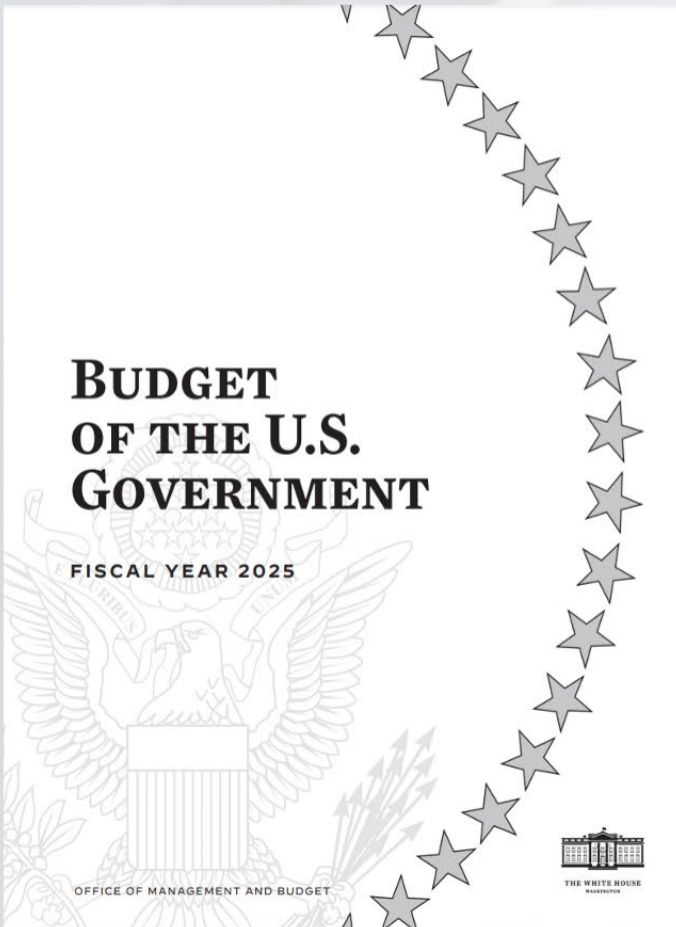
# NIAID Funding, FY 2000-2025



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



# Status of the FY 2025 Budget



- President's Budget released March 11, 2024
  - NIH Proposed Program level budget \$50.1 billion (excluding ARPA-H)
  - **NIAID budget request \$6.581B** (\$19.6M over FY 2024)
- House Appropriations Bill released July 9, 2024
  - **Would split NIAID funding into two Institutes:**
    - National Institute on Infectious Diseases
    - National Institute on the Immune System & Arthritis
- Senate Appropriations Bill released August 1, 2024
- Continuing resolution through **March 14, 2025**

# NIH Budget Comparison by Institute/Center

(Dollars in thousands)

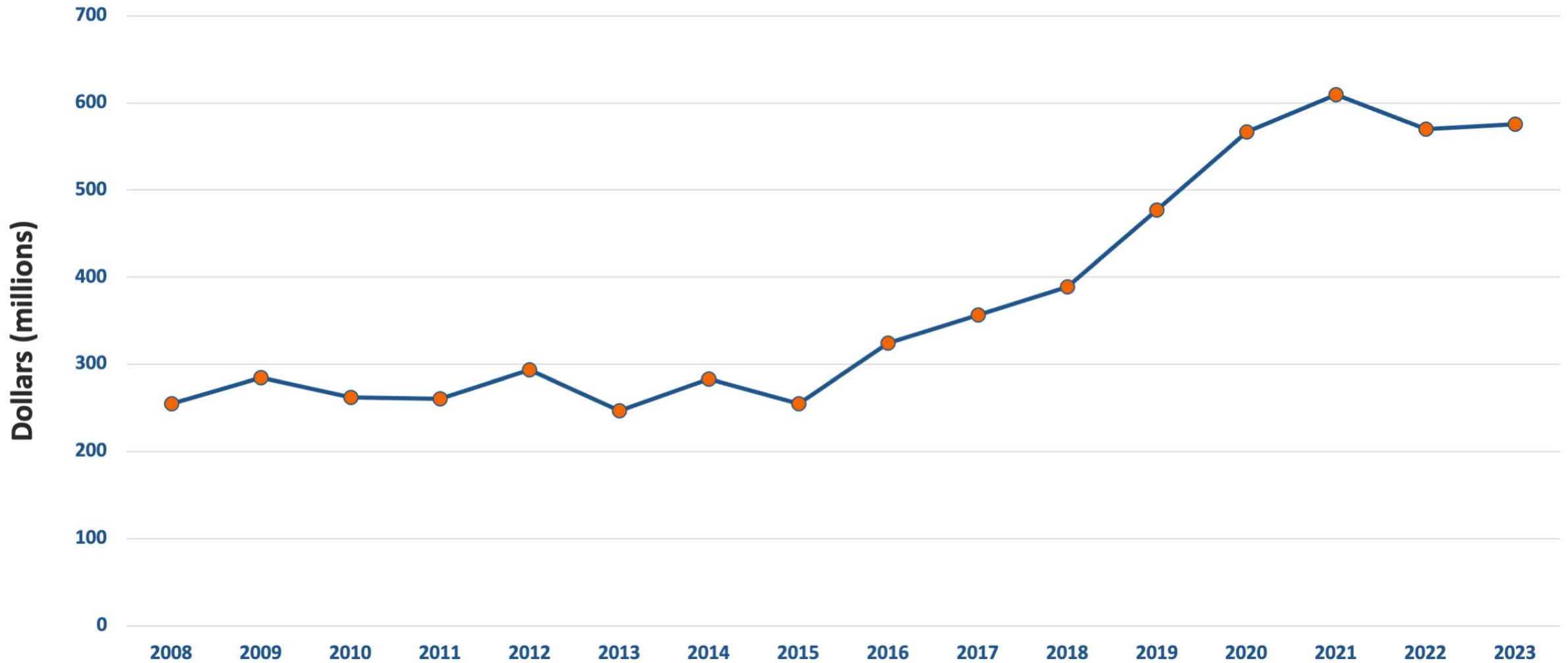
Fiscal Year (FY)

Institute	FY 2024 Enacted	FY 2025 House	FY25 vs. FY24 % Change	FY 2025 Senate	FY25 vs. FY24 % Change
NCI	\$7,224,159	\$7,875,289	9.0%	\$7,490,159	3.7%
<b>NIAID</b>	<b>\$6,562,279</b>	<b>\$6,631,104*</b>	<b>1.0%</b>	<b>\$6,692,279</b>	<b>2.0%</b>
NIA	\$4,507,623	\$4,604,899	2.2%	\$4,645,123	3.1%
NIMH	\$2,273,843	\$2,256,289	-0.8%	\$2,687,843	18.2%
Other ICs	\$26,242,810	\$25,434,748	-3.1%	\$27,067,210	3.1%
Subtotal	\$46,810,714	\$46,802,329	0.0%	\$48,582,614	3.8%
ARPA-H	\$1,500,000	\$1,500,000	0.0%	\$1,500,000	0.0%
B&F	\$350,000	\$353,671	1.0%	\$350,000	0.0%
NIH Program Level**	\$48,660,714	\$48,656,000	0.0%	\$50,432,614	3.2%

\* FY 2025 House funding for NIAID split into two Institutes: *National Institute on Infectious Diseases* (\$3.3B) and *National Institute on the Immune System and Arthritis* (\$3.3B)

\*\*Includes Type 1 Diabetes, Non-HHS Appro. (Superfund). Excludes NIH-OAR AIDS transfers

# NIAID Pediatric Funding: FY 2008 - 2023



Source data: NIH RePORT (ARRA funding not included)

# ADVANCES IN CHILD HEALTH

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# Learning Early About Peanut Allergy (LEAP)-Trio

Following the original LEAP trial participants prospectively to age 12 years

## Learning Early About Peanut Allergy Study

2015

Early introduction of peanut products reduced risk of peanut allergy at age 5 by 81%

## LEAP-On Study

2016

LEAP participants in the consumption group remained protected at age 6 after avoiding peanut products for one year

## LEAP-Trio Study

2024

Peanut consumption from infancy to age 5 years provides lasting tolerance to peanut into adolescence irrespective of subsequent peanut consumption



ORIGINAL ARTICLE

### Follow-up to Adolescence after Early Peanut Introduction for Allergy Prevention

George Du Toit, M.B., B.Ch.,<sup>1,2,3</sup> Michelle F. Huffaker, M.D.,<sup>4</sup> Suzana Radulovic, M.D.,<sup>1,2,3</sup> Mary Feeney, M.Sc., R.D.,<sup>2,3</sup> Helen R. Fisher, M.Sc., Ph.D.,<sup>2,3</sup> Margie Byron, M.S.,<sup>5</sup> Lars Dunaway, Ph.D.,<sup>5</sup> Agustin Calatroni, M.S.,<sup>5</sup> Molly Johnson, M.S.,<sup>5</sup> Ru-Xin Foong, M.B.,<sup>1,2,3</sup> Andreina Marques-Mejias, M.D., Ph.D.,<sup>1,2,3</sup> Irene Bartha, M.D., Ph.D.,<sup>1,2,3</sup> Monica Basting, M.A.,<sup>1,2,3</sup> Helen A. Brough, M.B., Ph.D.,<sup>2,3</sup> Carolyn Baloh, M.D.,<sup>6,7</sup> Tanya M. Laidlaw, M.D.,<sup>6,7</sup> Henry T. Bahnson, M.S.,<sup>8,9</sup> Graham Roberts, D.M.,<sup>10,11</sup> Marshall Plaut, M.D.,<sup>12</sup> Lisa M. Wheatley, M.D., M.P.H.,<sup>12</sup> and Gideon Lack, M.B., B.Ch.,<sup>1,2,3</sup> for the Immune Tolerance Network LEAP-Trio Trial Team\*

Almost 80% of the original LEAP study participants were enrolled in LEAP-Trio

NEJM Evid 2024

# NIAID Clinical Genomics Program Tackles Pediatric Disease

*Accelerating research aimed at better understanding, diagnosing, and treating disorders of the immune system*

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

CD55 Deficiency, Early-Onset Protein-Losing Enteropathy, and Thrombosis

Ozen A, et al. 2017

Evaluating the efficacy and safety of pozelimab in patients with CD55 deficiency with hyperactivation of complement, angiopathic thrombosis, and protein-losing enteropathy disease: an open-label phase 2 and 3 study

Ahmet Ozen, Voranush Chongrisawat, Asema Pinar Sefer, Burcu Kulukisa, Jessica J Jalbert, Caroline A Meagher, Taylor Brackin, Hagit Baris Feldman, Safa Baris, Elif Karakoc-Aydiner, Rabia Ergelen, Ivan J Fuss, Heather Mooman, Narisana Suratannan, Kanya Suphapeetipom, Lorah Perle, Olivier A Harari, George D Yancopoulos, Michael J Lenardo, on behalf of the Pozelimab CHAPLE Working Group\*

Ozen A, et al. *Lancet* 2024



FDA approves Veopoz™ for treatment of CD55-deficient protein-losing enteropathy (CHAPLE disease)

**Discover**

**CHAPLE syndrome** is caused by abnormal complement activation due to biallelic loss-of-function mutations in CD55, resulting in loss of protein expression. Patients die of starvation before 30 years old

**Evaluate**

Pozelimab inhibits complement overaction and resolves clinical and laboratory manifestations of CHAPLE disease

**Success!**



Before & After Treatment

# International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)

*Evaluating novel treatments and interventions for HIV and its complications to improve health outcomes for infants, children, and adolescents*

## IMPAACT 2023: Phase I Study of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1

- *Multi-centered study to evaluate dolutegravir in infants in first 4-6 weeks of life born to mothers living with HIV*
- *Analysis of 1<sup>st</sup> cohort complete and proposed dosing for chronic administration has been modeled & simulated*
- **Next steps:** *evaluate chronic dolutegravir dosing administration (5 mg dispersible tablet every other day for 2 weeks, followed by once-daily through 28 days of life) in subsequent cohort*

## European Medicines Agency Approves Triumeq PD<sup>®</sup> for Infants and Young Children Based on IMPAACT 2019 Data

*Lancet HIV 2023*



Pharmacokinetics, safety, and tolerability of dispersible and immediate-release abacavir, dolutegravir, and lamivudine tablets in children with HIV (IMPAACT 2019): week 24 results of an open-label, multicentre, phase 1-2 dose-confirmation study

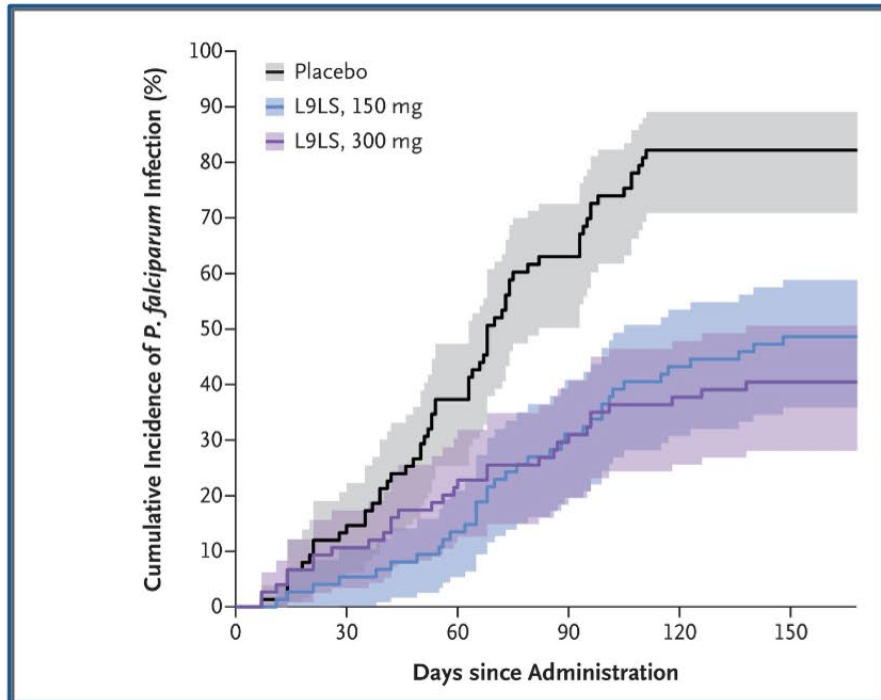
Kristina M Brooks, Jennifer J Kiser, Lauren Ziamba, Shawn Ward, Yasha Rani, Tim R Cressay, Gaerolwe R Masheto, Haseena Cassim, Jaime G Deville, Puneo L Panatshago, Faeezah Patel, Linda Aurpibul, Shaun I Barnabas, Iris Mustich, Anne Coletti, Barbara Heckman, Chelsea Krotje, Mark Lojaccono, Dwight E Yin, Ellen Townley, Jack Moye, Sai Majji, Edward P Acosta, Kevin Ryan, Hardik Chandasana, Cynthia H Brothers, Ann M Buchanan, Helena Rabie, Patricia M Flynn, on behalf of the IMPAACT 2019 Study Team

**IMPAACT 2019:** *Phase I/II open-label, multicenter, multiple-dose study of Triumeq<sup>®</sup> and Triumeq PD<sup>®</sup> in children living with HIV*

- *Triumeq PD<sup>®</sup> contains dolutegravir, abacavir, and lamivudine in a dispersible tablet*
- *Safe, well-tolerated and effective at controlling HIV when taken daily*

# NIAID Supported Research to Combat Malaria

Phase 2 study of a single SC injection of L9LS mAb in Malian children 6 – 10 years of age

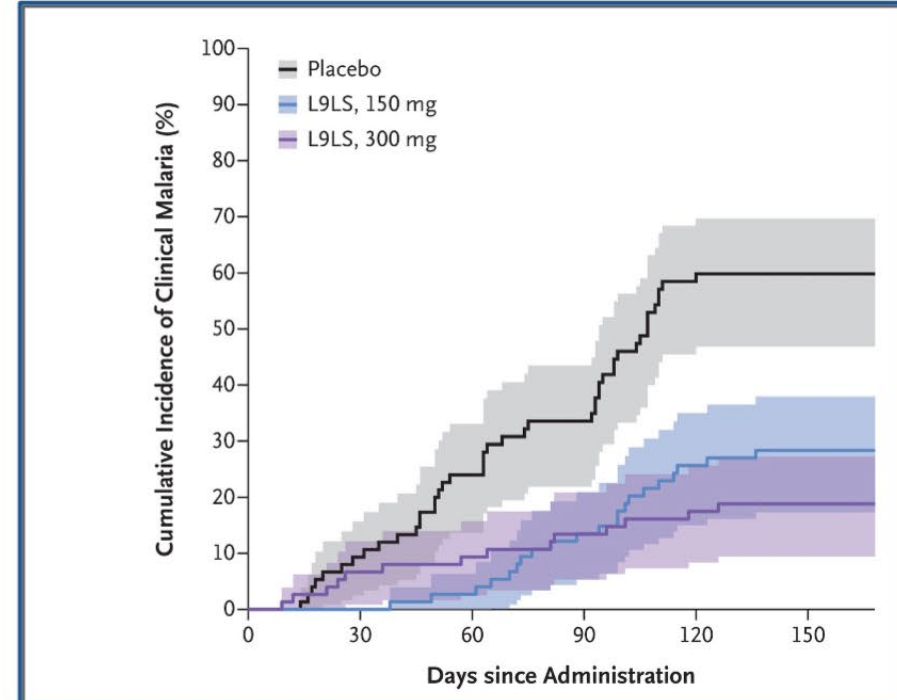


**81% infected  
(61 of 75)**

**66% efficacy  
vs. placebo**

**70% efficacy  
vs. placebo**

**Cumulative incidence of the first *P. falciparum* blood-stage infection during a 6-month malaria season**



**59% with  
clinical malaria**

**67% efficacy  
vs. placebo**

**77% efficacy  
vs. placebo**

**Cumulative incidence of the first clinical malaria episode due to *P. falciparum* infection during a 6-month malaria season**

Kayentao et al. NEJM, 2024





National Institute of  
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# OPPORTUNITIES FOR COLLABORATION

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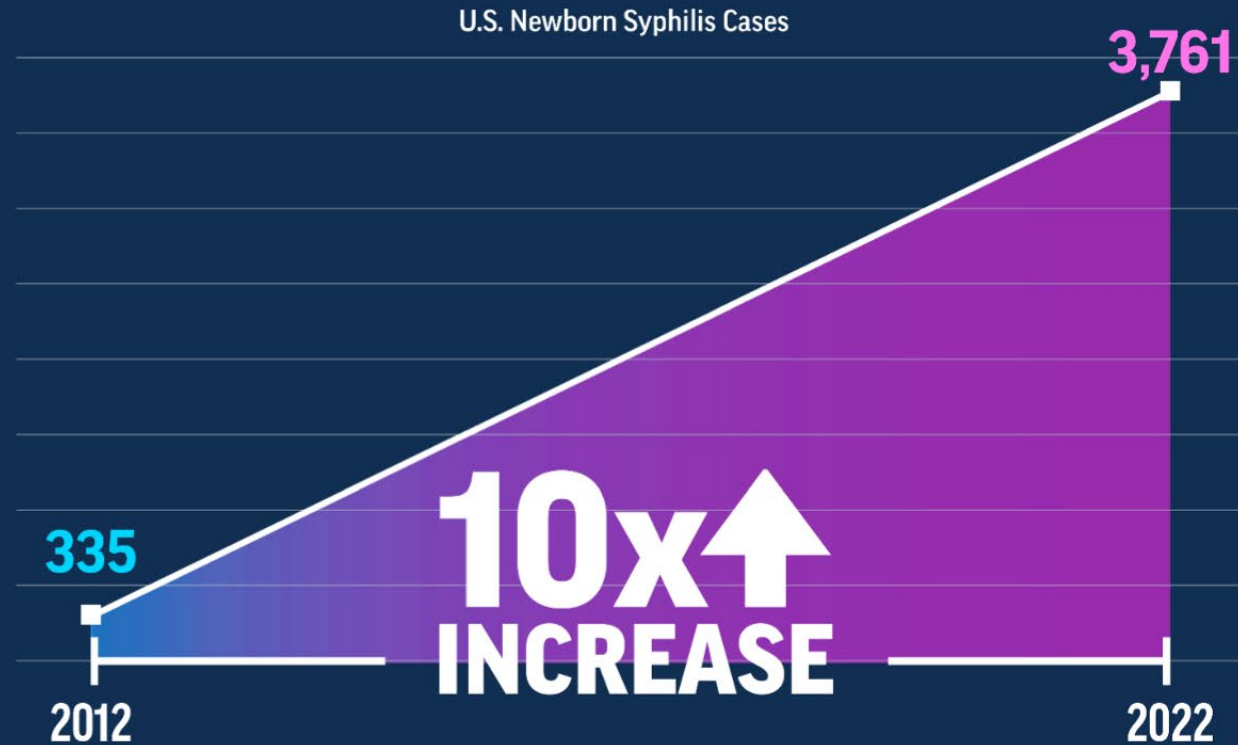


*Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

*Healthy pregnancies. Healthy children. Healthy and optimal lives.*

# CDC Recommends Action to Stop the Increase in Newborn Syphilis Cases

**U.S. Newborn Syphilis Cases Surge Over 10 Years**



**Vitalsigns<sup>™</sup>**

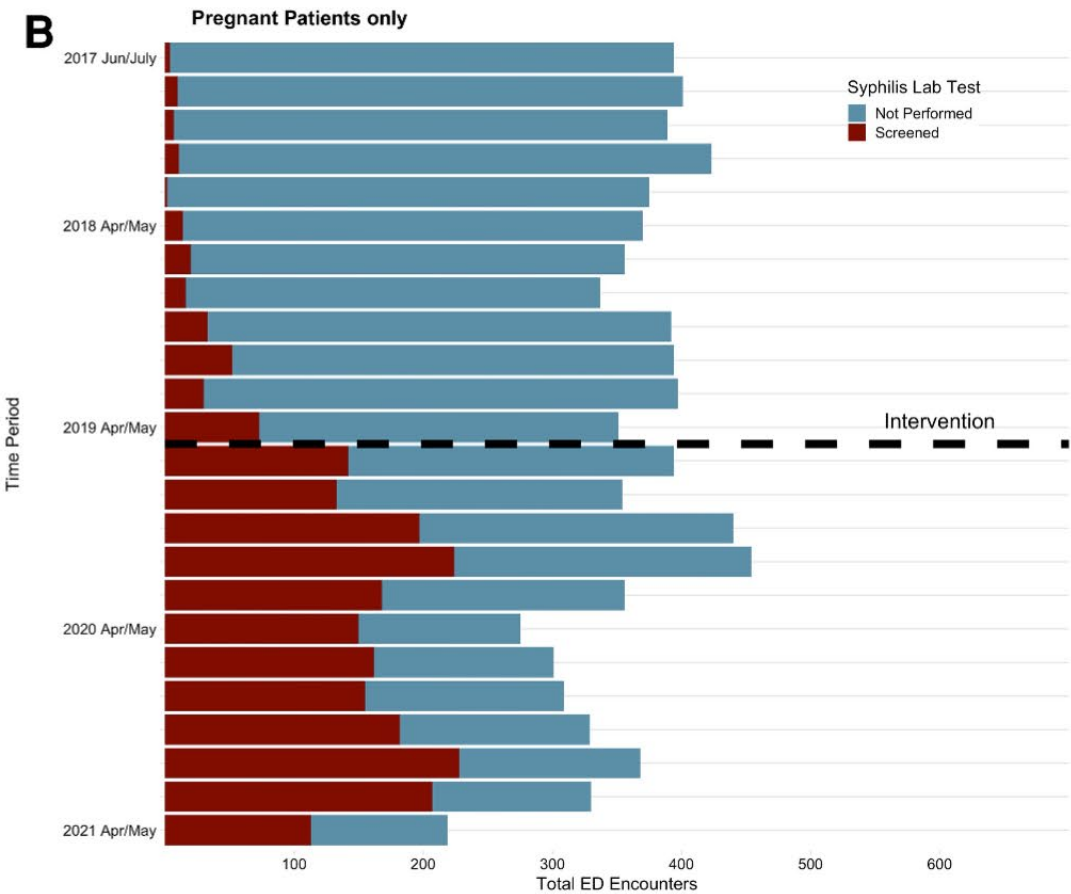
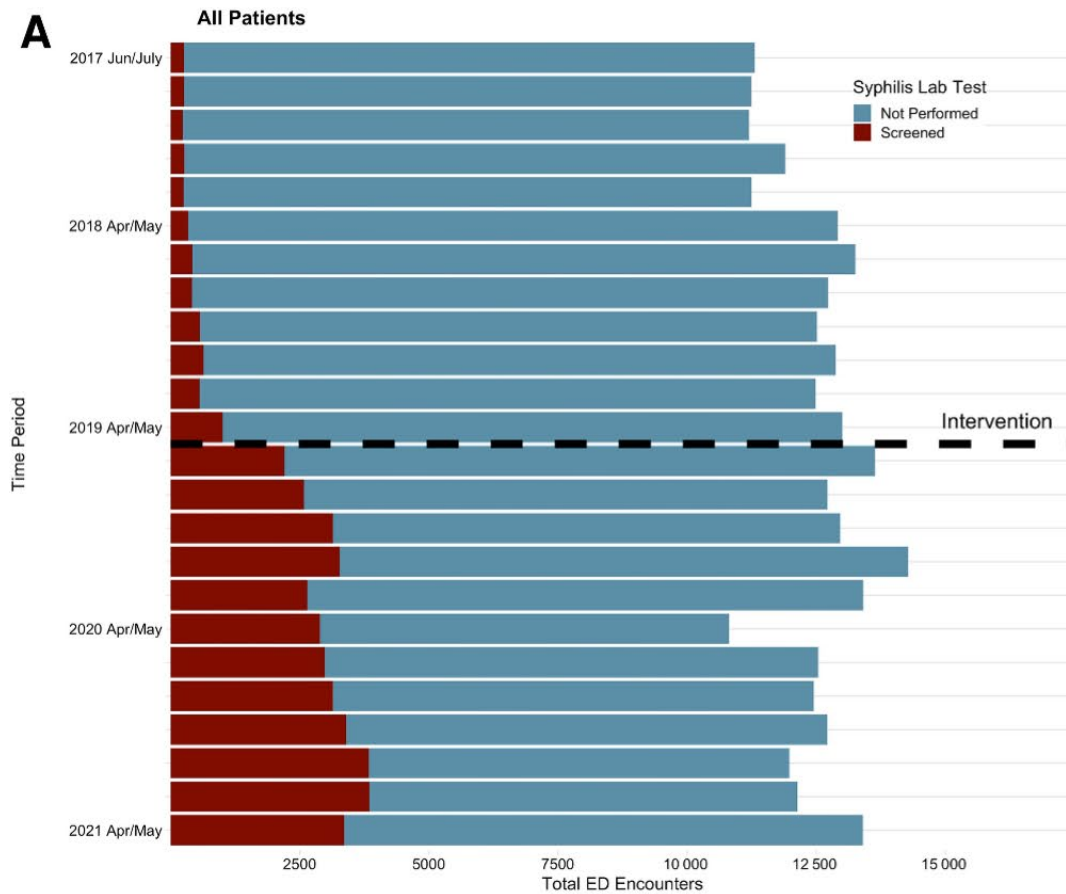
Source: November 2023 Vital Signs



CS341746

# Strategy to Increase Diagnosis & Treatment

*Offering optional syphilis tests to most people seeking care at a large emergency department leads to a dramatic increase in screening and diagnosis*



Stanford KA et al. *Open Forum Infectious Diseases*, 2024

# Opt-Out Emergency Department Screening by the Numbers

Assessing screening and diagnosis outcomes 2 years prior to implementation & 2 years after implementation



## 299,651 Emergency Department Encounters



### Screening of Pregnant People



Pre-intervention: 272 of 4,579 (5.9%)

Post-intervention: 2,061 of 4,129 (49.9%)



**750% increase** in confirmed cases  
(from 2 to 15)



### Overall Screening



Pre-intervention: 5,209 of 146,644 (3.6%)

Post-intervention: 37,289 of 153,007 (24.4%)



**288% increase** in presumed active infection (PAI)

- Pre-intervention: **161 syphilis cases** (3.1% of those screened)
- Post-intervention: **624 syphilis cases** (1.7% of those screened)

*Most individuals with syphilis did NOT exhibit STI symptoms*

Stanford KA et al. Open Forum Infectious Diseases, 2024

April 3, 2023

## Antiretroviral Treatment of HIV/AIDS During Pregnancy

Ahizechukwu C. Eke, MD, PhD, MPH<sup>1,2</sup>; Shahin Lockman, MD<sup>3,4,5</sup>; Lynne M. Mofenson, MD<sup>6</sup>

» Author Affiliations | Article Information

JAMA. 2023;329(15):1308-1309. doi:10.1001/jama.2023.5076



# Prevention of Mother-to-Child Transmission of HIV

- In 2021, ~160,000 new perinatal infections occurred
- ~48% of these perinatal infections were in infants born to women who did not receive ART during pregnancy due to either:
  - ❑ lacked knowledge of HIV serostatus;
  - ❑ acquired HIV during pregnancy or breastfeeding;
  - ❑ stopped ART during pregnancy or breastfeeding; or
  - ❑ inadequate viral suppression
- Prevention of MTCT of HIV remains a major public health challenge

# Ethical Inclusion of Pregnant/Breastfeeding Populations in Prevention Research Critical for Addressing Vertical Transmission

PREVENTION RESEARCH: PREVENTION RESEARCH

## DELIVER: A Safety Study of a Dapivirine Vaginal Ring and Oral PrEP for the Prevention of HIV During Pregnancy

Bunge, Katherine MD, MPH<sup>a</sup>; Balkus, Jennifer E. PhD<sup>b</sup>; Fairlie, Lee MBChB<sup>c</sup>; Mayo, Ashley J. MSPH<sup>d</sup>; Nakabiito, Clemensia MBChB<sup>e</sup>; Mgodini, Nyaradzo MMed<sup>f</sup>; Gadama, Luis MMed<sup>g</sup>; Matrimbira, Moleen MBChB<sup>h</sup>; Chappell, Catherine Anne MD<sup>i</sup>; Piper, Jeanna MD<sup>j</sup>; Chabwano, Nabisa MEd<sup>k</sup>; Daniel W. MSc<sup>l</sup>; Richardson, Barbra PhD<sup>m</sup>; Hillier, Sharon L. PhD<sup>n</sup>

Author information

JAIDS Journal of Acquired Immune Deficiency Syndromes 95(1): 10.1097/QAI.0000000000003312



## Pharmacokinetics of Dapivirine Transfer into Blood Plasma, Breast Milk, and Cervicovaginal Fluid of Lactating Women Using the Dapivirine Vaginal Ring

Lisa M. Noguchi,<sup>a</sup> Craig Hoesley,<sup>b</sup> Cliff Kelly,<sup>c</sup> Rachel Schechter,<sup>d</sup> Katherine Bunge,<sup>e</sup> Annalene Nel,<sup>f</sup> Mark A. Marzinko,<sup>g</sup> Craig W. Hendrix,<sup>h</sup> Charlene S. Dezzutti,<sup>i,j,k,l</sup> Sharon L. Hillier,<sup>e,l</sup> Debra L. Bogen,<sup>m</sup> Jeanna M. Piper,<sup>n</sup> Richard H. Beigzadeh,<sup>o</sup>

RECRUITING

## Optimizing PrEP Regimens for Pregnant Women in Sub-Saharan Africa

ClinicalTrials.gov ID NCT06435026

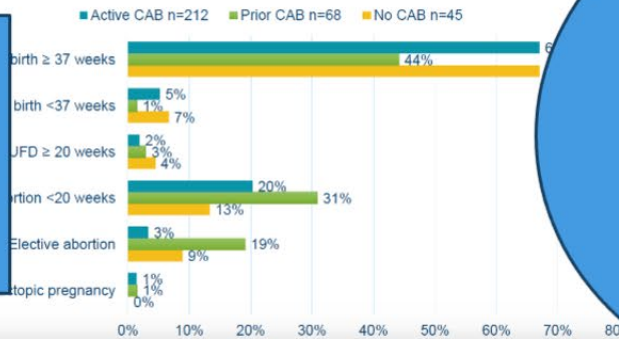
Sponsor University of North Carolina, Chapel Hill

Information provided by University of North Carolina, Chapel Hill (Responsible Party)

Last Update Posted 2024-08-27

23% of vertical transmissions attributed to HIV acquired during pregnancy/breastfeeding

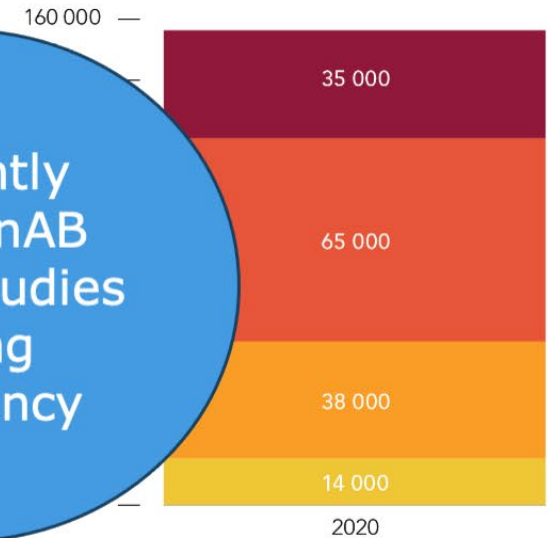
## OLE pregnancy outcomes, by exposure



Reassuring data for CAB and LEN but more needed

Currently zero bnAB safety studies during pregnancy

## New vertical HIV infections by cause of transmission, global, 2020



## Pregnancies Were Common and Outcomes Similar to Expected Rates in the Population

Participants and Pregnancies, n (%)	LEN n = 2138	F/TAF n = 2137	F/TDF n = 1070
Participants with confirmed pregnancies	184	208	95
Confirmed pregnancies	193	219	98
Completed pregnancies	105 (54.4)	119 (54.3)	53 (54.1)
Ongoing pregnancies	88 (45.6)	100 (45.7)	45 (45.9)
Births*	55 (28.5)	45 (20.5)	21 (21.4)
Interrupted pregnancies	50 (25.9)	74 (33.8)	32 (32.7)
Induced abortion	30 (15.5)	40 (18.3)	20 (20.4)
Spontaneous miscarriage <sup>b</sup>	20 (10.4)	34 (15.5)	12 (12.2)



Expected spontaneous miscarriage rate<sup>1,2</sup>:

- 10-20% of clinically recognized pregnancies
- 30% of biochemically detected pregnancies

- Mother acquired HIV during pregnancy or breastfeeding
- Mother did not receive antiretroviral therapy during pregnancy or breastfeeding
- Mother did not continue with treatment during pregnancy or breastfeeding
- Mother was on antiretroviral therapy but not virally suppressed

Source: UNAIDS epidemiological estimates, 2021 (<https://aidsinfo.unaids.org/>).

# U.S. Guidelines to Reduce Perinatal HIV Transmission



## Testing

- All pregnant people be tested as early as possible
- Testing in 3rd trimester and during labor for people with increased risk or previously untested

## Treatment

- ART during pregnancy
- IV zidovudine and cesarean section delivery for mothers with unknown or unsuppressed viral load at delivery
- Neonatal ART prophylaxis after delivery

*Perinatal HIV transmission risk in the U.S. has decreased to less than 1%*

# Perinatal HIV Transmission in Maryland

PEDIATRICS®

CASE REPORT | OCTOBER 10 2024

## Increase in Cases of Perinatal HIV Transmission in Maryland in 2022 ✓

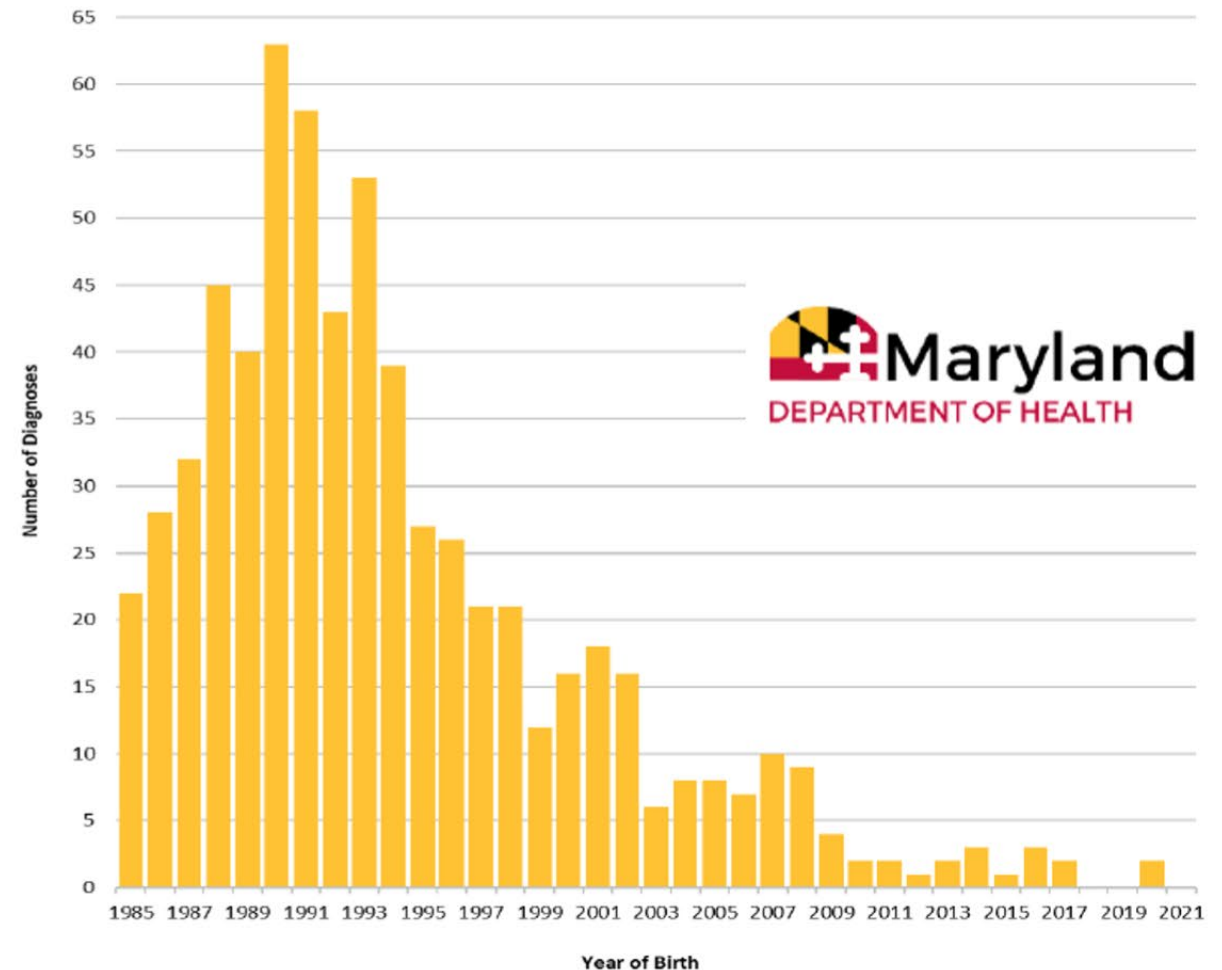
David C. Griffith, MD; Matthew Grant, MD; Wei Li Adeline Koay, MBBS, MSc; Natella Rakhmanina, MD, PhD, FAAP, FCP, AAHIVS; Anna Maya Powell, MD, MSc; Allison Agwu, MD, ScM, FAAP, FDSA

**2018-2021:** 2 perinatal HIV cases reported  
**2022:** 6 new diagnoses reported

### *Some Contributing Risk Factors:*

- Delayed HIV diagnosis until pregnancy & HIV acquisition during pregnancy
- Delayed linkage to HIV care & ART initiation
- Poor ART adherence
- Lack of dosing of preventative antiretrovirals for premature infants
- Substance use and lack of perinatal/HIV care
- Missed diagnosis in pregnancy & lack of testing after parental diagnosis

Pediatric Reported HIV Diagnoses





# Immune Mechanisms at the Maternal-Fetal Interface

Understanding the interactions of immune cells that enable pregnancy and modulate immunity in offspring

Program began in 2019

43 of 154 publications cite both NIAID and NICHD funding



American Journal of Obstetrics and Gynecology

Volume 225, Issue 3, September 2021, Pages 303.e1-303.e17



Original Research  
Obstetrics

## Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study

Showed mRNA COVID-19 vaccines generated **robust humoral immunity** in pregnant & lactating women, with **similar reactogenicity and immunogenicity** observed in nonpregnant women. Immune transfer to neonates occurred via placenta and breastmilk.



# Translational Research in Maternal and Pediatric Pharmacology and Therapeutics Program Announcement

Eunice Kennedy Shriver National Institute of  
Child Health and Human Development

National Institute of Allergy and Infectious  
Diseases

National Institute of Drug Abuse

National Institute of Mental Health

Office of Research on Women's Health

*Improving safe and effective precision therapeutics for pregnant and lactating persons, fetuses, neonates, and children, including those with disabilities*

- Develop novel tools, models, and other technologies that have a direct clinical or health impact
- Enhance understanding of the underlying mechanisms of drug action
- Discover and develop novel therapeutics or enhance the usage of existing drugs

**PAR-25-110** (R01 Clinical Trial Optional)

**PAR-25-111** (R21 Exploratory/Developmental Grants)

# Looking to the Future



Apply genomics to treat pediatric diseases



Eliminate perinatal infectious disease transmission



Reduce the burden of childhood asthma and allergy



Develop vaccines to prevent infectious disease



# Thank You!

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