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Office of AIDS Research, DPCPSI

NIH HIV/AIDS Research Agenda: The OAR Role

NIH Council of Councils

May 17, 2019

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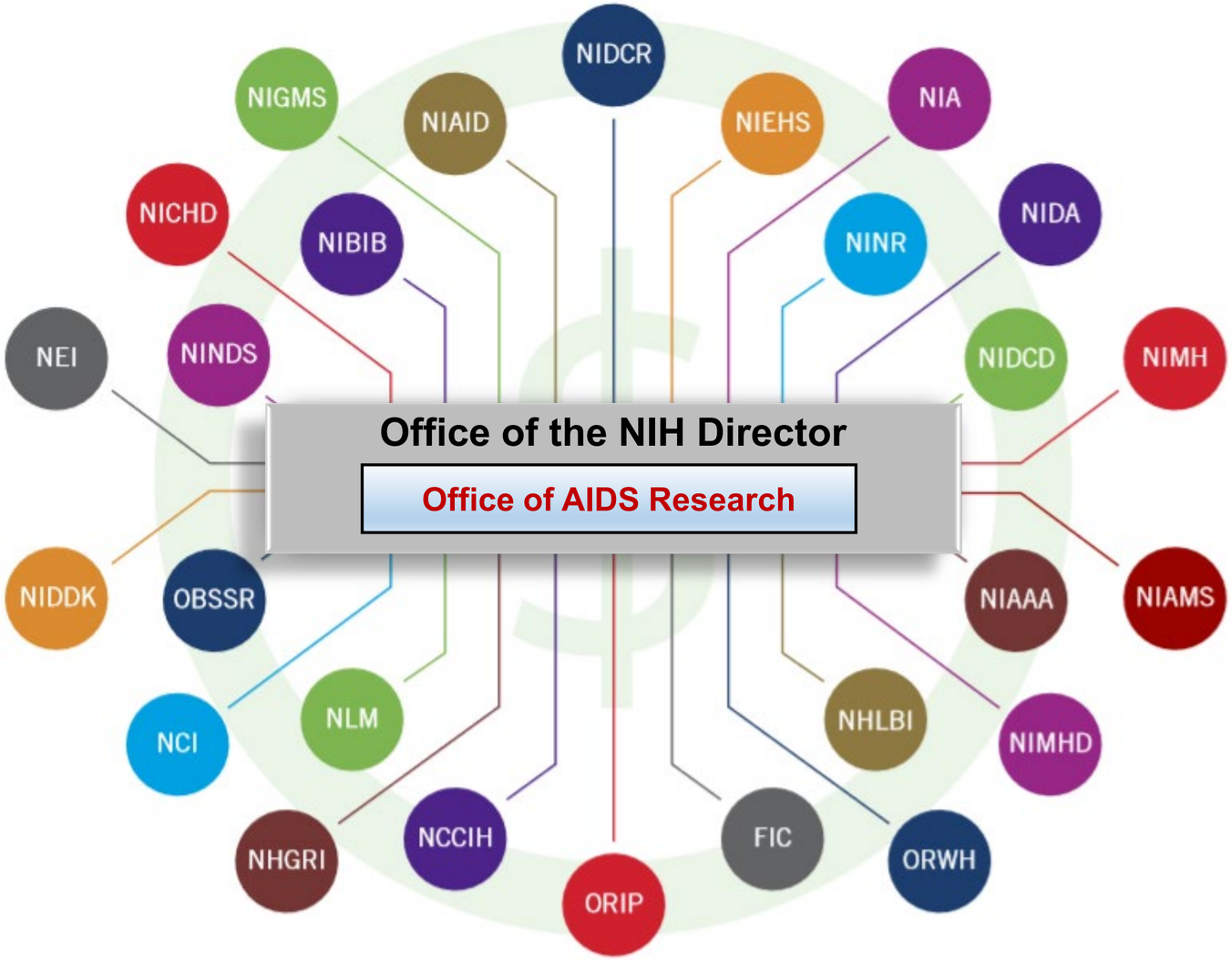
Vision for NIH-wide HIV Research

End the HIV/AIDS pandemic

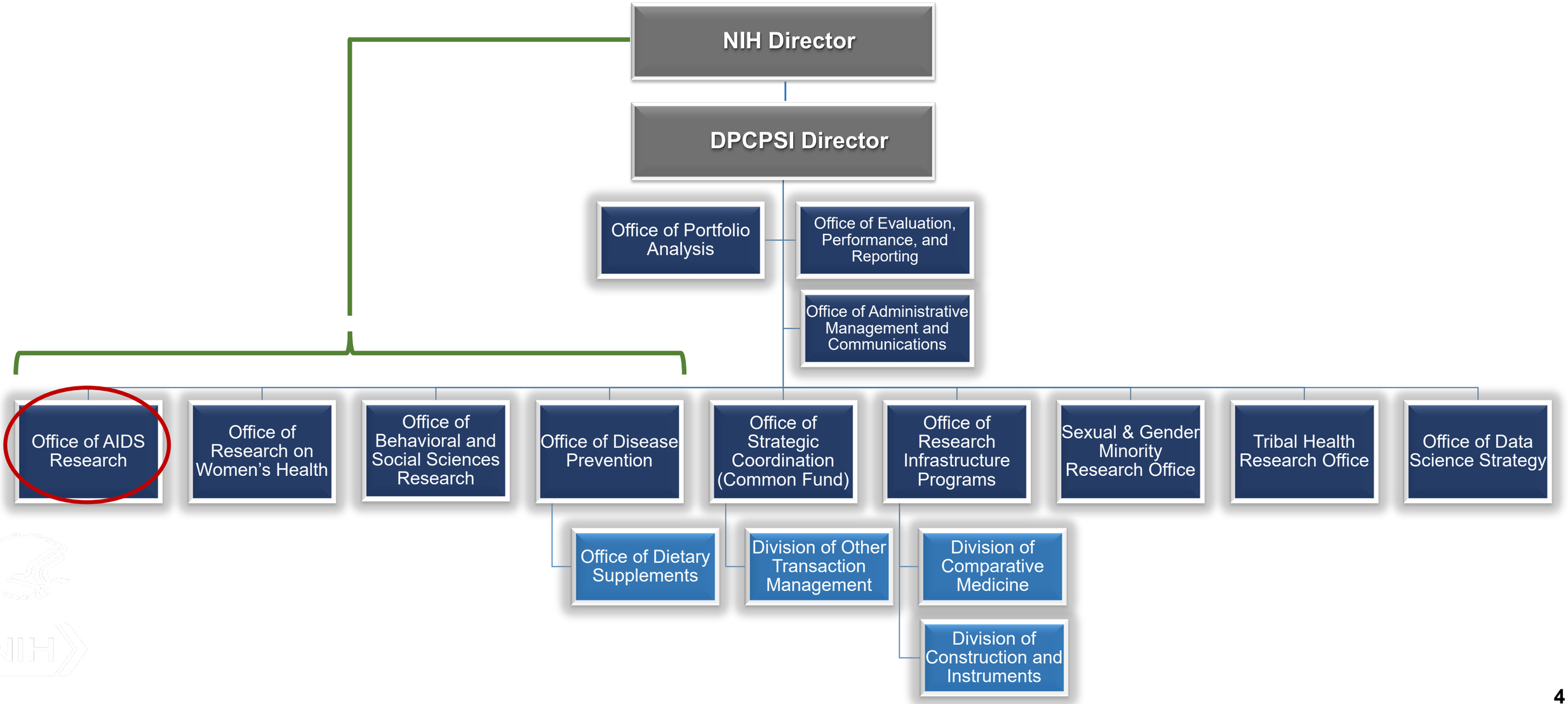
AND

Improve the health of people with, at risk for, or affected by HIV.

HIV Funds Allocation Across ICOs



OAR Within DPCPSI



OAR Role in NIH HIV/AIDS Research

- Coordinates the largest public investment in HIV/AIDS research globally.
- Establishes scientific priorities.
- Allocates research funds in line with scientific priorities to nearly every NIH IC.
- Manages HIV/AIDS research across the NIH: scientific, budgetary, legislative, and policy components.

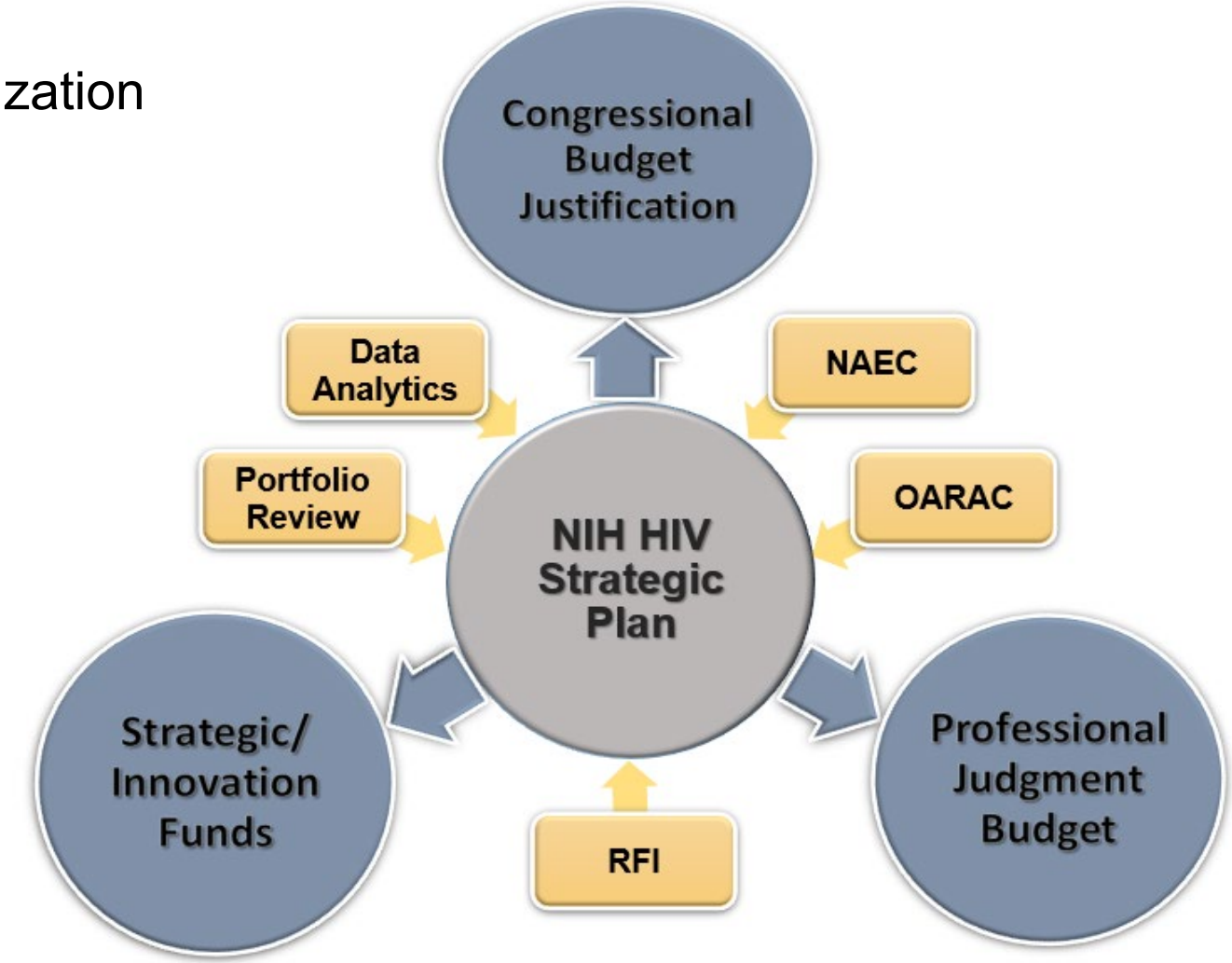
OAR Authorities

Authorizing Legislation–

- **Develop a comprehensive plan for HIV/AIDS research**
  - *NIH Strategic Plan for HIV and HIV-Related Research*.
- **Professional Judgment (By-Pass) Budget**
  - Estimates funding to optimally implement the NIH HIV research agenda.
- **Transfer Authority**
  - May transfer up to 3% of NIH HIV research funds among ICs if Congress is notified in advance.
- **Construction Authority**
  - May authorize up to $8M of funding for the construction or renovation of facilities.

NIH HIV Strategic Planning Framework

- Response to Congressional Authorization
- Ensure Transparency
- Maximize Stakeholder Input
- Justify the Congressional Budget
- Develop the Professional Judgment Budget
- Distribute Strategic and Innovation Funds



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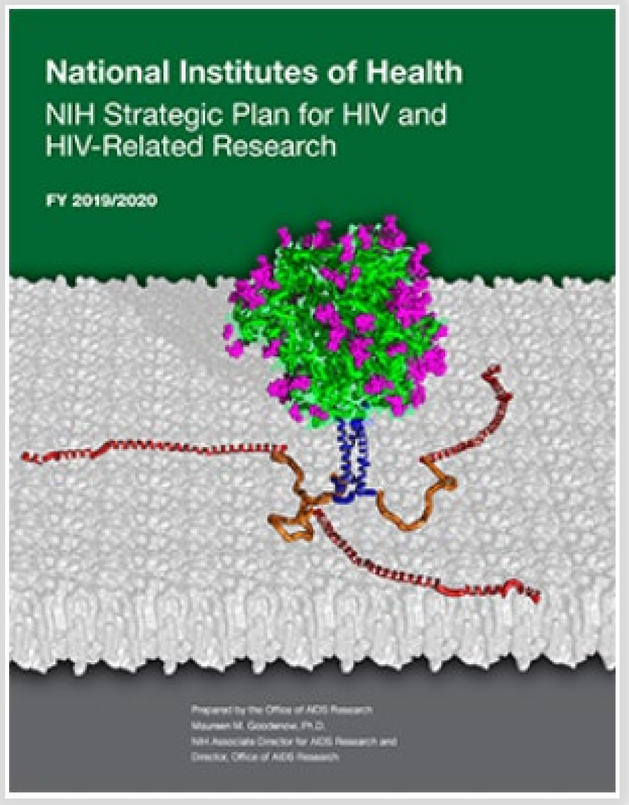
NIH Strategic Plan for HIV and HIV-Related Research

- Provides a roadmap for NIH HIV/AIDS research.
- Ensures that funds are allocated based on NIH HIV research priorities.
- **Transitioning to a 5-year cycle for FY 2021−2025.**



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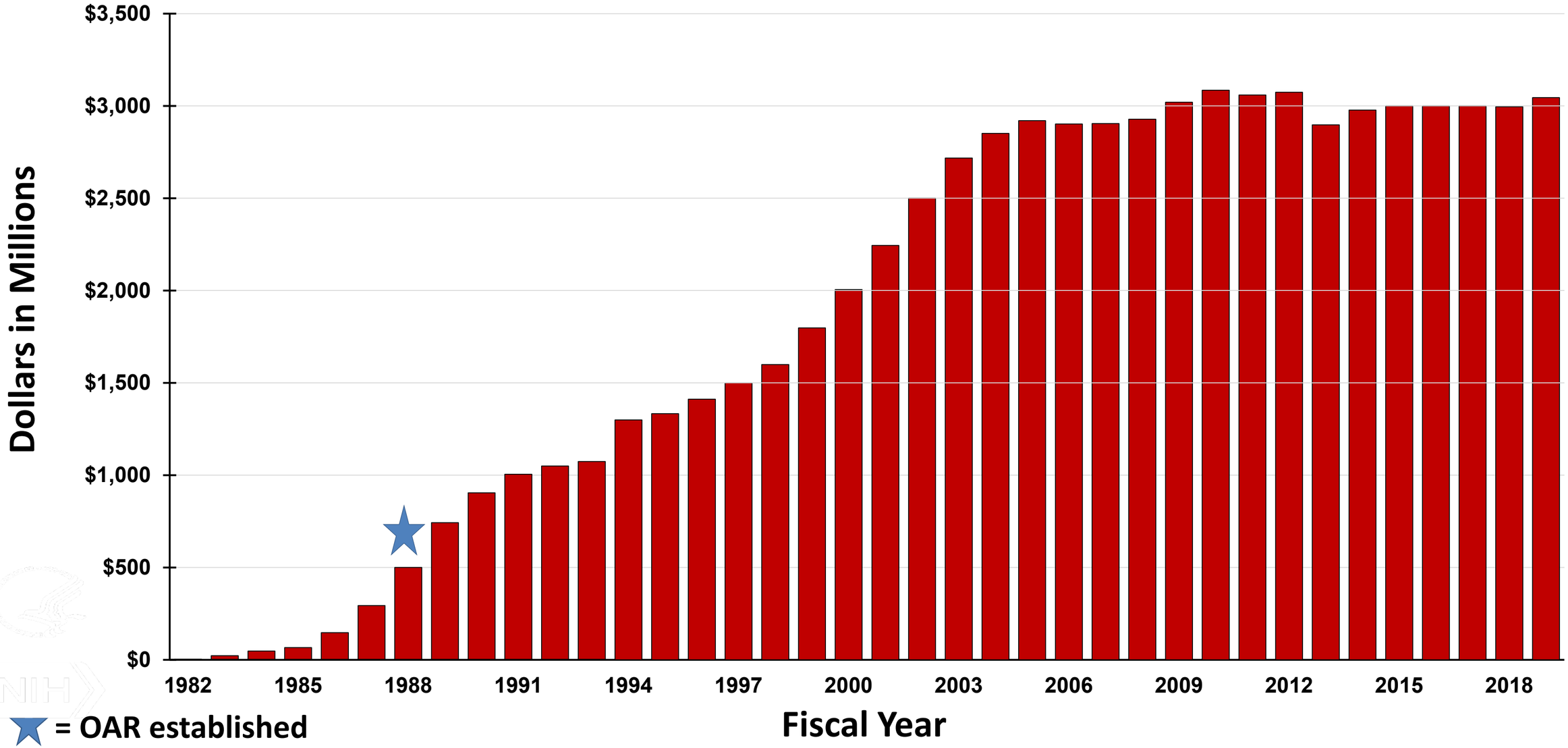
NIH HIV/AIDS Funding History, 1983 – Present



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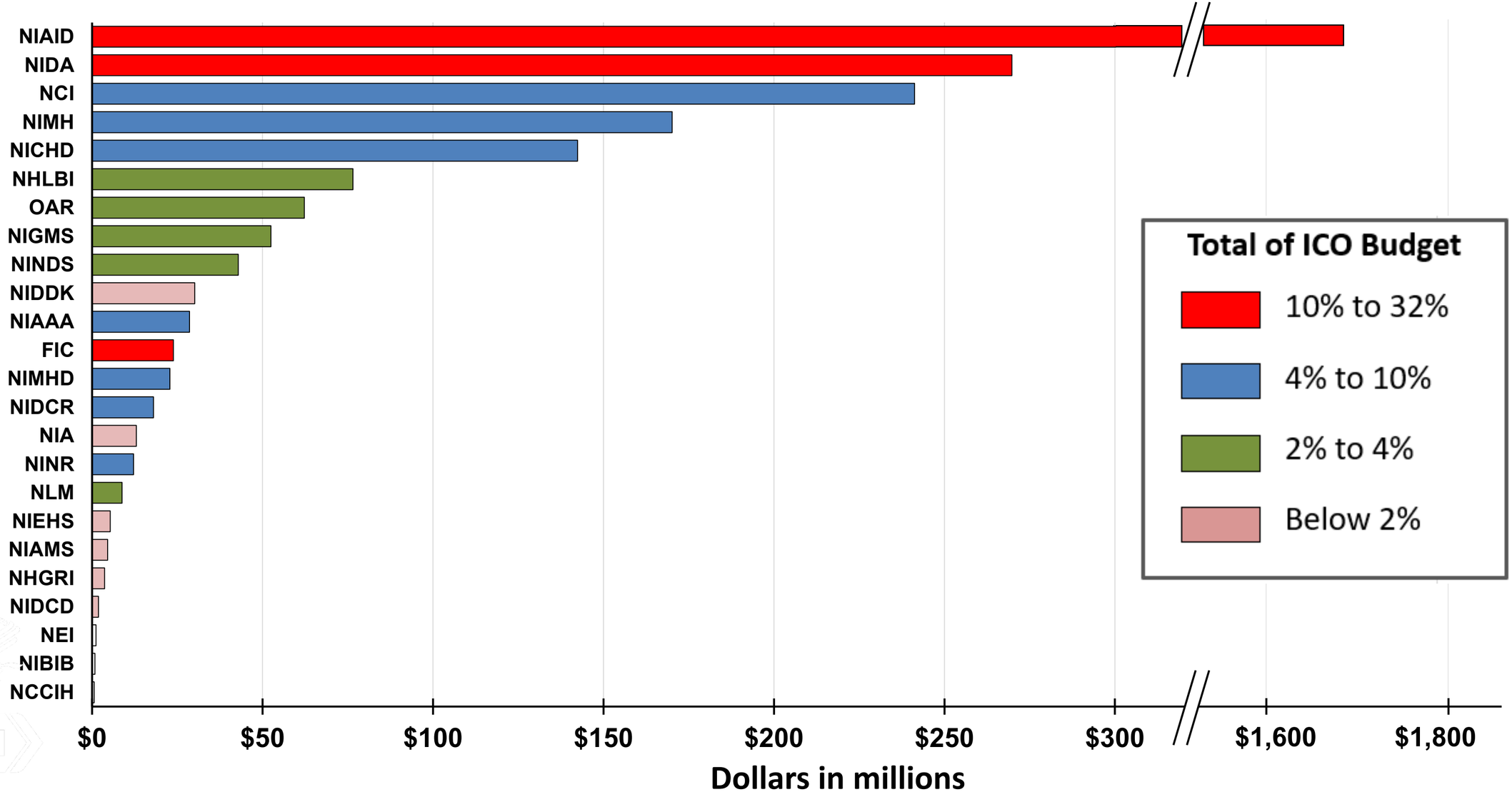
FY 2018 HIV Funding Distribution by ICO



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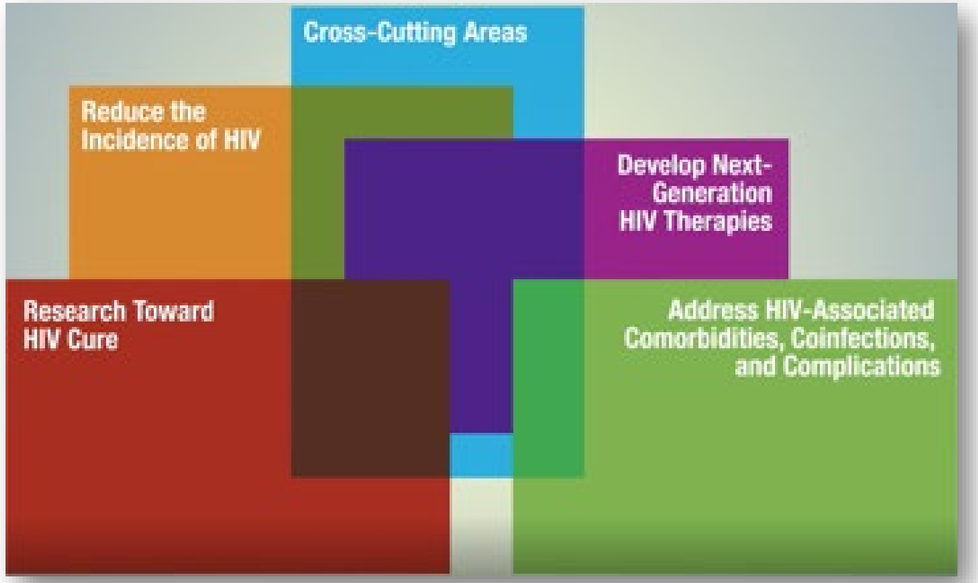
NIH Priorities for HIV and HIV-Related Research



Reduce Incidence

- Vaccines
- PrEP, U=U
- Microbicides & MPTs
- HIV Testing
- Treatment as Prevention
- Monoclonal Antibodies

Research Toward A Cure

- ART-free Viral Remission
- Viral Eradication
- Viral Latency & Sanctuaries
- Cure Ethics & Acceptability

Cross-Cutting Areas

- Virology & Immunology
- Behavioral & Social Sciences
- Epidemiology
- Health Disparities
- Information Dissemination
- Implementation Science
- Infrastructure, Capacity Building

Next-Gen HIV Therapies

- Less Toxic, Longer Lasting ART
- Novel HIV Targets & Inhibitors
- Novel Immune-Based Therapies
- Adherence & Retention-Care

Comorbidities, Coinfections, & Complications

- Coinfections
- Neurologic Complications
- Malignancies
- Cardiovascular Complications
- Mental Illness/Substance Use
- Metabolic Disorders
- Across the Lifespan

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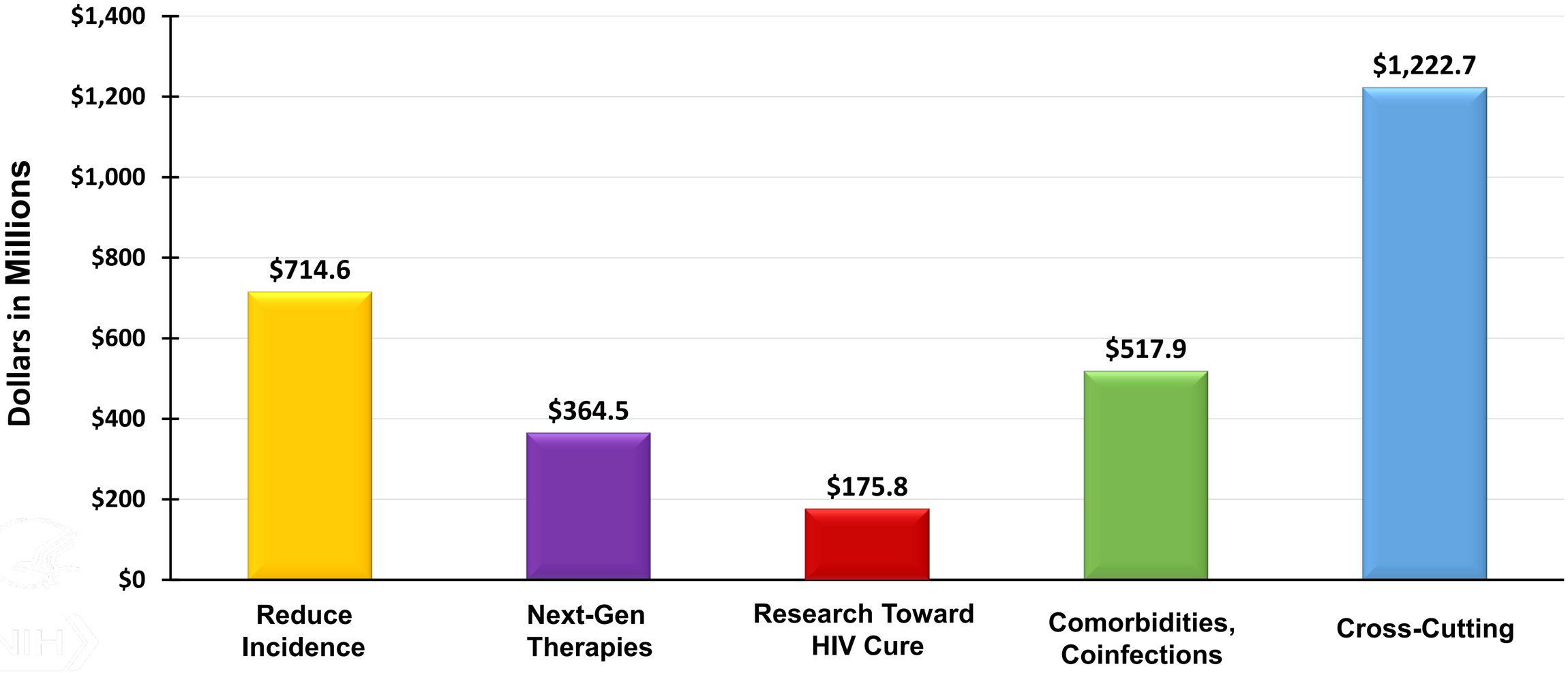
FY2018 HIV/AIDS Portfolio by Research Priority



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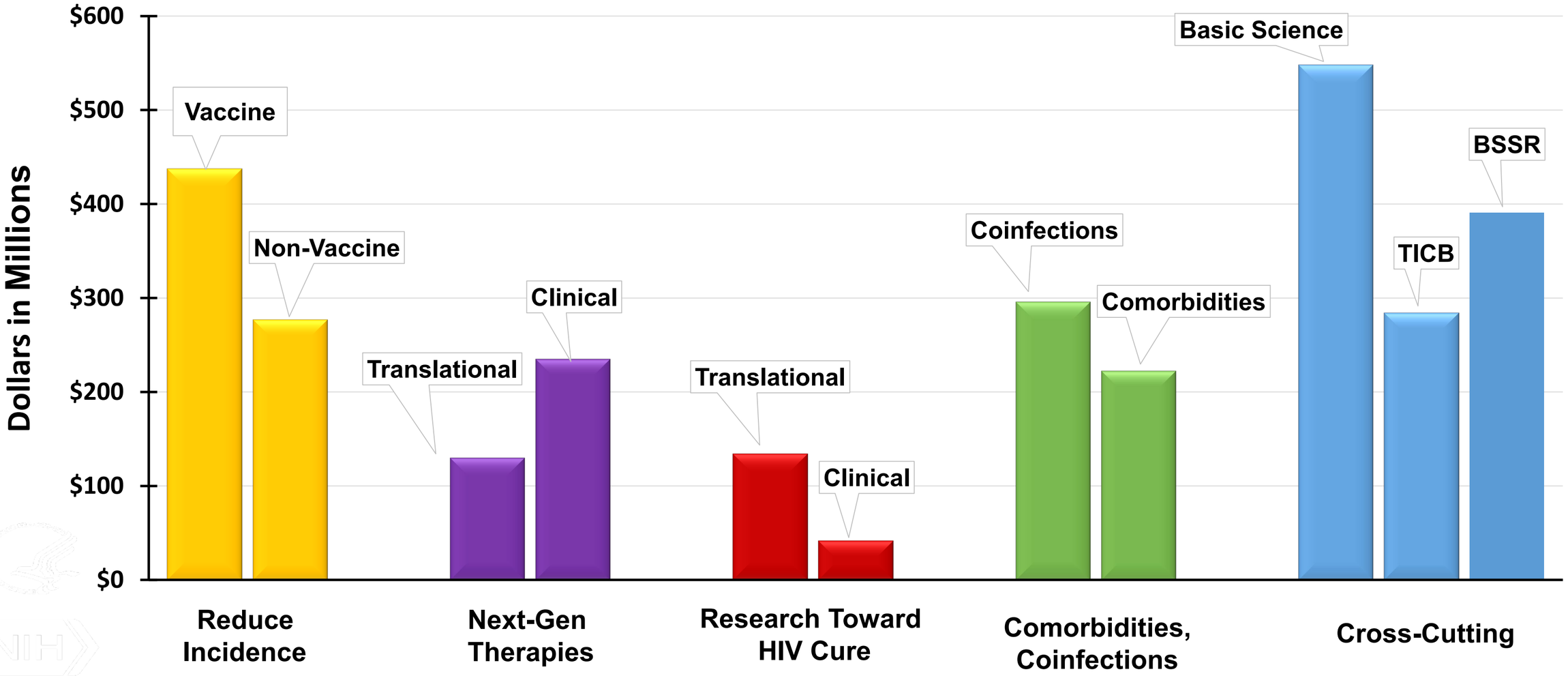
FY2018 HIV/AIDS Budget by Research Priority



FY 2019 Budget Increase

- The Director of NIH in consultation with the Director of OAR provided a **funding increase of <u>$45 M</u> above the FY 2018 budget**.

- **Funds are focused on key scientific areas:**
  - ✓ Reducing Incidence – Vaccine Research
  - ✓ Comorbidities, Coinfections, and Complications

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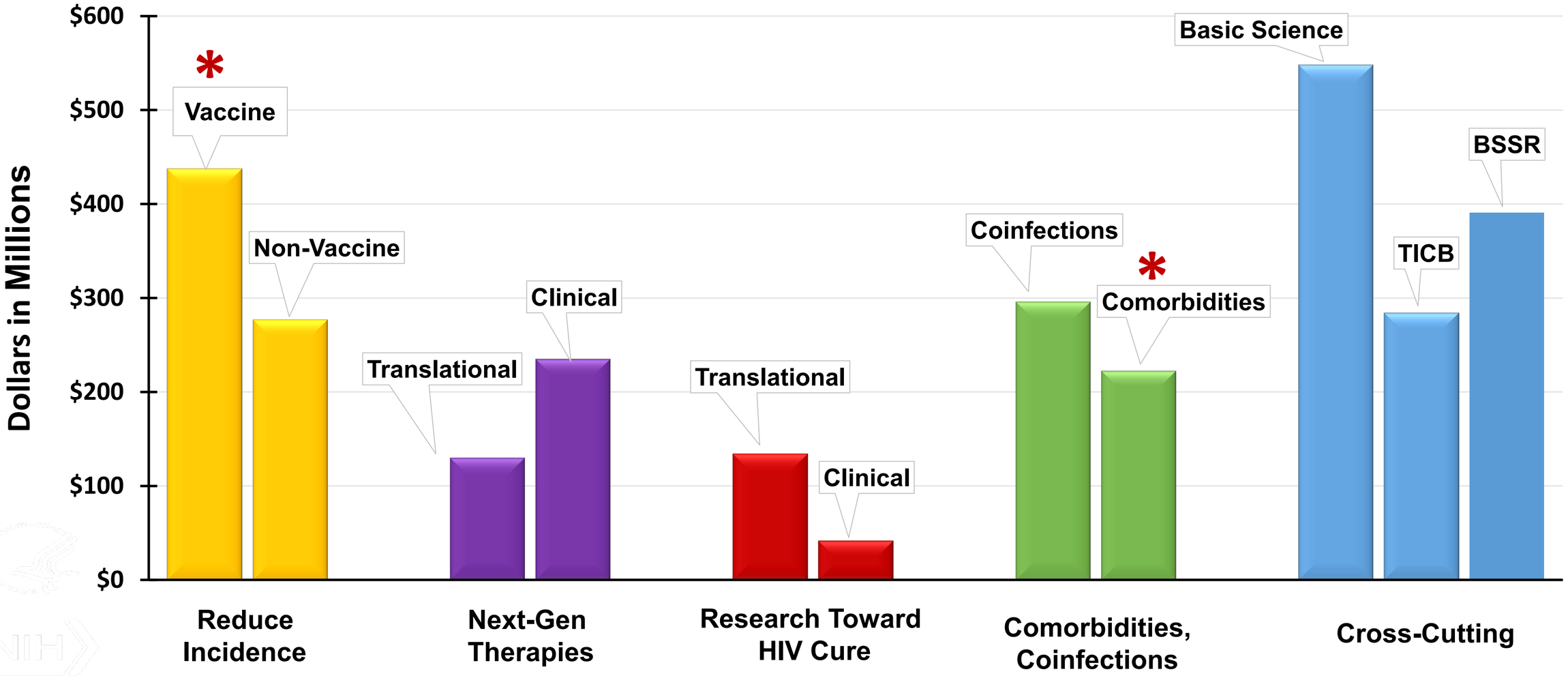
FY2019 HIV/AIDS Budget by Research Priority



* New dollars

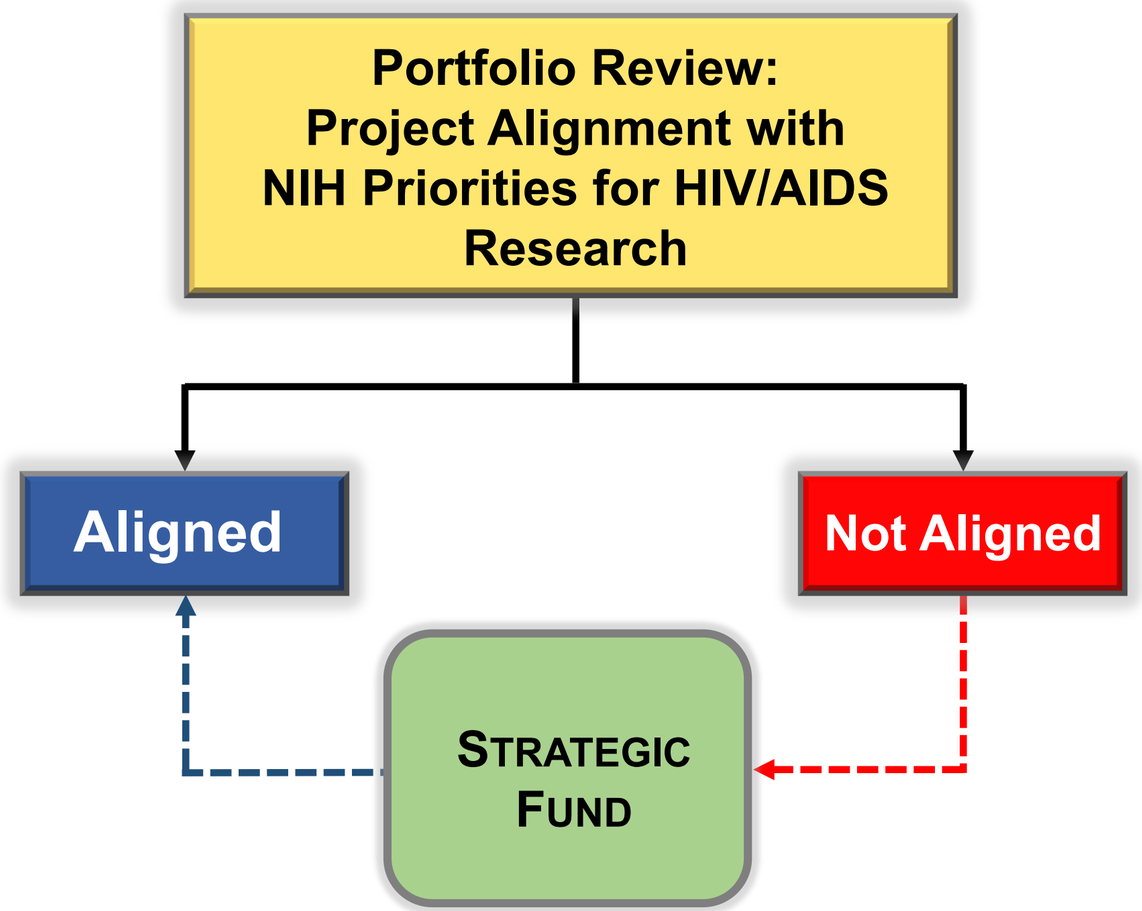
Portfolio Review and Strategic Fund

Each year, OAR reviews the research portfolio.

- Funds for completed projects that are no longer aligned with current research priorities are moved to a **Strategic Fund.**
- New projects receive support from the Strategic Fund in response to changing science.

Implementation of the Pivot

Review of ICO's HIV Portfolio by Project



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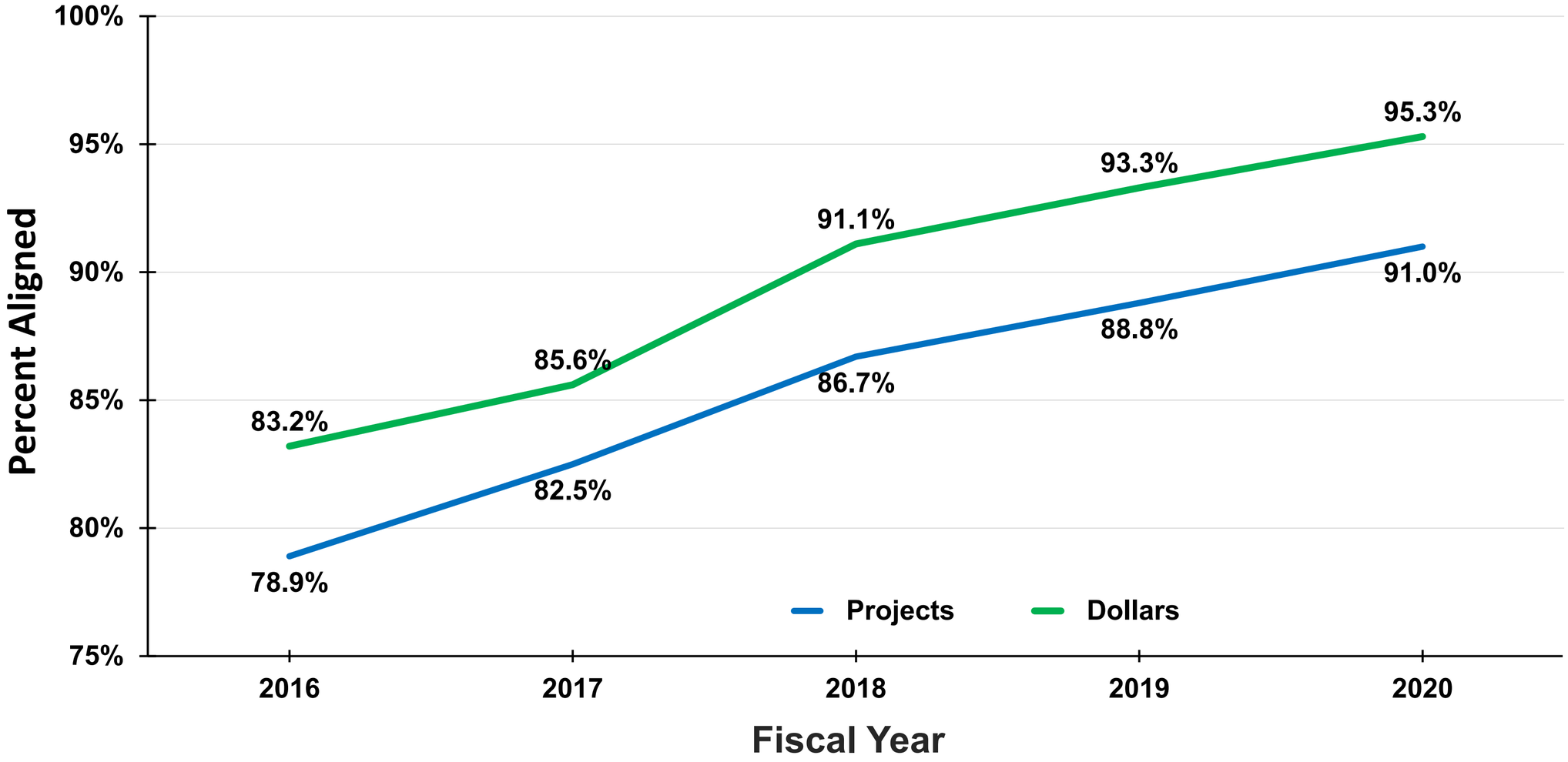
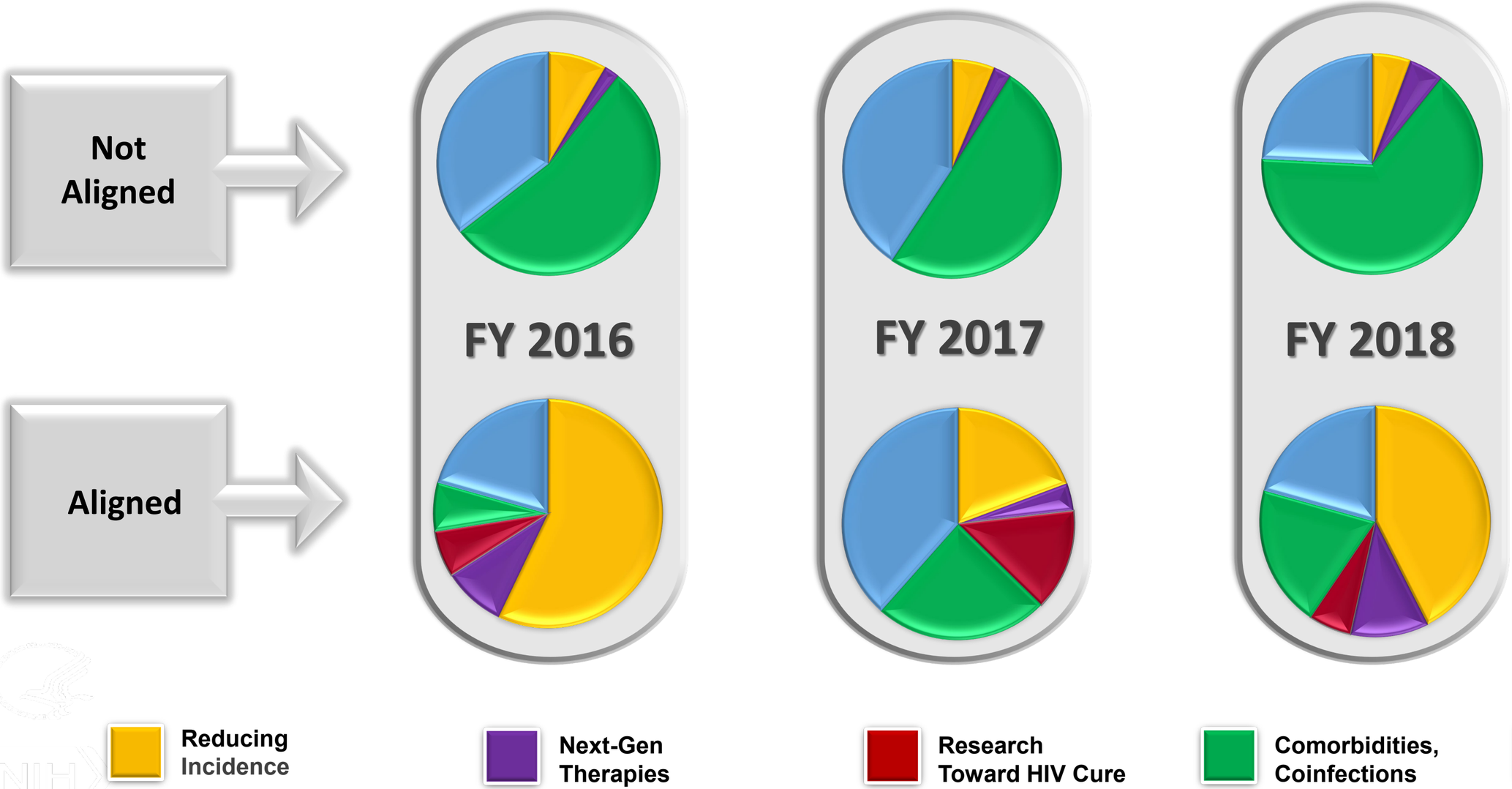
Increased Alignment of Projects and HIV/AIDS Priorities



Strategic Fund by Research Priority Area



OAR and Cost Sharing

Cost sharing – a collaborative funding approach

- Combines non-HIV with HIV dollars to support research with high potential to inform HIV research priorities
- Helps NIH “follow the science”
- OAR-NIA pilot – RFA-AG-18-023 – “Pathogenesis of Age-Related HIV Neurodegeneration”
  - Eight projects funded in 2018

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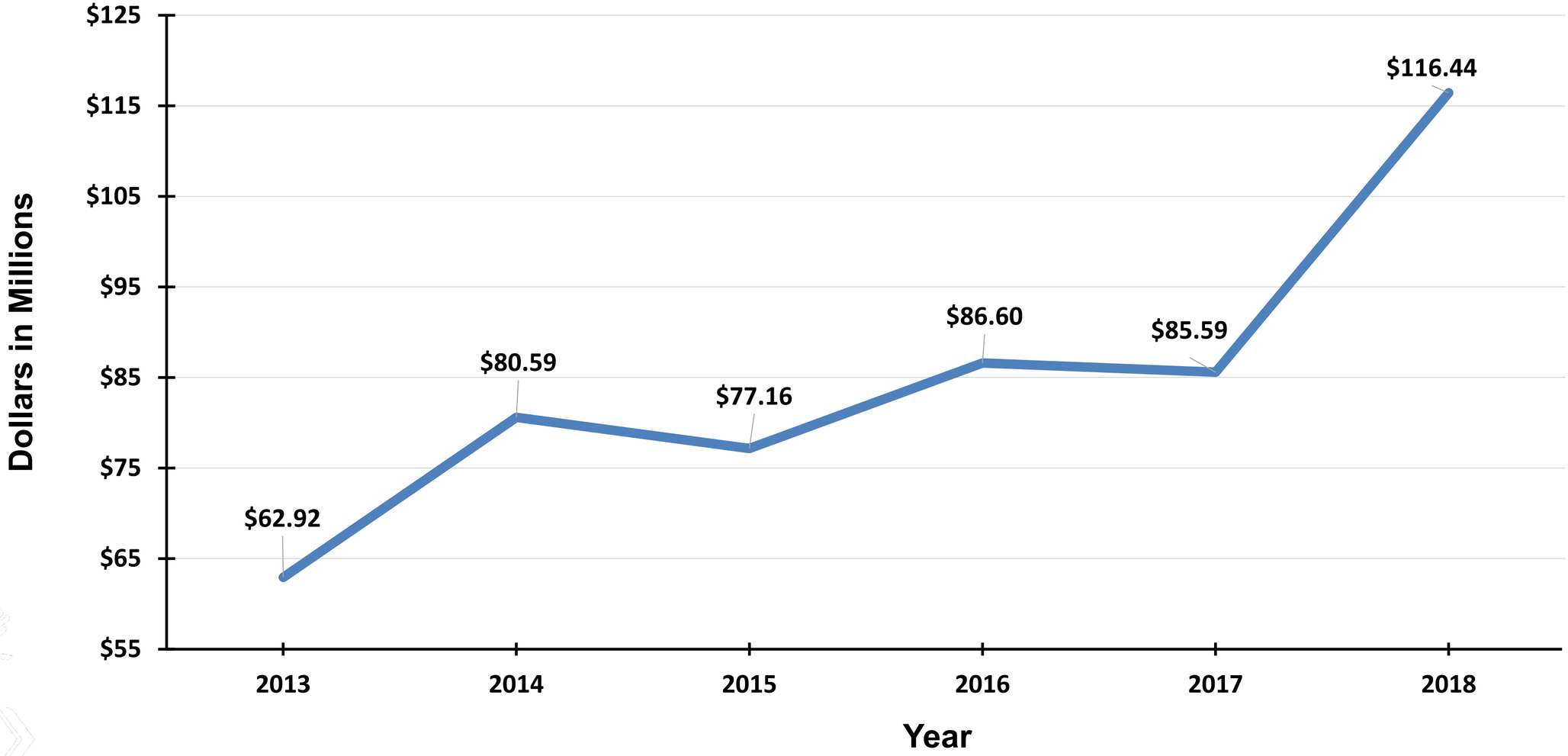
NIH Investment in HIV/AIDS and Aging-Related Research, FY 2013 - 2018



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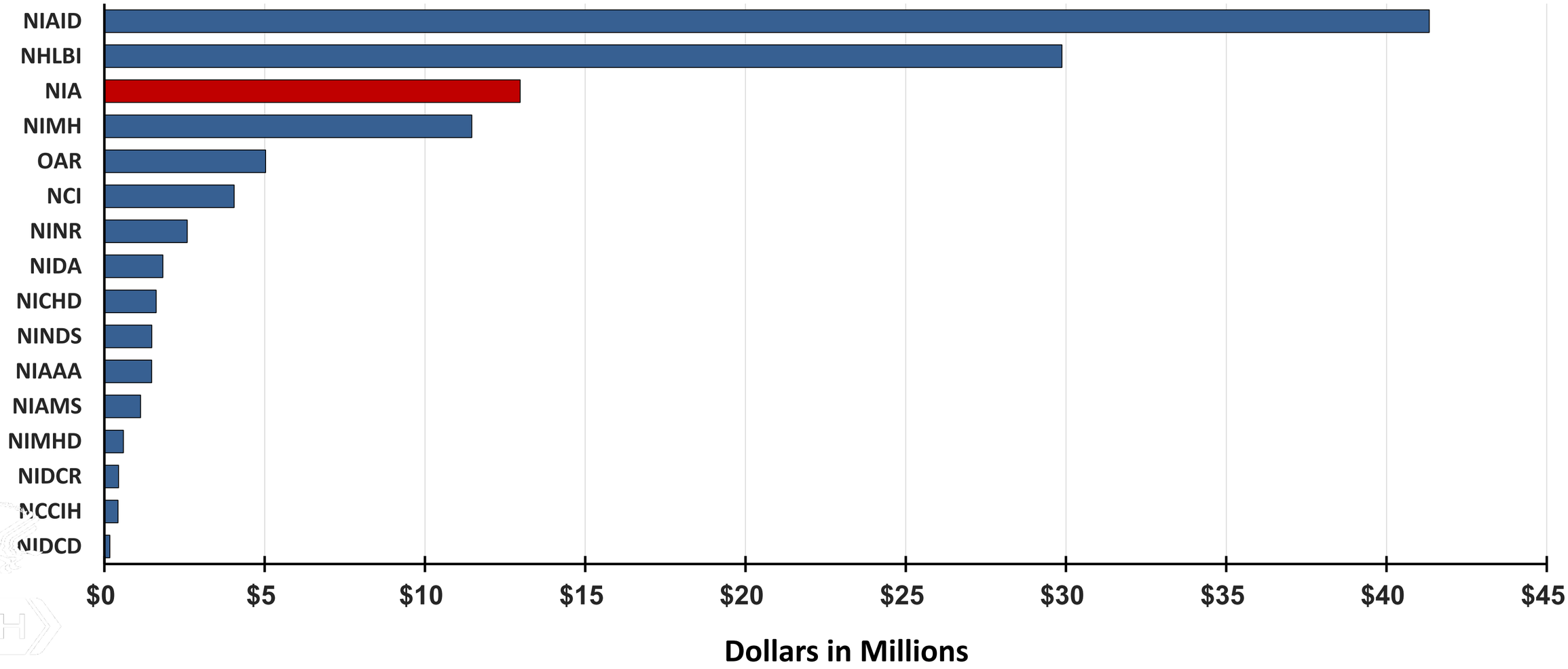
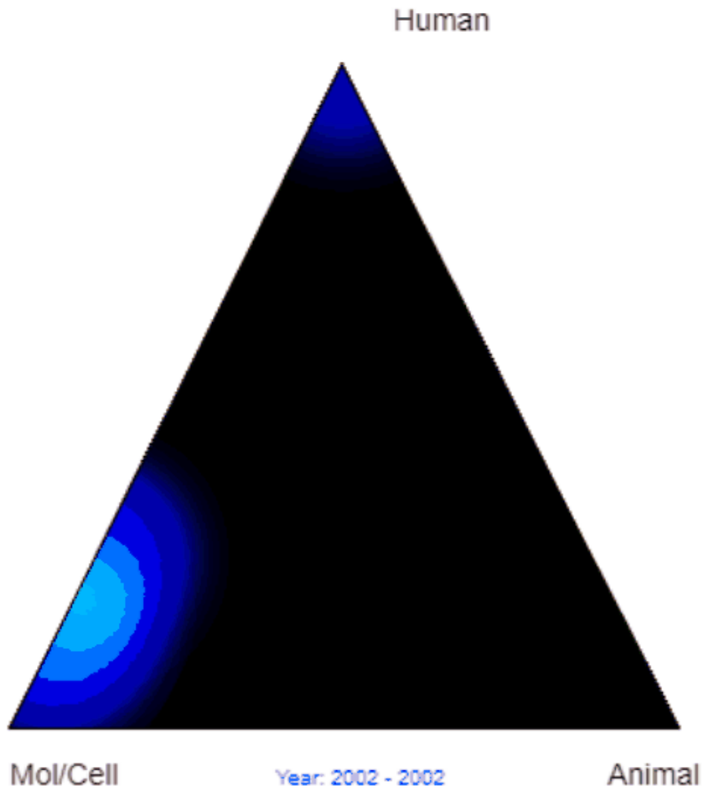
NIH Investment in HIV/AIDS and Aging-Related Research by NIH ICO, FY 2018



Implementing Data Analytics



Cure research in HIV/AIDS: Translation from bench to bedside

- Publication analysis of NIH-funded HIV/AIDS investigators
- Includes more than 10,000 publications over 16 years (2002 to 2018)
- Shows gradual transition of research from basic to clinical

Early Stage Investigators (ESI)

PNAS PNAS PNAS

OPINION

The Next Generation Researchers Initiative at NIH

Michael Lauer[a,1], Lawrence Tabak[a], and Francis Collins[a]

Growing concerns about the wellbeing and stability of the biomedical research workforce are well documented. Over the last 15 years (since the end of the doubling of the NIH budget), we have observed worsening "hypercompetition" as more scientists vie for fewer available dollars (1, 2). Within this hypercompetitive environment, the research workforce is growing older at a rate that is disproportionate to the general American labor force (3). Late-career investigators have been awarded a greater proportion of available research funding, raising concerns that early-career investigators risk being crowded out of the workforce before they have a chance to launch independent scientific careers (3). Other analysts have suggested that adverse effects are also being felt by midcareer investigators (4); large numbers of meritorious investigators may achieve research independence only to lose it because they are unable to renew their one grant or obtain a second new grant.

In our latest effort to tackle this problem, the NIH is launching the "Next Generation Researchers Initiative,"

Fig. 1. The NIH hopes its latest initiative will improve the grant-funding prospects for early- and midcareer investigators. Image courtesy of Shutterstock/Stephen_Payne.

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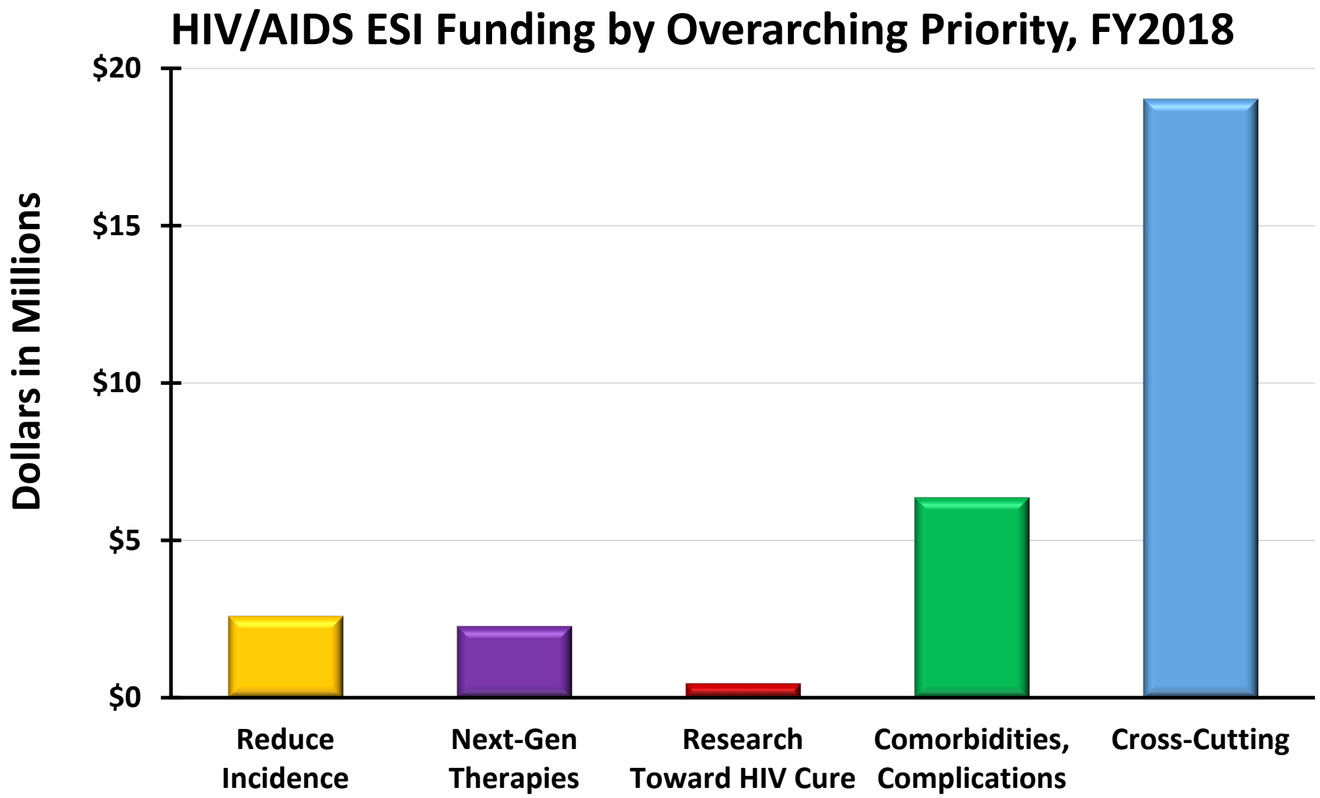
HIV Research Awards to ESI in FY2018

Of the 1,100 NIH-wide ESI projects, 51 were HIV R01-equivalent awards, totaling $30.6 M.



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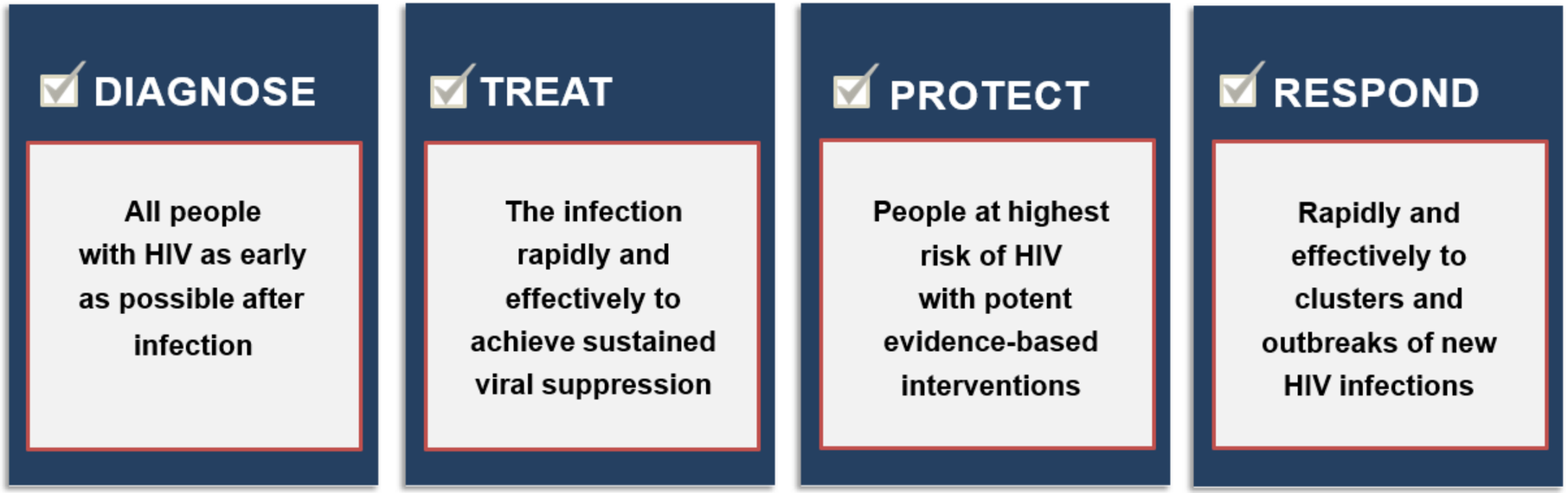
Ending the HIV Epidemic: A Plan for America



Overall goal is to reduce new infections:

- **By 75% in the next 5 years**; and
- **By 90% in the next 10 years**

Ending the HIV Epidemic

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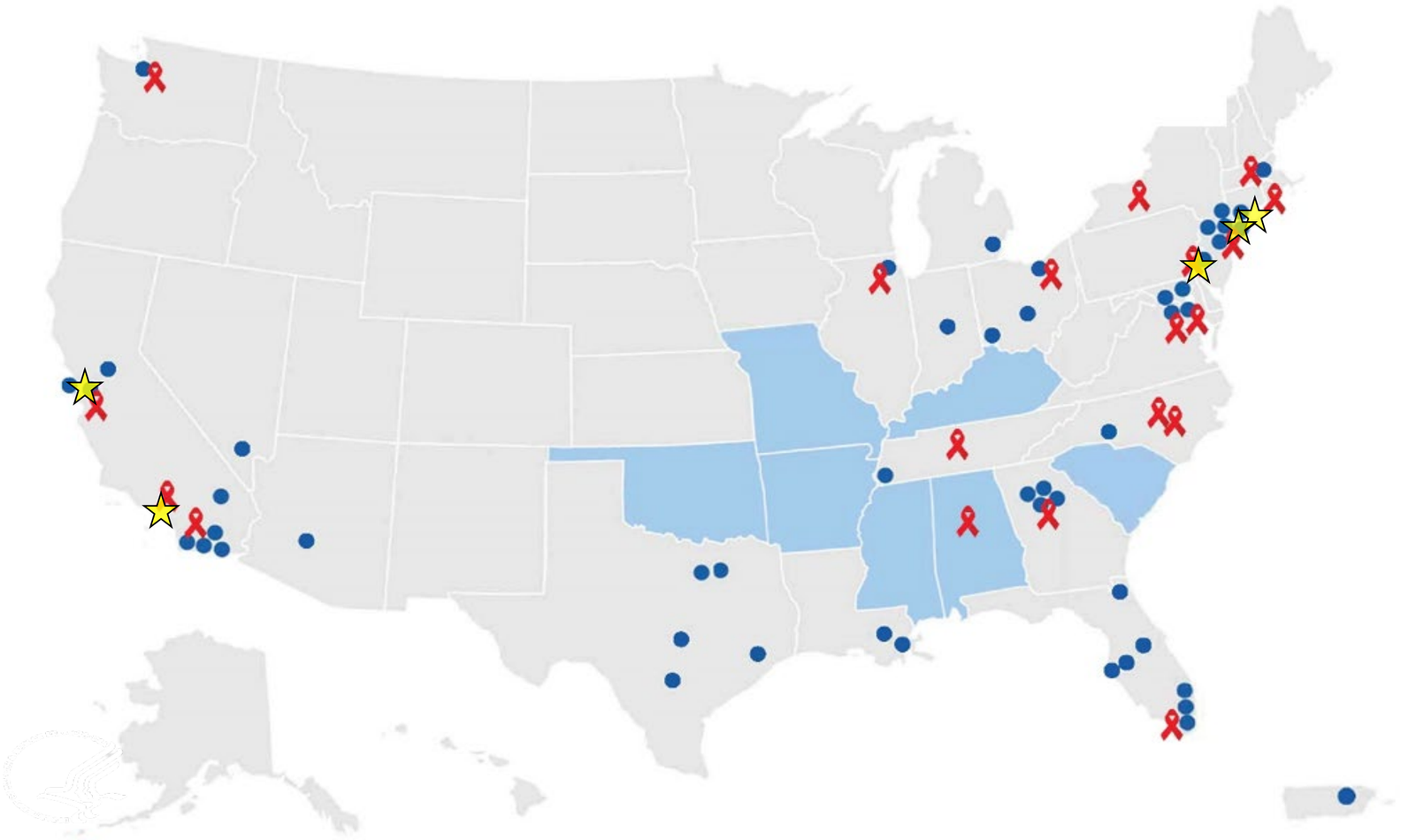
Ending the HIV Epidemic: A Focused Effort



Focus resources in:

- **48 highest burden counties**
- **Washington, D.C.**
- **San Juan, Puerto Rico**
- **7 states with a substantial rural HIV burden**

Ending the HIV Epidemic

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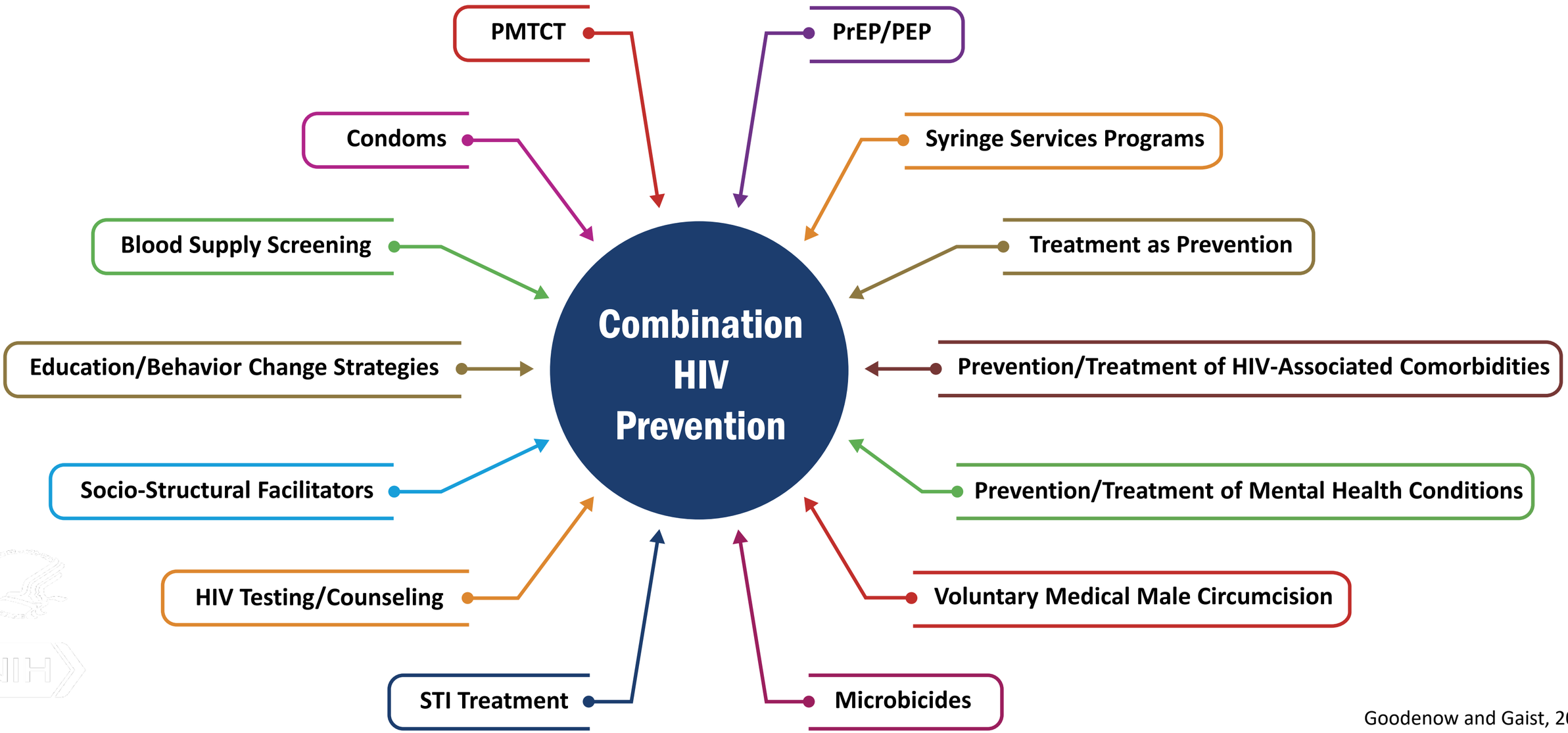
HIV Prevention Toolbox



Goodenow and Gaist, 2019

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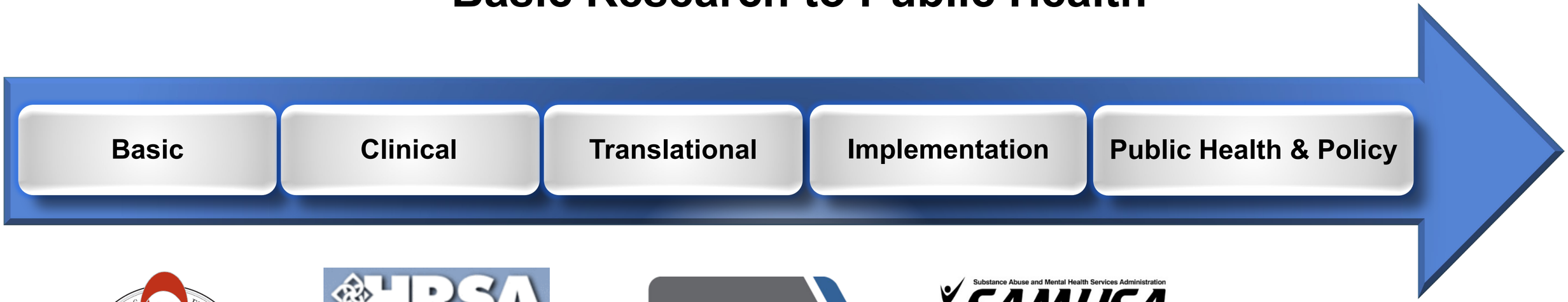
A Collaborative National Response to the HIV Epidemic

Basic Research to Public Health



Stay Connected

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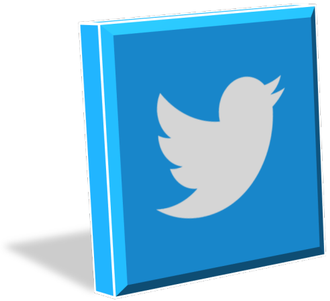


@NIH_OAR

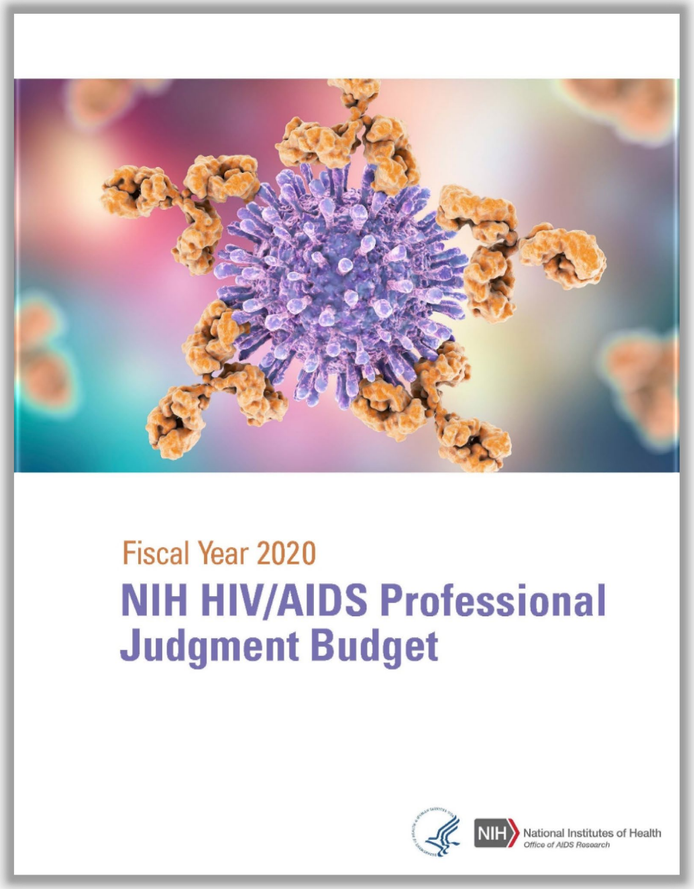
OARinfo@od.nih.gov

Additional Slides

Professional Judgment Budget

- Section 2353 of the Public Health Service Act requires that this budget:

  "Shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated."



Professional Judgment FY 2020 Budget Request

Research Priority	FY 2018 Actual*	FY 2019 Estimate*	FY 2019 Professional Judgment Percent Change	FY 2020 Professional Judgment*	FY 2020 Percent Change
Reduce Incidence	$714.5	$741.2	14.9%	$957.2	29.1%
Next-Gen HIV Therapies	364.5	369.7	1.1%	370.9	0.3%
Research Toward A Cure	175.8	190.7	3.5%	190.9	0.1%
Comorbidities, Coinfections, Complications	517.9	537.5	17.6%	587.5	9.3%
Cross-Cutting Areas	1,222.7	1,206.0	19.6%	1,395.3	15.7%
TOTAL	$2,995.4	$3,045.1	15.0%	$3,501.8	15.0%

* Dollars in Millions

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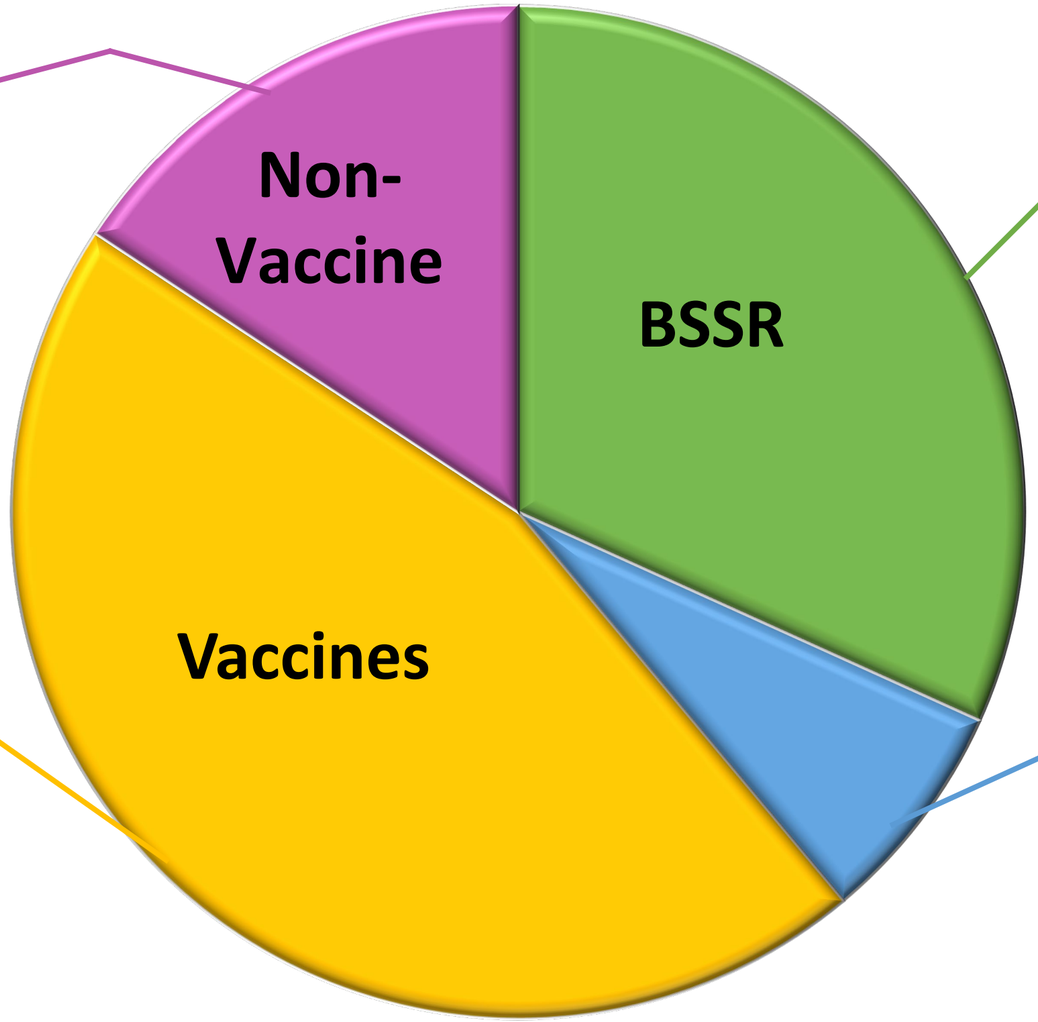
FY2018 NIH HIV/AIDS Prevention Portfolio

Total = $1.23B



$194,581,439 (16%)

$393,141,355 (32%)

$561,739,192 (45%)

Microbicides
$88,702,099 (7%)

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NIH-Funded HIV Studies – In Progress

Protocol Number	Associated NIH HIV Research Priority Area	Target Accrual	Study End Projected
HVTN702 (P5)	Reduce Incidence	5,400	2019
HVTN704 (AMP)	Next-Generation HIV Therapies	2,700	2020
HVTN703 (AMP)	Next-Generation HIV Therapies	1,900	2020
A5333s	Comorbidities, Coinfections, & Complications	800	2020
A5263	Comorbidities, Coinfections, & Complications	446	2020
A5354	Research Toward a Cure	150	2020
A5364	Next-Generation HIV Therapies	30	2021
HPTN 083	Reduce Incidence	4,500	2022
HPTN 084	Reduce Incidence	3,200	2022
HVTN705	Reduce Incidence	2,600	2022