NIH Director's Update

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Director, National Institutes of Health

Council of Councils
June 20, 2014

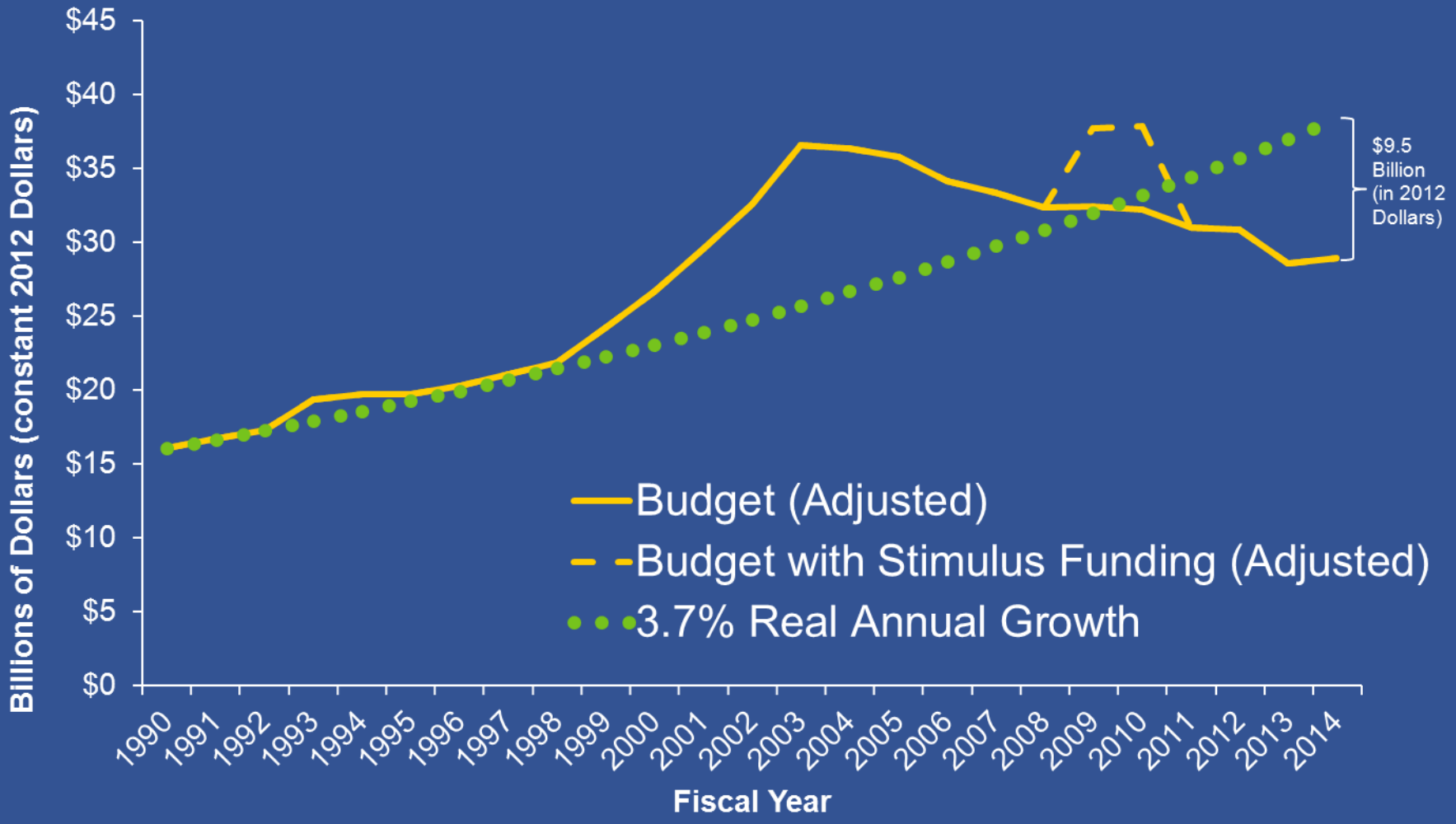
Topics

- Recent Hearings and Budget Update
- BRAIN Update
- Accelerating Medicines Partnership
- AIDS Portfolio Review

2014 Congressional Hearings

- **February 26:** Senate L/HHS Appropriations Subcommittee hearing about Alzheimer's disease
- **March 26:** House L/HHS Appropriations Subcommittee hearing on the future of biomedical research
- **April 2:** Senate L/HHS Appropriations Subcommittee hearing on FY15 budget request
- **April 29:** Senate full Appropriations Committee hearing on innovation
- ***May 6:*** *House Energy and Commerce Committee roundtable on 21st century cures*

National Institutes of Health Funding
1990-2014



The 3.7 % Real Annual Growth is based on average real growth between 1971–1997. Dollar values are adjusted to 2012 Dollars using the Biomedical Research and Development Price Index, http://officeofbudget.od.nih.gov/gbiPriceIndexes.html.
Source: NIH Office of Extramural Research and Office of Budget source data (March 29, 2014)

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BRAIN 2025: A scientific vision

Final report of the ACD BRAIN working group

Cornelia Bargmann, PhD
Investigator, HHMI
Torsten N. Wiesel Professor
The Rockefeller University
Co-Chair, ACD BRAIN Working Group

William Newsome, PhD
Investigator, HHMI
Harman Family Provostial Professor
Stanford University
Co-Chair, ACD BRAIN Working Group

BRAIN Working Group Process

Spring/Summer 2013

- Reviewed neuroscience landscape
- 4 workshops, 48 expert participants, public commentary
- Presented interim report with FY2014 research priorities

Autumn/Winter 2013

Conversations, presentations, feedback:

- Society for Neuroscience leadership and general membership
- Presidents of major clinical neuroscience professional societies
- NAS neuroscience members, NAS general membership, AAAS
- Public and private partners (NSF, DARPA, HHMI, AIBS, Kavli)

Spring 2014

Deliverables, milestones, implementation, budgets

BRAIN 2025, A Scientific Vision

The Scientific Plan

Emphasize technology development

Emphasize discovery driven science

Seven High Priority Research Areas

1. **Discovering diversity:** Identify and provide experimental access to the different brain cell types to determine their roles in health and disease.

2. **Maps at multiple scales:** Generate circuit diagrams that vary in resolution from synapses to the whole brain.

3. **The brain in action:** Produce a dynamic picture of the functioning brain by developing and applying improved methods for large-scale monitoring of neural activity.

4. **Demonstrating causality:** Link brain activity to behavior with precise interventional tools that change neural circuit dynamics.

Seven High Priority Research Areas

5. **Identifying fundamental principles:** Produce conceptual foundations for understanding the biological basis of mental processes through development of new theoretical and data analysis tools.

6. **Advancing human neuroscience:** Develop innovative technologies to understand the human brain and treat its disorders; create and support integrated human brain research networks.

7. **From BRAIN Initiative to the brain**: Integrate new technological and conceptual approaches produced in goals #1-6 to discover how dynamic patterns of neural activity are transformed into cognition, emotion, perception, and action in health and disease.

How To Accomplish These Goals: Principles

1. Pursue human and non-human animal studies in parallel
2. Cross boundaries in interdisciplinary collaborations
3. Integrate spatial and temporal scales
4. Establish platforms for sharing data and tools
5. Validate and disseminate technology
6. Consider ethical implications of neuroscience research
7. Accountability to NIH, taxpayers, and the scientific community

Budget Development

Funding base of $40M in FY 2014 and $100M in FY 2015

Project budgets FY 2016-2025

FIRST FIVE YEARS	SECOND FIVE YEARS
Emphasize technology development	Emphasize discovery driven science

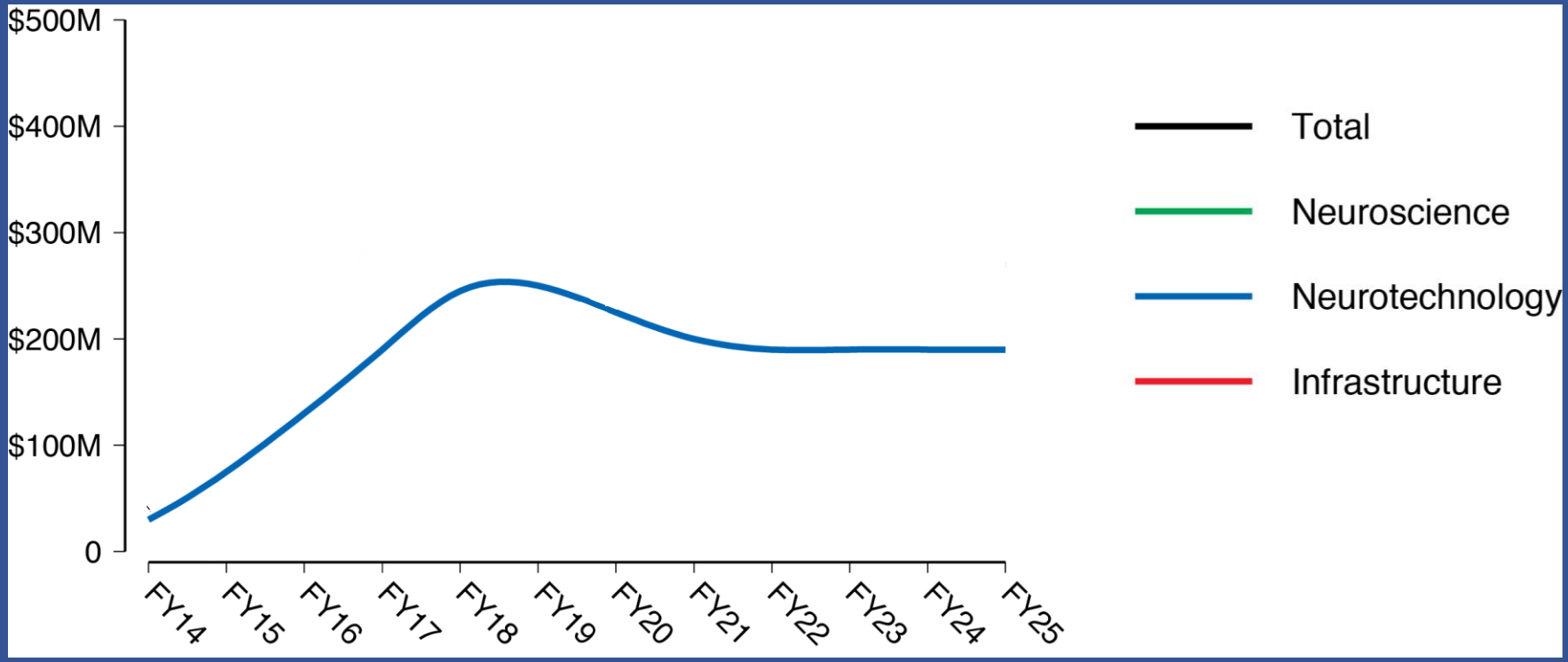
Working Group considered:

What would it cost to implement individual goals?

What number and types of grants could be supported?

What do similar ongoing projects cost?

Estimated Budget



Ramp up to $400M/yr by FY 2018 ⟹ Plateau at $500M/yr by FY2021

Total investment of $4.5B by FY 2025

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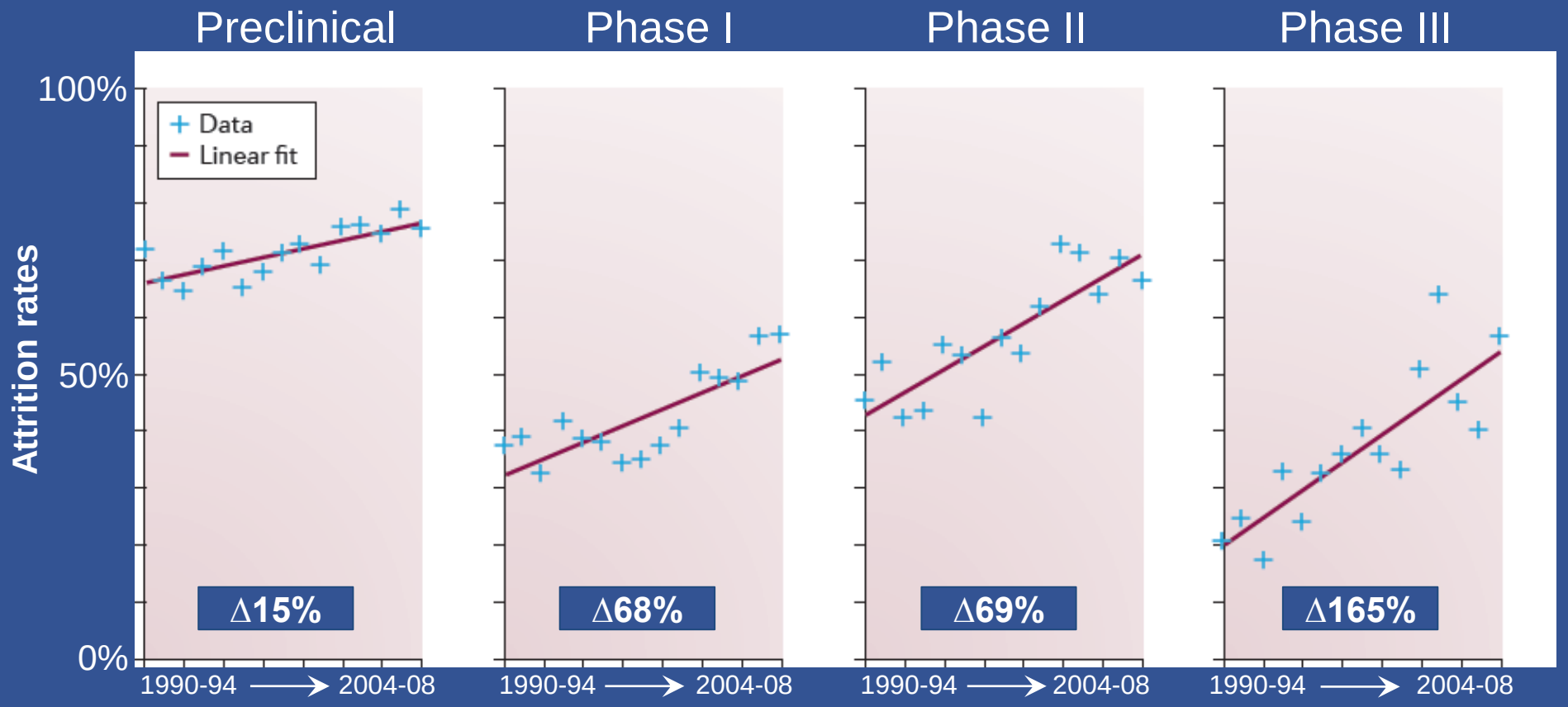
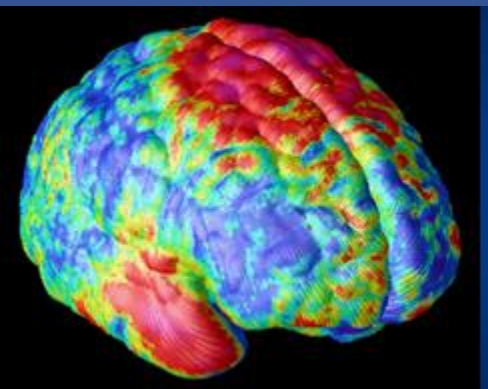
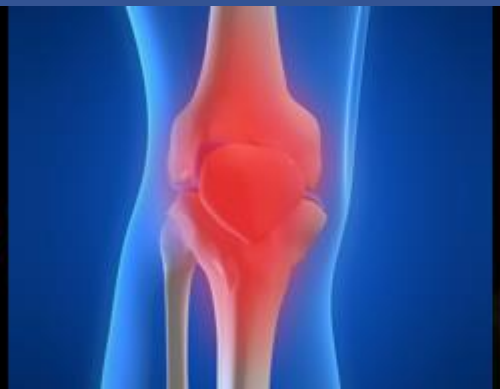
Drug Development: Late Stage Failures Related to Insufficient Target Validation



Source: Pammoli et. al, "The productivity crisis in pharmaceutical R&D" Nature Reviews Drug Discovery June 2011

Accelerating Medicines Partnership (AMP)

- Will invest >$230M over five years on pilot projects:
  - Alzheimer's disease
  - Type 2 diabetes
  - Autoimmune disorders (systemic lupus erythematosus and rheumatoid arthritis)
- Costs are shared equally between NIH and the private sector

Accelerating Medicines Partnership

Government	Industry	Non-Profit Organizations
NIH	AbbVie	Alzheimer's Association
FDA	Biogen Idec	American Diabetes Association
	Bristol-Myers Squibb	Arthritis Foundation
	GlaxoSmithKline	Foundation for the NIH
	Johnson & Johnson	Geoffrey Beene Foundation
	Lilly	Juvenile Diabetes Research Foundation
	Merck	Lupus Foundation of America
	Pfizer	Lupus Research Institute / Alliance for Lupus Research
	Sanofi	PhRMA
	Takeda	Rheumatology Research Foundation
		USAgainstAlzheimer's

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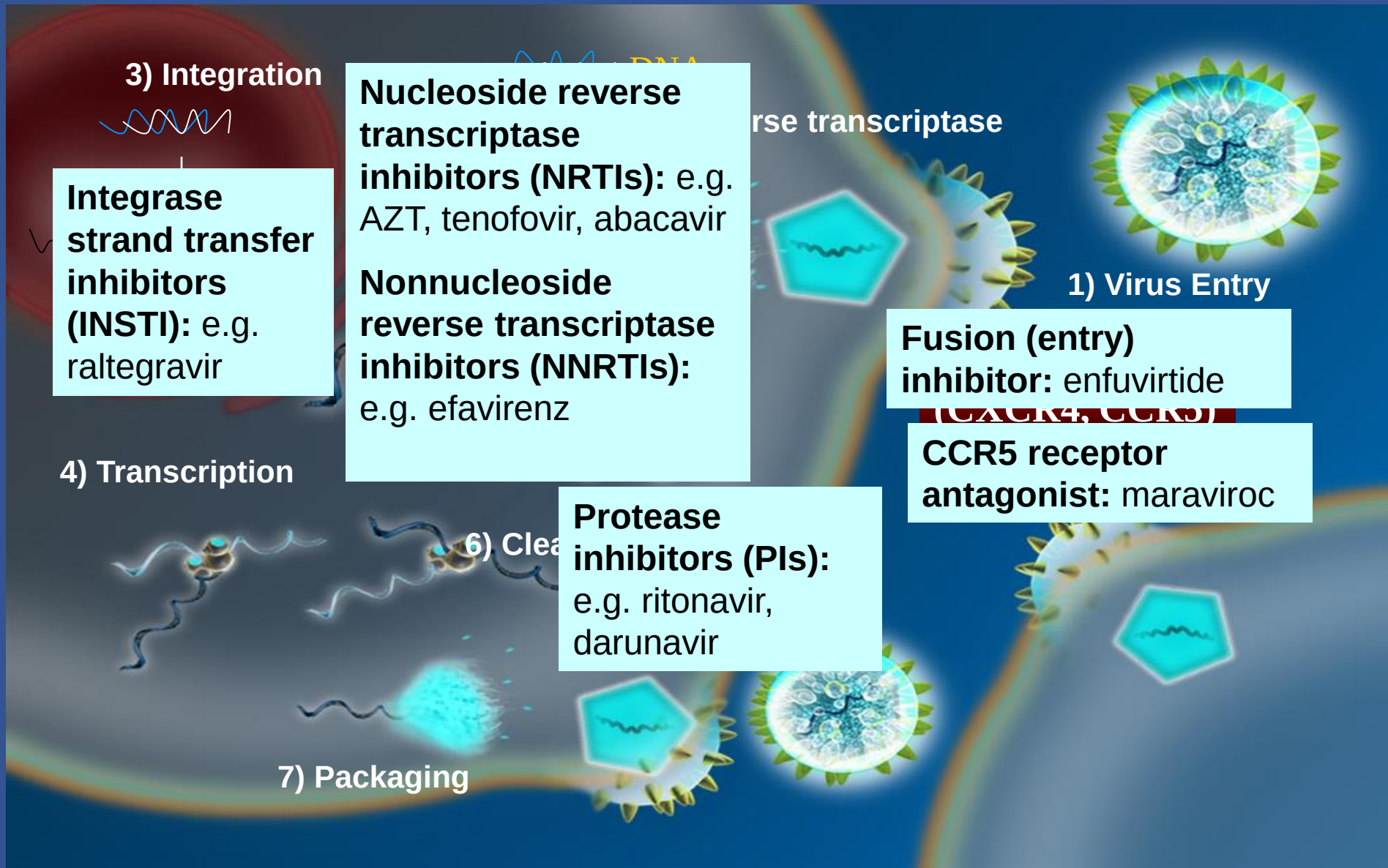
Therapies Now Available for HIV



Priorities and Resources Have Shifted Over Time

- Funds shifted:
  - from research on opportunistic infections no longer important for AIDS patients to new complications
  - from Epidemiology to Prevention
  - from drug development to therapeutics as prevention
- Funds shifted to new initiative on cure research
- Funds shifted for new advances in vaccine research

AIDS Research Priority Setting

Annual Strategic Plan

Charge to OAR Advisory Council (OARAC) November 14, 2013

- Develop a blueprint that identifies AIDS research priorities over the next 3 – 5 years.
- Outline highest priority AIDS research in 3 areas:
  - Prevention: including vaccines, microbicides, ARV-based prevention, behavioral research focused on risk reduction, stigma, and adherence
  - Treatment: including advances in therapeutic interventions and research toward a cure
  - Co-morbidities: neurologic, cardiovascular, oncologic, accelerated aging
- Identify high priority research in 3 cross-cutting areas: basic science, training (including capacity building), and information dissemination.
- Use whatever means necessary to obtain expert input

Process to Carry Out New Charge

- Established Working Group of OARAC: eminent experts and 2 community representatives
- November OARAC meeting devoted to presentations and discussions of AIDS research priorities
- Several meetings; numerous teleconferences; many emails
- Considered multiple sources of information, including OAR Strategic Plan, reports of meetings and workshops, OARAC discussions, etc.
- April OARAC meeting devoted to further discussions of priorities
- AIDS advocacy/stakeholder organizations comments presented
- Report presented to Advisory Committee to the NIH Director, June 6, 2014

OARAC Developed Priorities and Recommendations in the Following Areas:

- Basic research
- Prevention research
- Treatment: Anti-retroviral therapy, monoclonals
- The Prevention and Care Continuum
- Cure Research
- Behavioral and Social Science
- Co-infections, co-morbidities and complication
- Implementation Science
- Training, Infrastructure and Capacity-Building
- Information Dissemination

Next steps

- Portfolio Analysis to determine current alignment of projects with the priorities for AIDS-designated dollars
- Enhance internal processes to assure alignment of funding with priorities
  - Implement pro-active strategy for making decisions about whether specific FOAs will be supported by AIDS funds
  - Develop an approach to identify unsolicited R01s that are appropriate for AIDS funding support -- at time of receipt
  - ICs will be informed of projects that cannot be supported with AIDS-designated dollars; funds will ultimately be shifted
- NIH will report back to ACD in December 2014

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