

The Perspective from the NIH

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National Institutes of Health

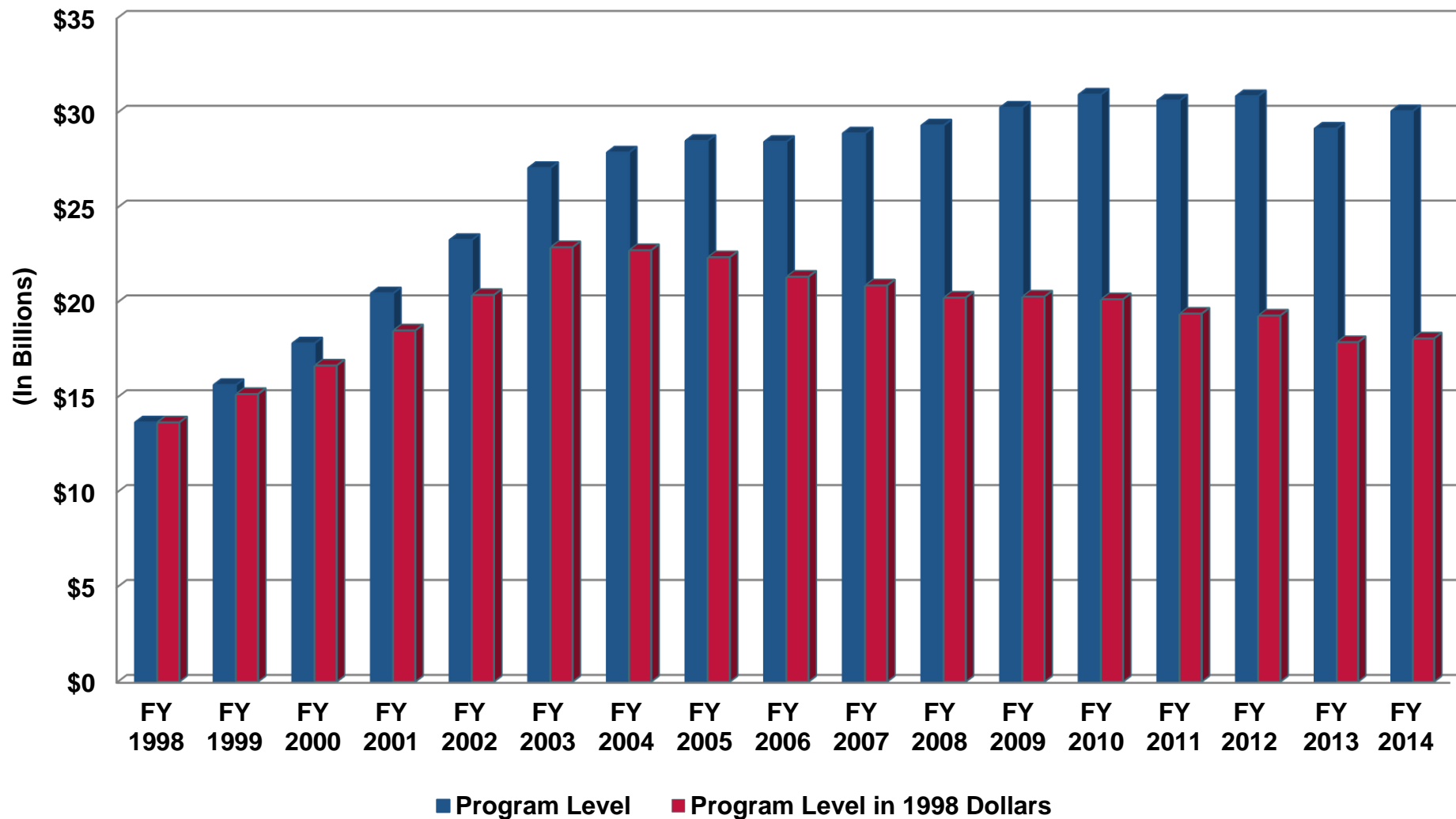
U.S. Department of Health and Human Services

September 26, 2015



National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

NIH Program Level in Nominal Dollars and Constant Dollars



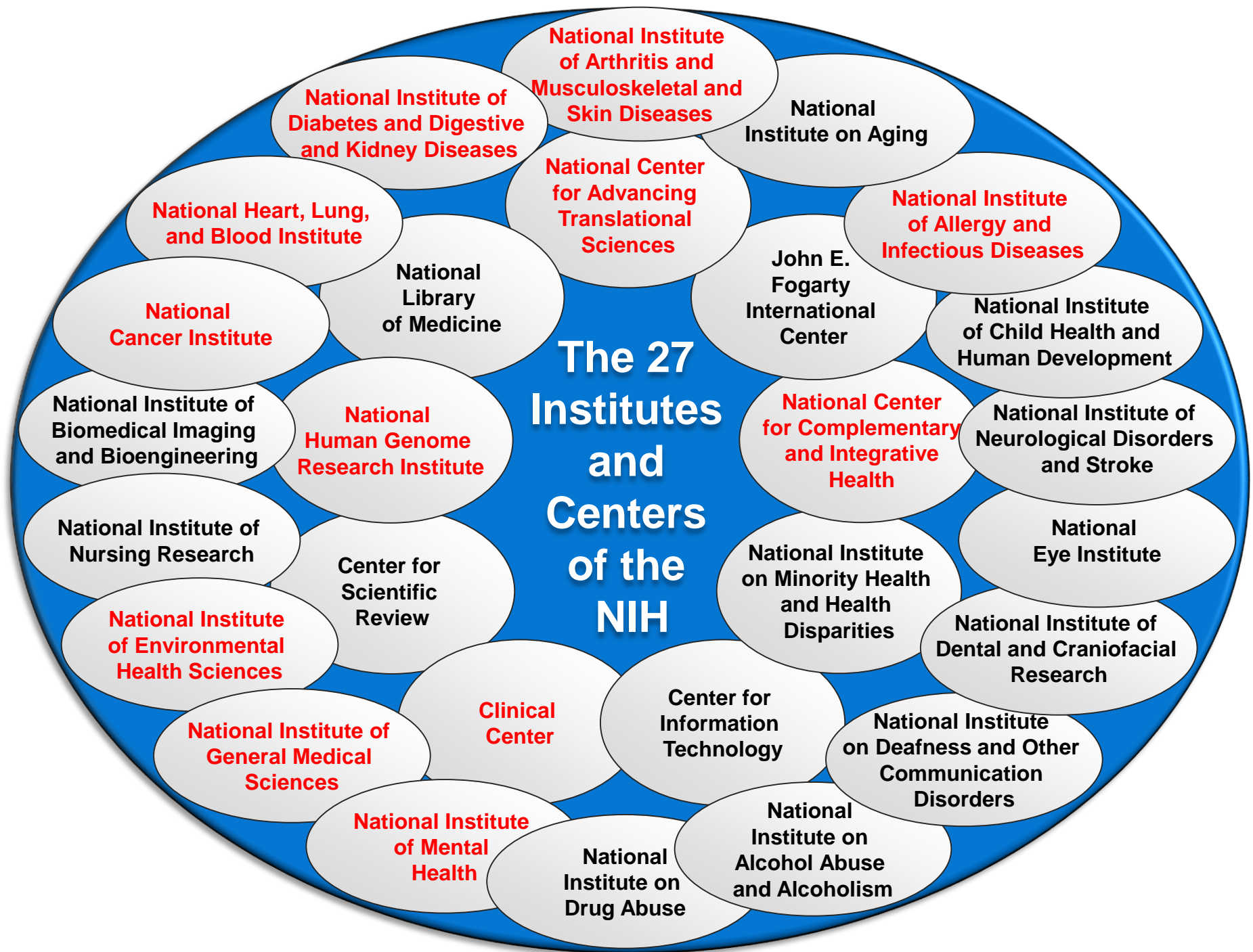
Source: NIH Office of the Director

NIAMS Research Project Grant Percentile Scores and Success Rates FY 1999 - FY 2014



Are We in Crisis???

- Yes, because we cannot fund all of the outstanding research that is being proposed.
- Are we going out of business?-No, because we still have a considerable budget to support outstanding research.
- Do we focus on supporting “Dermatology Departments?”
 - No, we focus on supporting the most outstanding research that is proposed, but strongly consider the pipeline.
- I will be presenting data that shows our support of people in Dermatology Departments as well Training Programs in skin biology and skin diseases-most of which are in Dermatology Departments (**does not include Dermatology Divisions**)
- I will include NIH-wide funding of Dermatology Departments
- I will also talk about priority setting

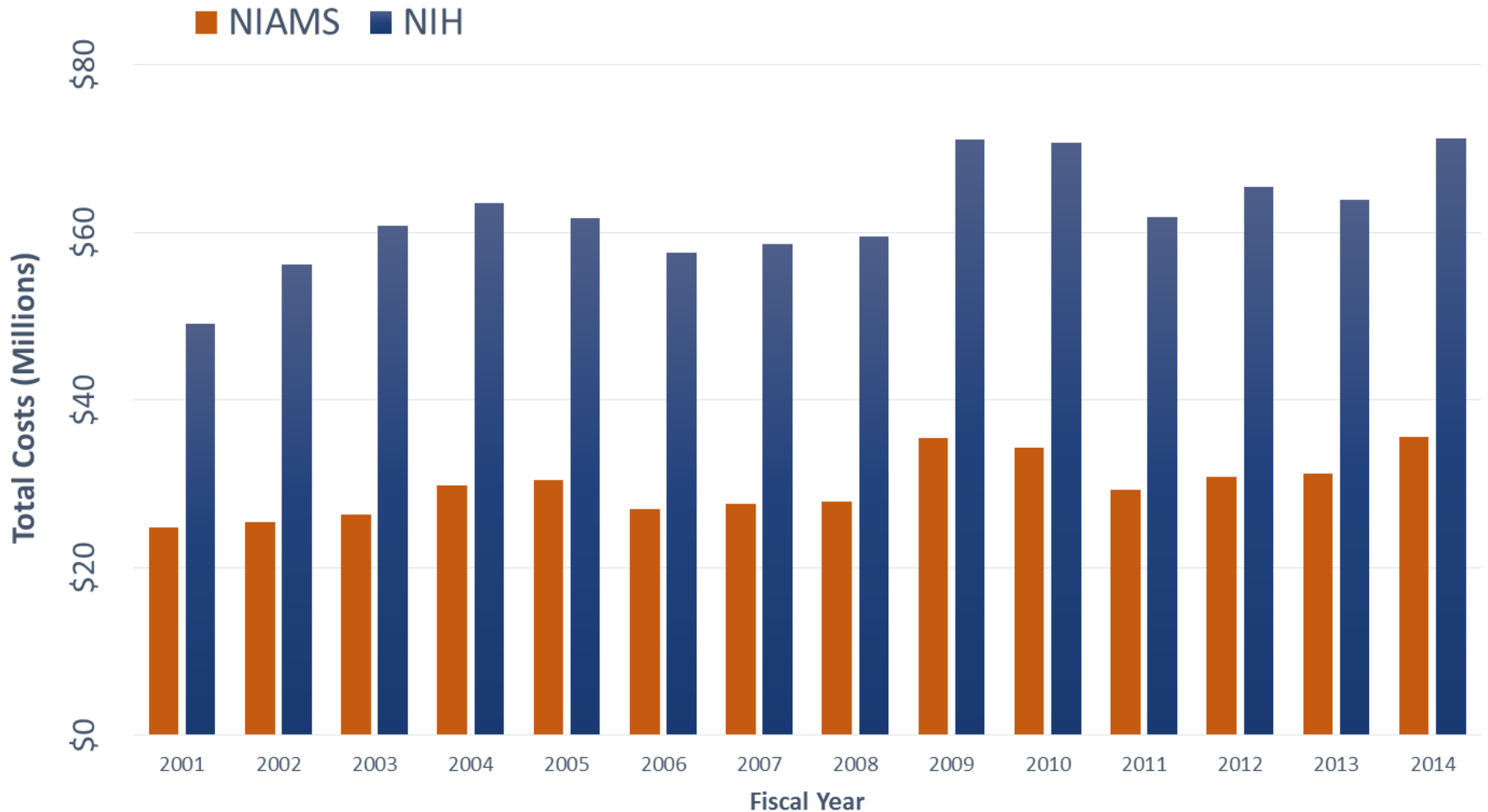


Dermatology Branch-NCI



Dermatology Department Funding

Fiscal Years 2001 - 2014



These data DO NOT include Dermatology Divisions.

NIH Funding to Dermatology Departments

FY	NIAMS Awards	NIAMS Total Costs	NIH Awards	NIH Total Costs	% NIAMS
2001	123	\$24,757,907	202	\$49,016,332	50.5%
2002	117	\$25,442,789	201	\$56,191,632	45.3%
2003	113	\$26,296,916	213	\$60,796,251	43.3%
2004	119	\$29,830,264	384	\$63,413,960	47.0%
2005	122	\$30,433,872	277	\$61,685,854	49.3%
2006	98	\$26,923,597	268	\$57,592,578	46.7%
2007	97	\$27,656,536	285	\$58,571,818	47.2%
2008	105	\$27,843,800	189	\$59,510,657	46.8%
2009	121	\$35,392,362	231	\$70,993,974	49.9%
2010	106	\$34,282,631	217	\$70,704,329	48.5%
2011	107	\$29,310,355	203	\$61,793,041	47.4%
2012	110	\$30,849,884	211	\$65,400,755	47.2%
2013	114	\$31,260,118	209	\$63,800,079	49.0%
2014	121	\$35,582,138	221	\$71,229,250	50.0%

These data DO NOT include Dermatology Divisions.

NIAMS Priorities

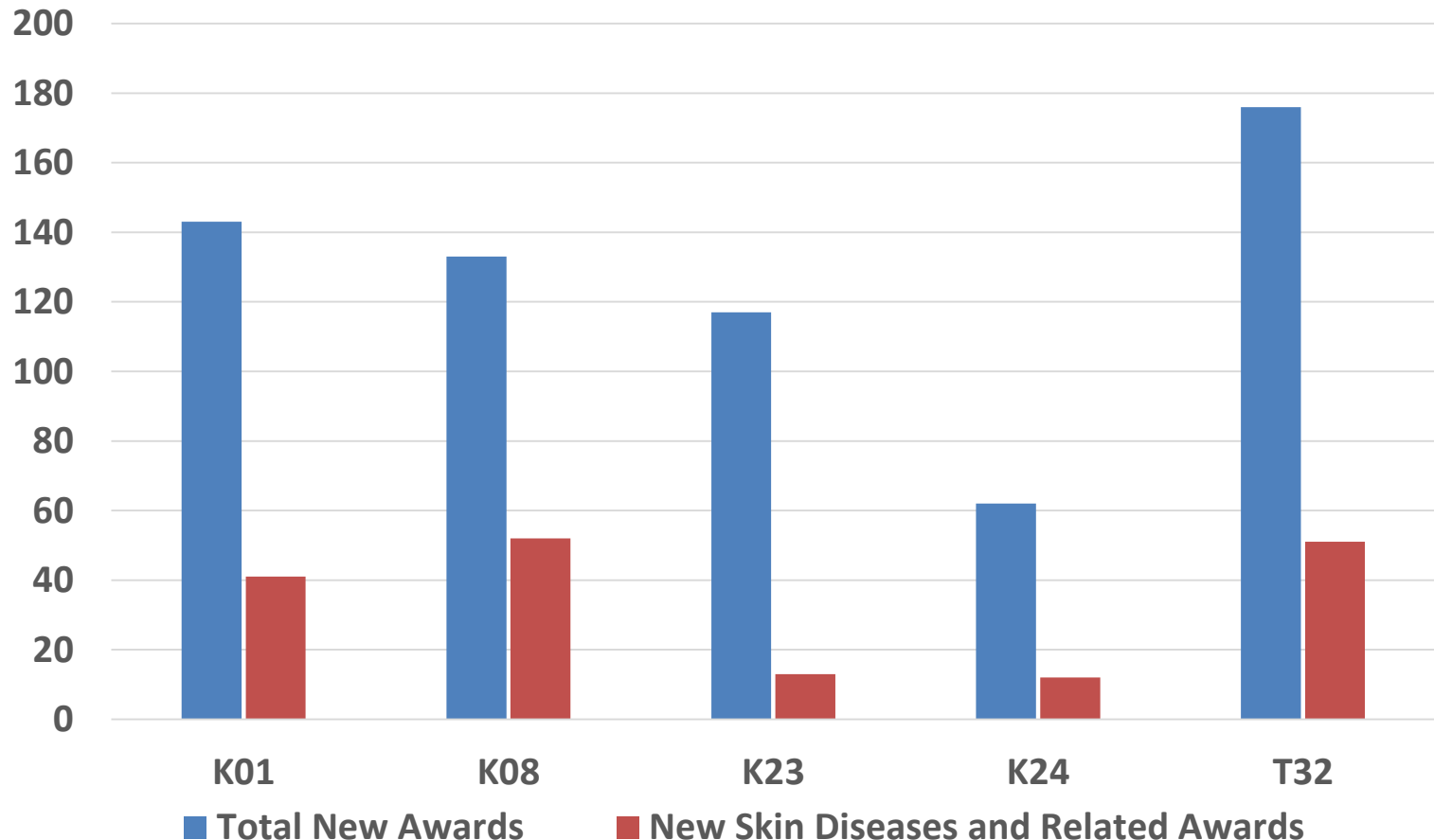
- **Supporting outstanding investigator-initiated research**



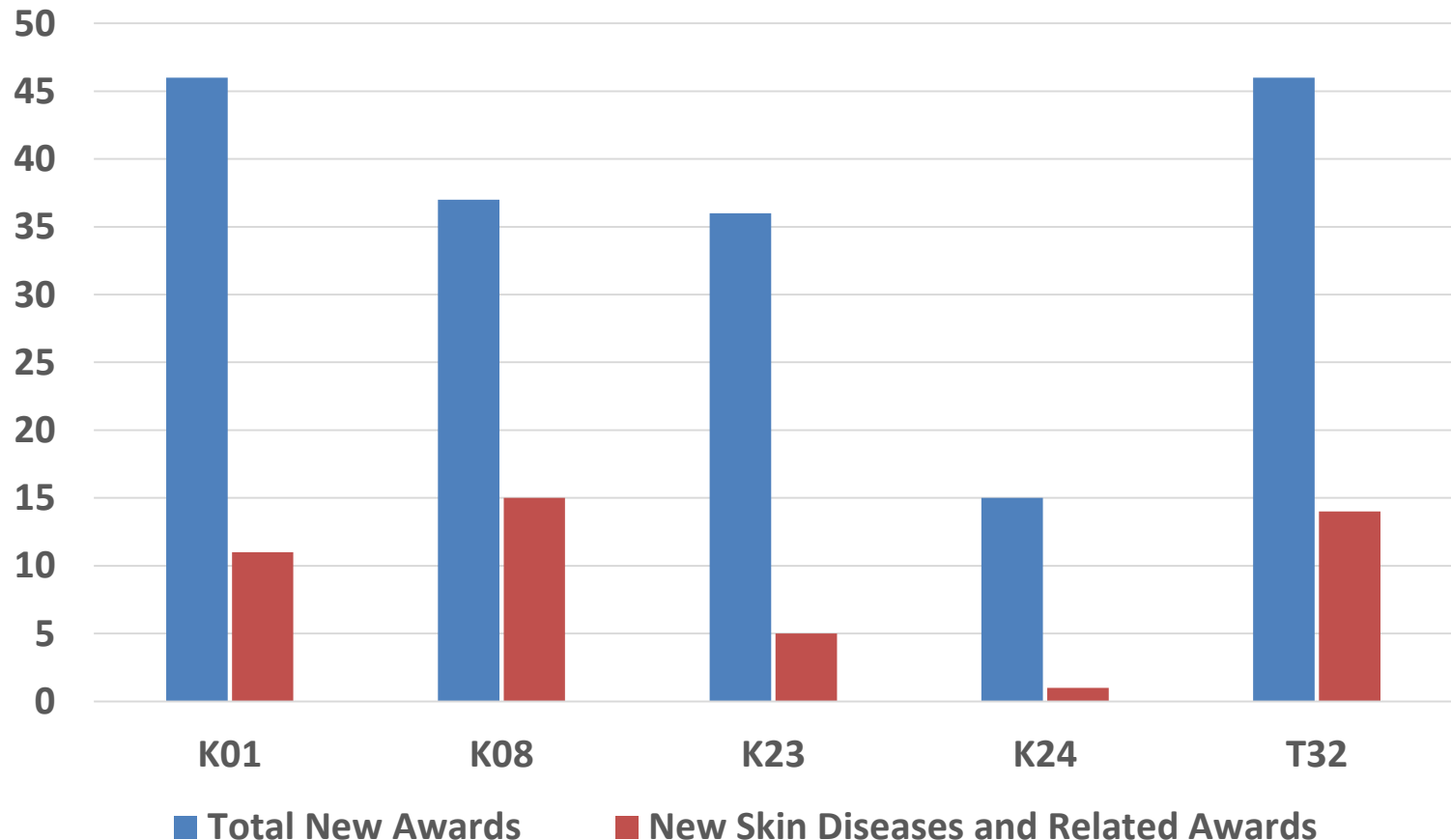
- **Investing in the future of research by supporting talented early-stage researchers**



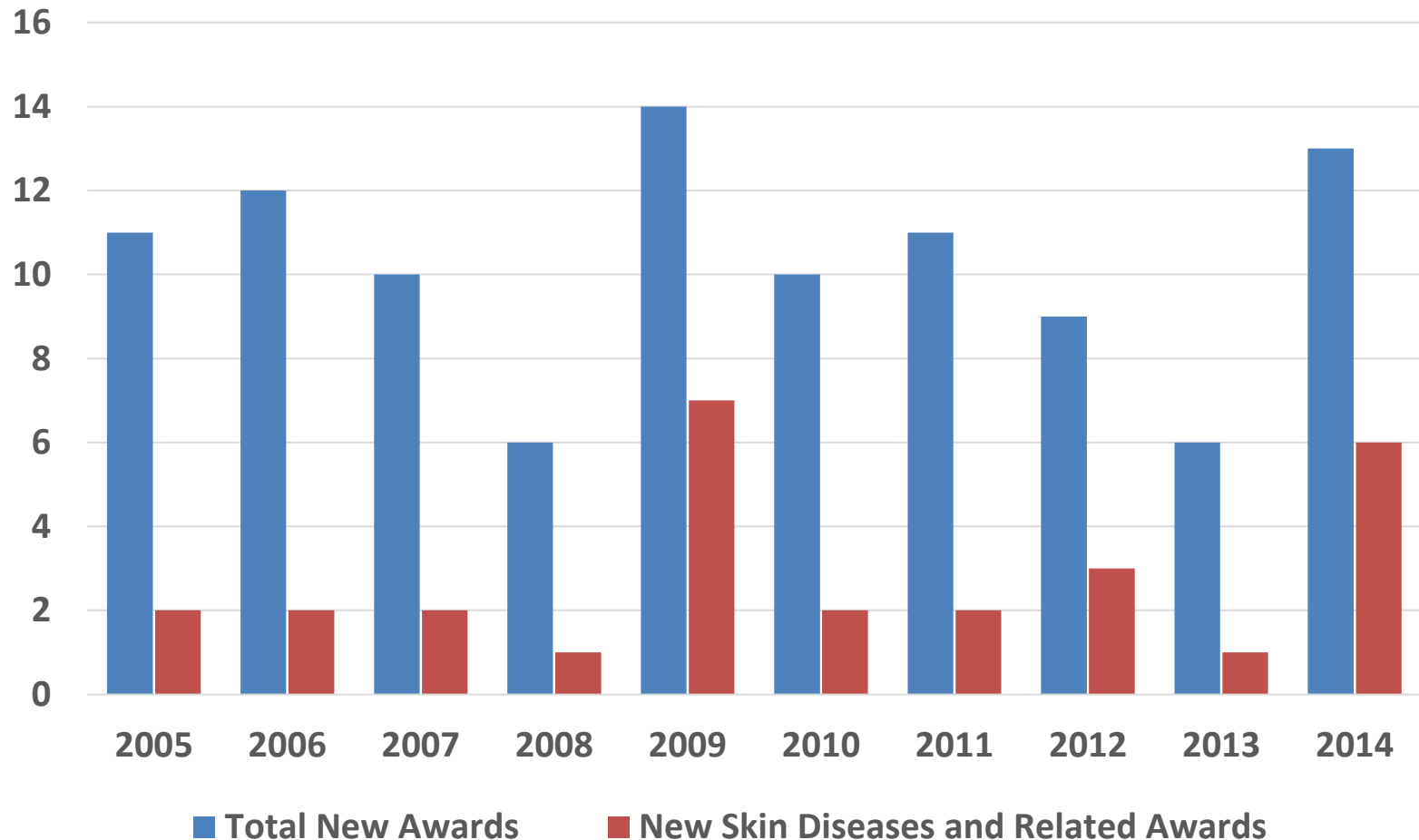
NIAMS Total New K and T32 Awards and Skin Biology and Diseases Awards FY 1999 – FY 2014



NIAMS Total New and Ongoing (Current Portfolio) K and T32 Awards and Skin Biology and Diseases Awards FY2015 (Estimate)



NIAMS Total New T32 Awards and Skin Biology and Diseases Awards



Transitions

K (08 or 23) to R (about 40-50% success)

- We know that supplements to the clinical K awardees enhance the success of those seeking to transition to an R
- We have discussed at our Council the feasibility of increasing this award, both for salary and for supplies
- We have also discussed, at Council, the possibility of having a special small grants program for clinical K awardees.
- Some organizations (RRF) and advocacy groups are considering doing this as well.

NRSA Fellowships in Skin Diseases

- NIAMS partnerships with the Herzog Foundation/ American Skin Association
- Epidemiology, clinical trials, and outcomes research in skin diseases
- Two years advanced training leading to MPH or other areas such as biostatistics and/or PhD in epidemiology
- Tuition and fees
- Salary supplementation provided by the ASA/Herzog up to \$30,000 per year
- Eligibility:
 - M.D or D.O., or equivalent
 - >2 yrs clinical dermatology training
 - <5 yrs since training completed on submission date

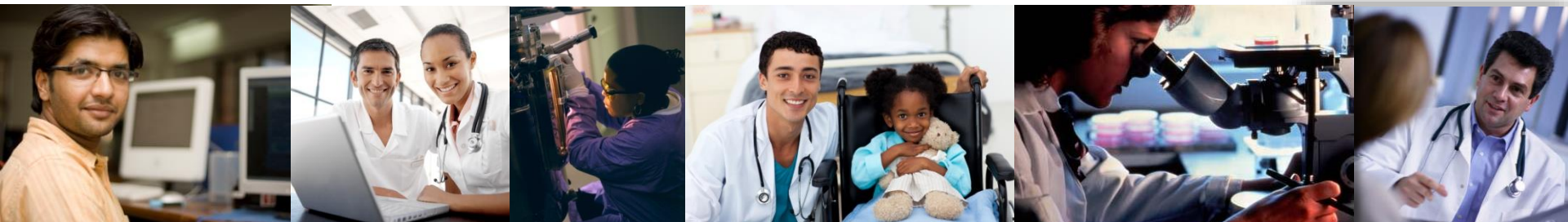
Successes- Gelfand, Qureshi, van Beek and Asgari

New Initiatives

- For the past three years we have had an on-site meeting of 3rd year clinical K awardees
- We have recently instituted a once a year webinar for 1st year clinical K awardees AND their mentors to discuss expectations
- And for all R01 awardees who have successfully competed for their renewal we have instituted the STAR program- Transition from project to program.

STAR Award Objectives

- To promote innovation and exploration of high-risk ideas by providing supplemental funding to early established investigators (EIs).
- To allow EIs to expand and explore new opportunities within the broader scope of a currently funded project to facilitate the transition from a single, structured research project to a research program.



NIAMS Priorities

- **Supporting outstanding investigator-initiated research**



- **Investing in the future of research by supporting talented early-stage researchers**



NIAMS Priorities: Other Considerations

- Does the research proposal address a critical public health need?
- Does it relate to an understudied area or disease?
- Is it mission-relevant?
- Can we afford to fund it?
- For clinical trials, is it likely to yield results that will change clinical practice?

Clinical Trials

The NIAMS' goal is to identify and fund trials that:

- **are as timely and informative as possible, and**
- **will lead to improvements in clinical practices or public health policy for disease prevention, diagnosis, and treatment**



Considerations for Strengthening the Impact of NIAMS Clinical Trials

- **Ways the current NIAMS suite of clinical trials Funding Opportunity Announcements can be improved**
 - **Goal: adequately provide opportunities for all types of clinical trials**
- **Types of funding support that are necessary for the different stages of clinical trial implementation**
 - **Conceptualization → full implementation**
- **Ways the NIAMS can optimize the early review of a future clinical trial concept**
 - **Benefits that might result from having the NIAMS review a clinical trial concept at an early stage**
- **Other areas relevant to optimizing NIAMS clinical trials support**

Request for Information: Strategies to Strengthen High-Impact NIAMS Clinical Trials

Notice Number: NOT-AR-15-019

Key Dates

Release Date: September 2, 2015

Response Date: October 15, 2015

Related Announcements

None

Issued by

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](#))

Purpose

The purpose of this Request for Information (RFI) is to solicit input from the extramural community that will inform the mechanisms and processes the NIAMS uses to support high-impact clinical trials. The NIAMS invites comments from researchers, patient advocacy groups, patients and their healthcare providers.

Background

In 2010, the NIAMS initiated an effort to support investigator-initiated clinical trials through a specific suite of funding opportunity announcements (FOAs). The goal of the NIAMS initiatives for clinical trial planning and execution was to enhance the rigor, timeliness and impact of the trials we support. When the NIAMS developed these clinical trials initiatives, the Institute envisioned a pathway to clinical trial implementation that would facilitate moving important ideas forward and allow some staging with pilot and feasibility grants as well as planning grants available to guide and support the process. Currently, the suite of clinical trials FOAs include the: (1) Exploratory Clinical Trial Grants (R21), (2) Clinical Trial Planning Cooperative Agreement (U34), (3) Clinical Trial Implementation Cooperative Agreement (U01) and Clinical Observational Studies (COS) in Musculoskeletal, Rheumatic and Skin Diseases (R01). The links to the current FOAs and detailed information about the current NIAMS policies related to clinical trials can be found at: http://www.niams.nih.gov/Funding/Clinical_Research/clinical_main.asp

The initial set of funding opportunities, the R21, U34 and U01, were designed to enable early phase pilot and feasibility studies, to provide support and time

Clinical Trials in Dermatology

- Very few
- Needs community identification of most important questions
- Most of these questions cannot be answered at an individual medical center
- So, we need collaboration....note last MDS meeting
- Collaboration not only amongst Dermatology Departments but also with our CTSAs
- Needs leadership as we have seen with the CARRA (peds rheumatology) network or now with PeDRA, an alliance of pediatric dermatology research groups
- It is time we stopped relying on industry to dictate our clinical agenda



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Welcome

Dermatologic disorders in children are more than skin deep. PeDRA was formed to accelerate collaborative research and provide answers for hard-hitting skin diseases. PeDRA's mission is to produce groundbreaking discoveries, and one day, cures that benefit countless young patients.

Current Studies

Find out what researchers are currently working on, as well as what opportunities might fit your interest or expertise.

Upcoming Conference

We are looking forward to our third annual research conference, planned for November 6-7, 2015, in Irving, TX near DFW Airport. [Click to learn more.](#)

Get Involved

Our mission is ambitious and there are many opportunities to help achieve it!

[I am a researcher
or clinician](#)

[I am a patient or
organization with
interest](#)



NIH VideoCasting and Podcasting

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The National Arthritis and Musculoskeletal and Skin Diseases Advisory Council

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footage at
videocast.nih.gov

Are We in Crisis???

- Yes
- Can we do something about it?
- Yes
 - work together toward common goals
 - continue to leverage foundation and advocacy group funding, particularly to support new and early stage investigators through difficult transition periods
 - identify people who will lead collaborative research efforts

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