

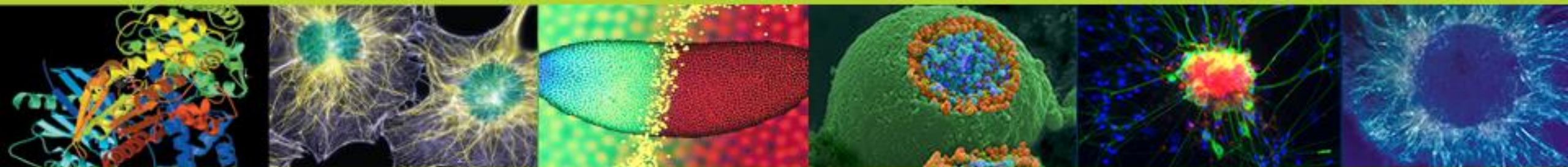


National Institute of
General Medical Sciences



Update from NIGMS

Jon Lorsch
Director
NIGMS



COVID-19 – Urgent Competitive Revisions

- NIGMS issued 2 Notices of Special Interest ([NOT-GM-20-025](#), [NOT-GM-20-027](#)) to support areas of critical research need related to COVID-19:
 - Research on modeling and forecasting the spread of SARS-CoV-2 and the effects of possible intervention strategies
 - Repurposing of diagnostics or therapeutics currently under development by small businesses for use against COVID-19
- *NIGMS has made 32 awards to 26 projects, with an investment of nearly \$10M*
 - *5 to IDeA state institutions for a total of \$2.2M*

Additional NIGMS IDeA COVID-19 Supplement Programs

- **NOT-GM-21-031: Urgent Competitive Revisions to IDeA and NARCH Programs for SARS-CoV-2 Surveillance Studies**
 - **21 awards, \$15 million**

- **NOT-GM-21-021: Urgent Competitive Revisions to IDeA and NARCH Programs to Address SARS-CoV-2 Vaccine Hesitancy**
 - **7 awards, \$2 million**

IDeA COVID-19 Registry & National COVID Cohort Collaborative

- N3C: A national repository of COVID-19 clinical data
 - Federated data model with data harmonized via AI/ML and NLP
 - Encourages collaboration and provides data science help to researchers
- 8 IDeA-CTRs stood up a COVID-19 Registry that became a component of the N3C
 - An electronic health record (EHR)-based data hub for COVID-19 research
 - Viral genome data and clinical imaging data to be integrated
 - More CTRs to be added
- CTR data ensures inclusion of rural and underserved populations in N3C



N3C Data Enclave Statistics

Release Set: July 15, 2021

Sites: 56

Persons: 6.5 million

COVID+ Cases: 2,177,828

Total Number of Data Rows: 7.2 billion

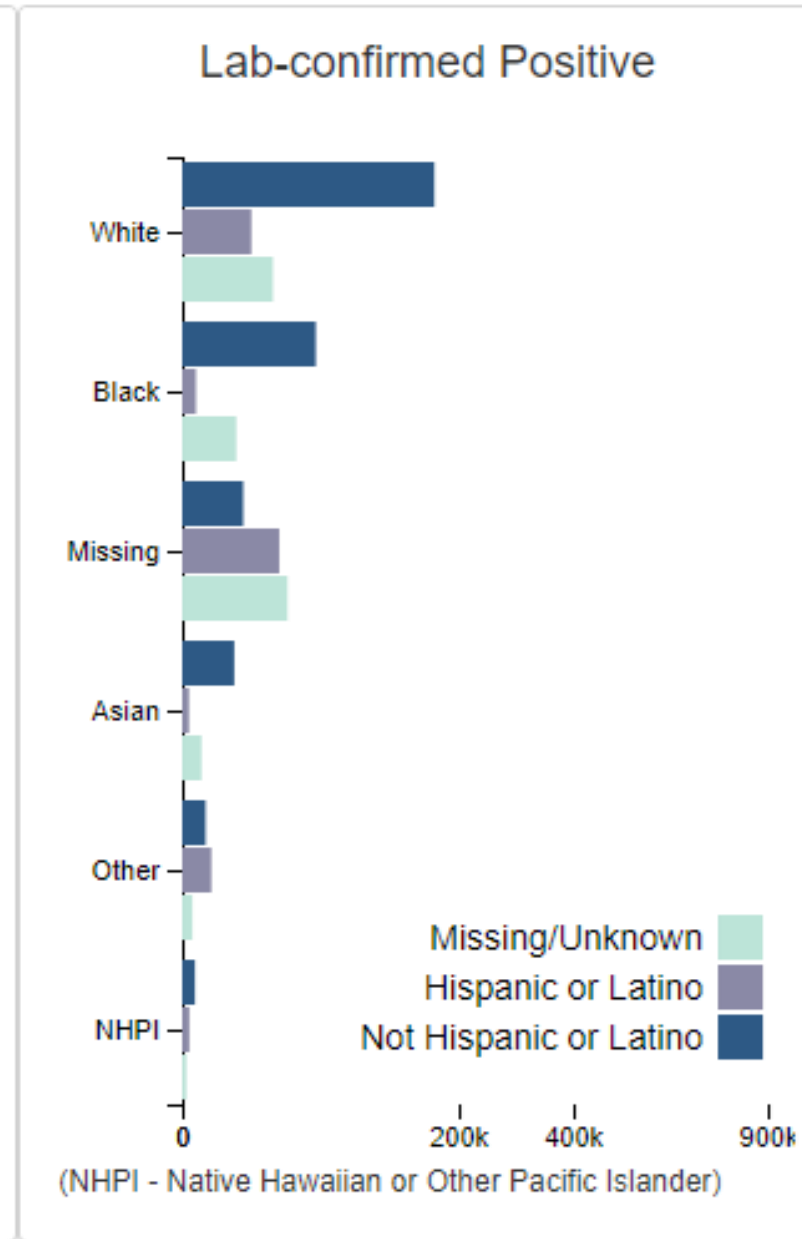
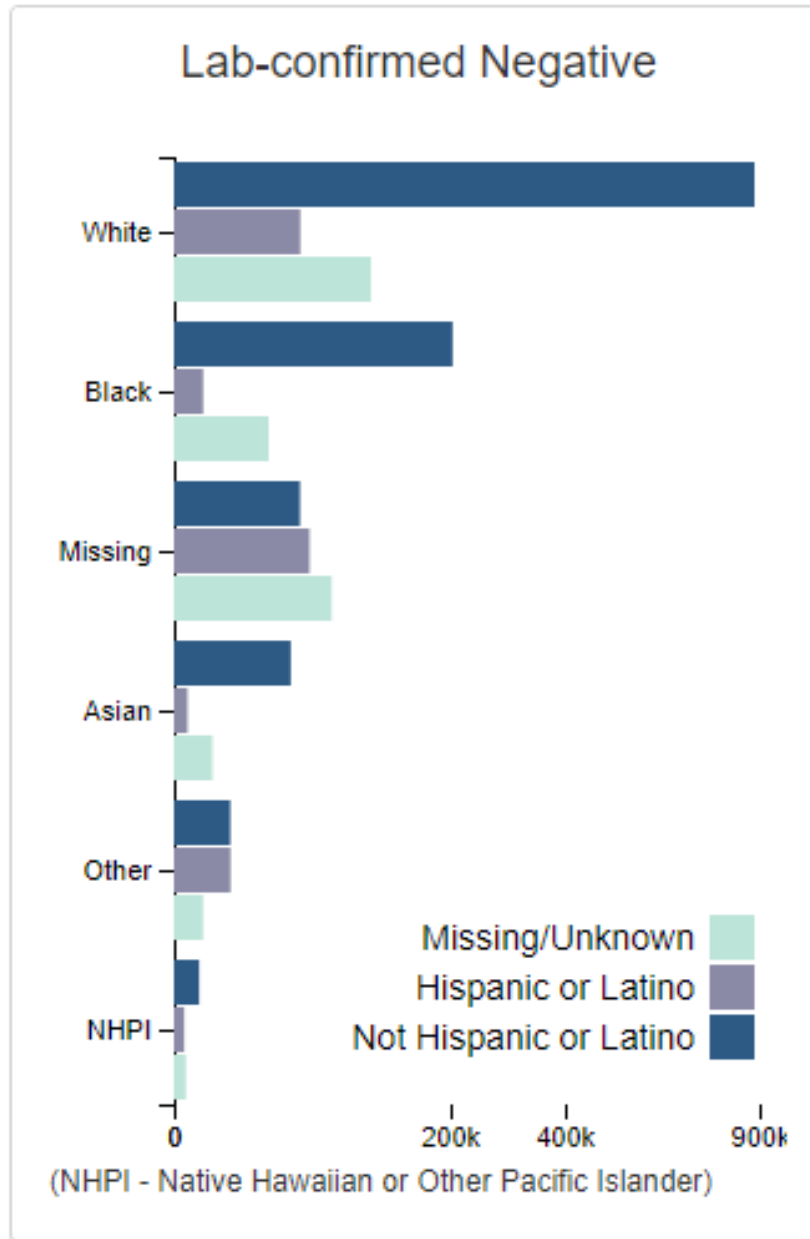
Clinical Observations: 597.6 million

Lab Results: 3.5 billion

Medication Records: 1.2 billion

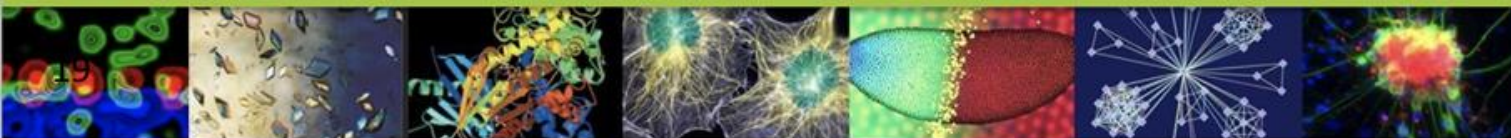
Procedures: 344.84 million

Visits: 322.3 million



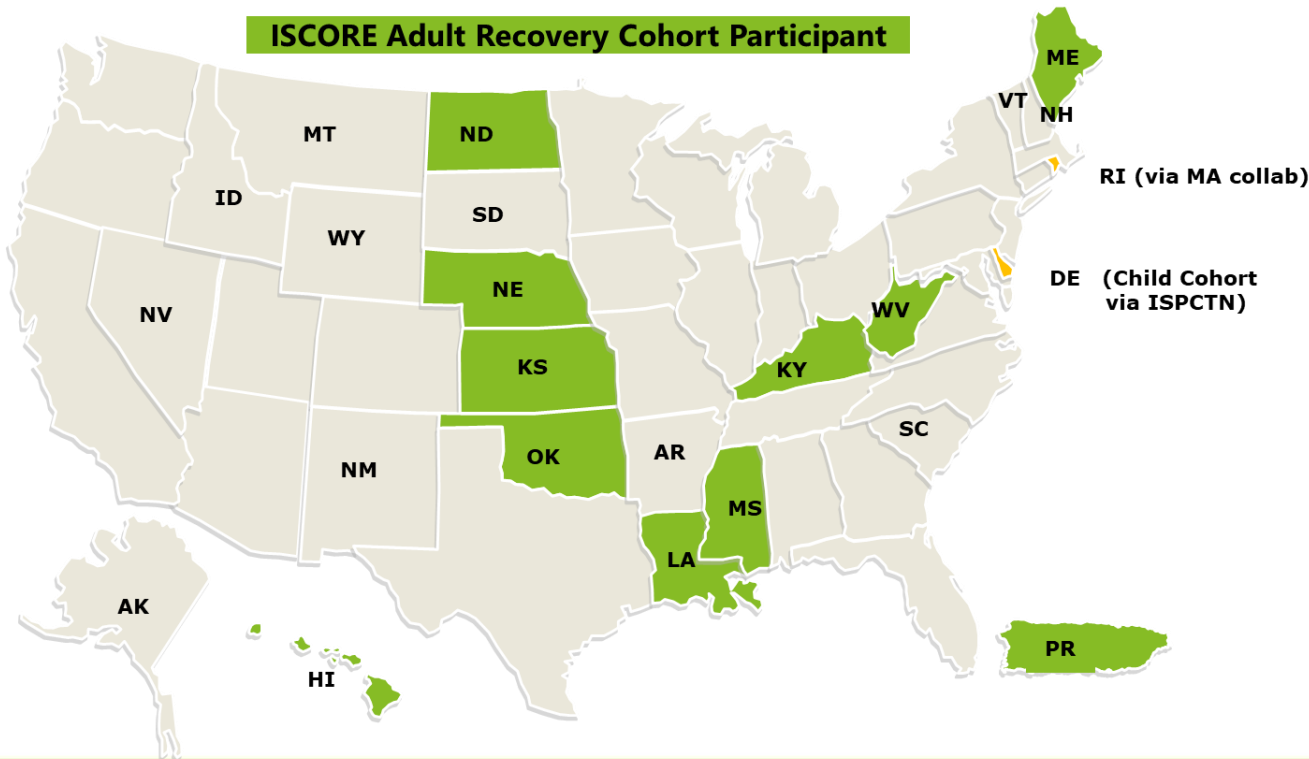
Can We Build on this CTR-CTSA Partnership?

- HUGE need for better ways to harmonize, share and use electronic health record (EHR) and other clinical data for research
- Could the N3C partnership form the starting point for a national EHR data resource for research, beyond just COVID-19-related information?




Post Acute Sequelae of COVID-19 (PASC) Study of Long-term Effects

- Expansion of the IDeA Registry to ISCORE, the IDeA States Consortium for Clinical Research
- Selected for funding as a PASC Adult Clinical Recovery Cohort
- DE-CTR participating in a PASC Pediatric Clinical Recovery Cohort



RECOVER Initiative Components

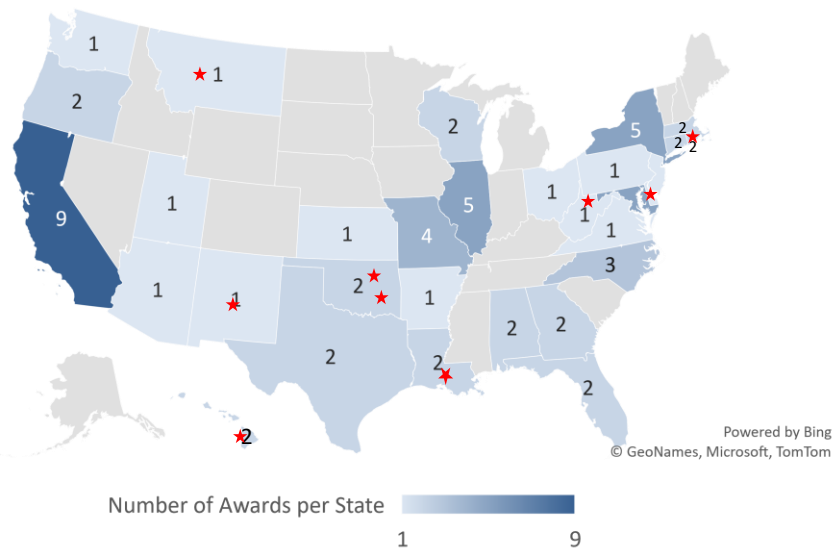
SARS-CoV-2 Recovery Meta-Cohort	Investigator Consortium
<ul style="list-style-type: none"> • Clinical Recovery Cohort (Adult, Peds, and Pregnancy) • Autopsy Cohort (Acute and PASC) • EHR-/ Other Real-World Data-Based Studies 	<ul style="list-style-type: none"> • Cross-disciplinary investigator teams will work together to: <ul style="list-style-type: none"> • Achieve speed and scale/breadth • Implement common data elements and adaptive Master Protocols • Conduct systematic screening and in-depth follow-up evaluations
Clinical Science Core	Data Resource Core
Biorepository Core	Admin Coord Ctr

RECOVER
Researching COVID to Enhance Recovery

RADx-UP Phase I Snapshot: 70 Funded Sites and Research Projects

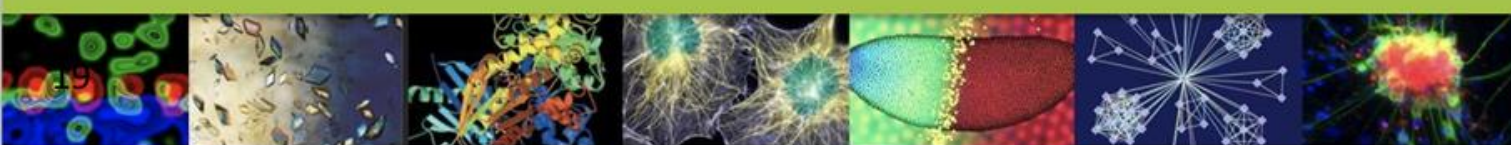
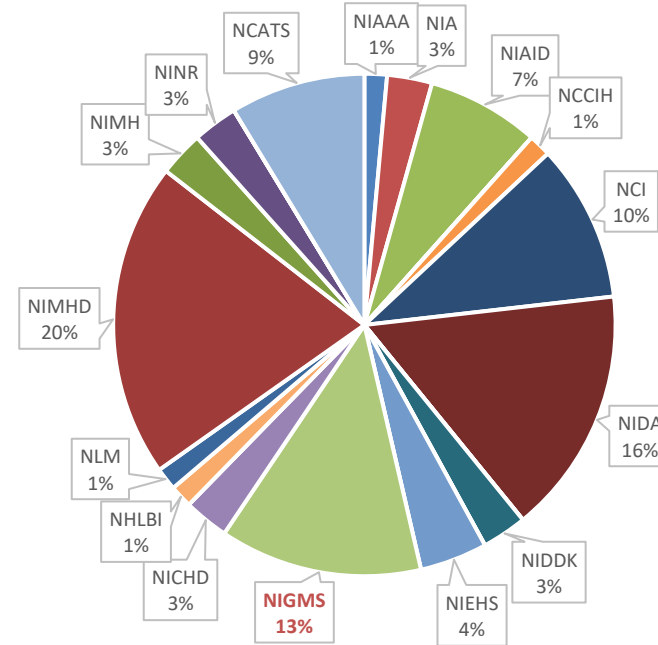
Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **54 institutions**.

Geographic Distribution of Award Institutions



Awards were distributed among **16 Institutes and Centers** across the NIH.

Award Distribution by IC

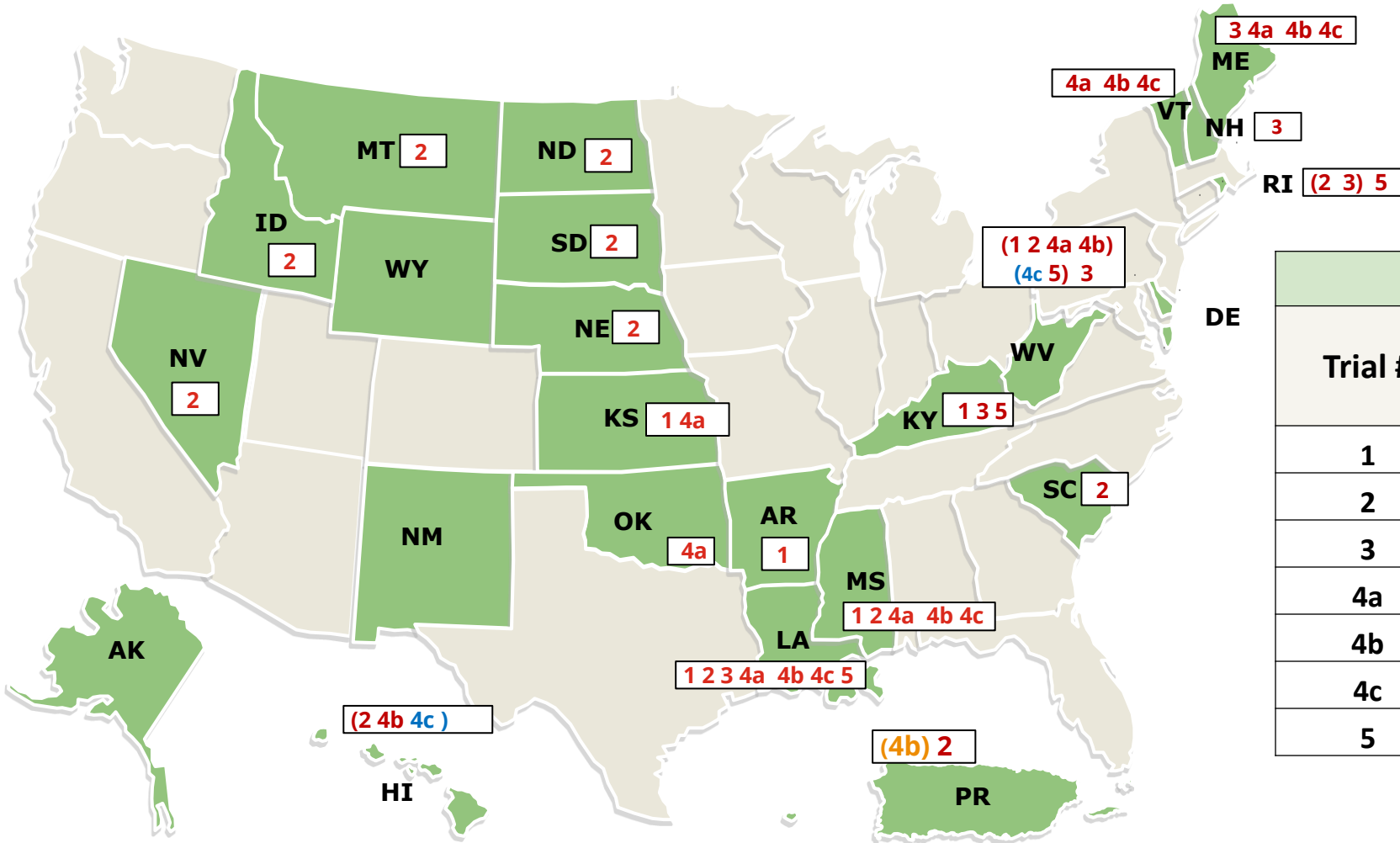


RADx-UP Phase I Awards to IDeA Grantees

Grant Numer	PI Name(s)	Institution	Total Costs (2-yr)
3P20GM103653-09S1	HARRINGTON, MELISSA A; DILLARD, DOROTHY ; GOODMAN, XUANREN	DELAWARE STATE UNIVERSITY	\$1,129,224
3P20GM104417-07S1	ADAMS, ALEXANDRA K	MONTANA STATE UNIVERSITY - BOZEMAN	\$1,797,141
3P30GM114737-05S1	YANAGIHARA, RICHARD (contact); SY, ANGELA U; TAUASOSI, TINA ; WANG, WEI- KUNG	UNIVERSITY OF HAWAII AT MANOA	\$1,437,920
3U54GM104938-08S1	JAMES, JUDITH A	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	\$4,999,993
3U54GM104940-05S3	KIRWAN, JOHN P ; KATZMARZYK, PETER TODD	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	\$1,923,930
3U54GM104942-05S3	HODDER, SALLY LYNN	WEST VIRGINIA UNIVERSITY	\$4,998,604
3U54GM115677-05S1	PADBURY, JAMES F	BROWN UNIVERSITY	\$1,673,494

ACTIV Trials in IDeA States: Status as of July 22, 2021

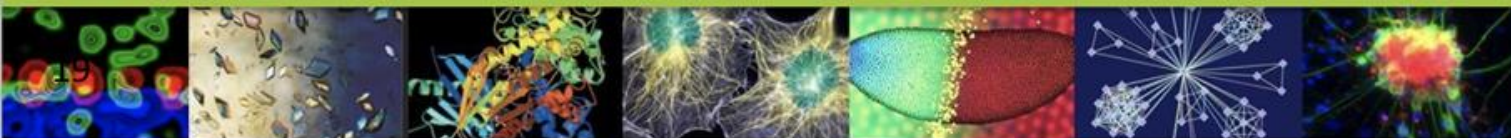
Open Selected Pending () additions facilitated by NIGMS



ACTIV Therapeutic Clinical Trials		
Trial #	In-Patient (IP) or Out-Patient (OP)	Therapeutic Type
1	IP	Immune Modulators
2	OP	Monoclonal Antibodies
3	IP	Monoclonal Antibodies
4a	IP	Antithrombotics
4b	OP	Antithrombotics
4c	OP (post-hospital)	Antithrombotics
5	IP	Big Effect Trial

Lessons Learned from ACTIV Trials

- Very large heterogeneity in IDeA states' abilities to support large scale clinical trials
- Some states said they still did not have the capacity to do major clinical trials at all
- Some states said they could not join the ACTIV trials because their capacity was already being used for other trials
 - Were the other trials as valuable nationally or to the state's population as the ACTIV trials would have been?

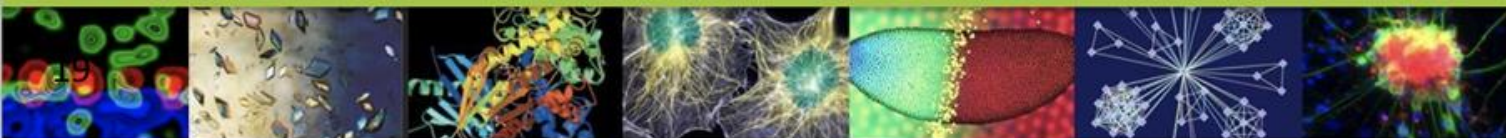


Cloud Computing Resources for IDeA States and Minority-Serving Institutions

- The cloud can help democratize high-performance computing and artificial intelligence-based research
- The NIH STRIDES program provides discounted cloud services and training through Google, AWS and Microsoft
- What are IDeA state needs and challenges for cloud-based data science and computational research?



<https://datascience.nih.gov/strides>



Cloud Computing RFI and Workshop

- RFI - Seek input on current and future needs and utilization of cloud computing from institutions within [IDeA-eligible states](#), [RCMIs](#), and [MSIs](#).
 - Released: July 8, 2021
 - Response period: July 8-September 30, 2021
- NIH Workshop on Broadening Cloud Computing Usage in Biomedical Research (Sept 13 – 14, 2021)
 - Website for meeting registration will be available soon
 - Participants in breakout sessions will be selected from attendees

Cloud Computing Training for INBREs & NIGMS Diversity Programs

- 30 Free Cloud Training days, 15 by Amazon, 15 by Google
 - Three levels: Beginner, Intermediate, Advanced (at least half at the beginner's level)
 - 15 - 17 students per day (~ 500 total training seats)
 - 2 Training Sessions conducted in June – 32 participants
 - 6 Training Sessions on going – 100 participants
 - 11 Training Sessions scheduled in August – 200 participants
 - 11 more to be scheduled in the Fall
 - ~ 90 Institutions signed-up so far.
 - To sign up, contact: lakshmi.matukumalli@nih.gov

Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC)

Postdoctoral Career Transition Award to Promote Diversity (K99/R00) – [PAR-19-343](#)

Institutionally Focused Research Education Cooperative Agreement to Promote Diversity (UE5) – [PAR-19-342](#)

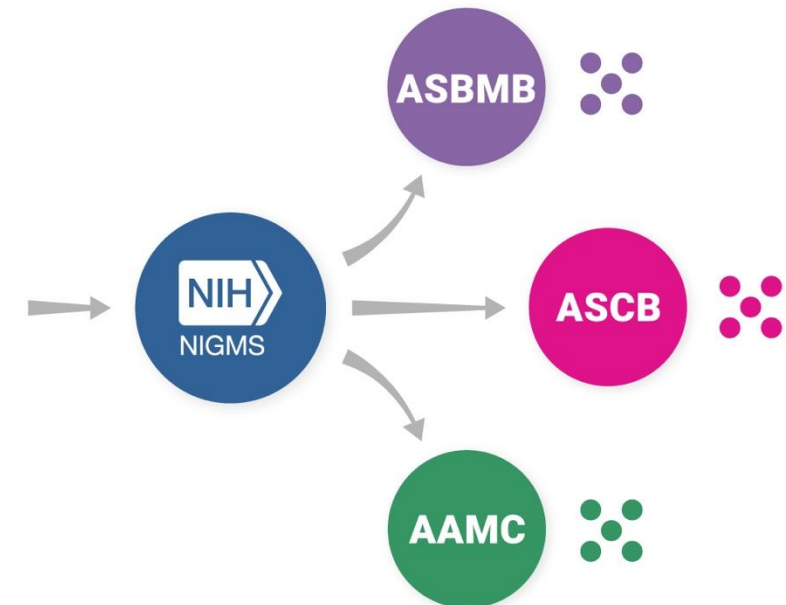
Awards to scientific societies (UE5) and time to stand up the program



MOSAIC K99/R00 Applicants Compete



MOSAIC K99/R00 Scholars Participate in Cohorts Organized by UE5



Support for Research Excellence (SuRE) Program

Purpose: to develop and sustain research excellence of faculty at under-resourced institutions that serve underrepresented and socioeconomically disadvantaged students

- **PAR-21-169: Support for Research Excellence (SuRE) Award (R16)**
 - For investigators with no other NIH research funding. \$100K DC/yr, 4 years, renewable
- **PAR-21-173: Support for Research Excellence – First Independent Research (SuRE-First) Award (R16)**
 - For investigators with no prior research funding. \$125K DC/yr, 4 years, mentored, not renewable
- **PAR-21-227: Resource Center for the Support for Research Excellence (SuRE) Program (U24)**
 - To build administrative infrastructure, thus broadening participation. \$750K DC/yr, 5 years

New Features of the SuRE Program

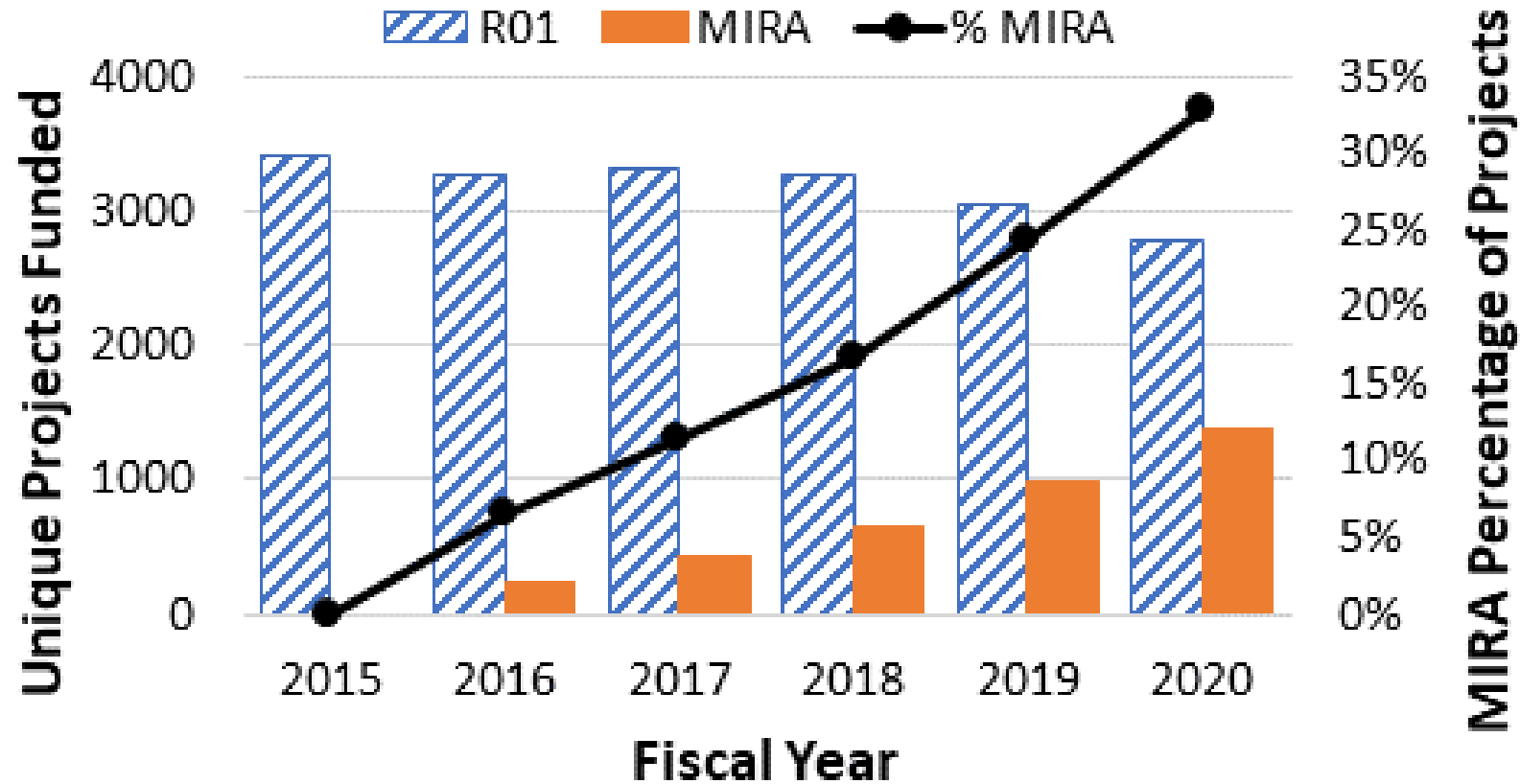
R16s replace SCORE awards: focus is on supporting research excellence in eligible institutions, which includes many INBRE institutions

- Require participation of students in funded research
- Require applicant institutions to have a strategic plan for developing research capacity and culture
- Uses publicly available data to determine institutional eligibility
 - Receive < \$6 M/year TC from NIH Research Project Grants
 - Enroll \geq 25% undergrads supported by Pell grants or are medical/health professional schools founded to educate students from nationally underrepresented backgrounds

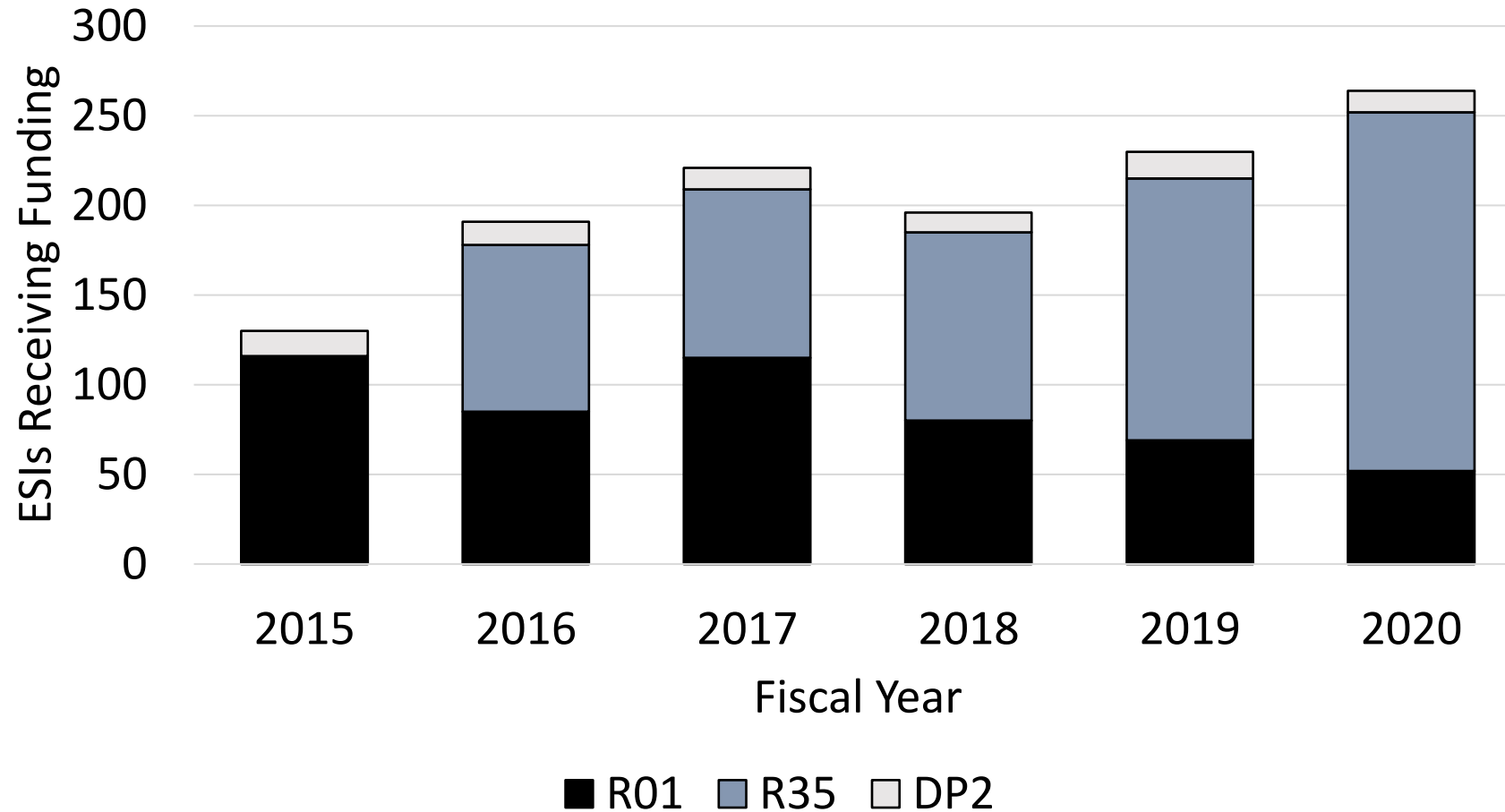
A new U24 resource center to serve SuRE-eligible institutions and applicants

- Build/strengthen Offices of Sponsored Programs (OSPs) through a seed grant program
- Provide administrative training by Center staff and regional outreach coordinators
- Track institutions' progress in research capacity building and its own service efficacy

MIRA Makes Up an Increasingly Large Share of NIGMS Grants



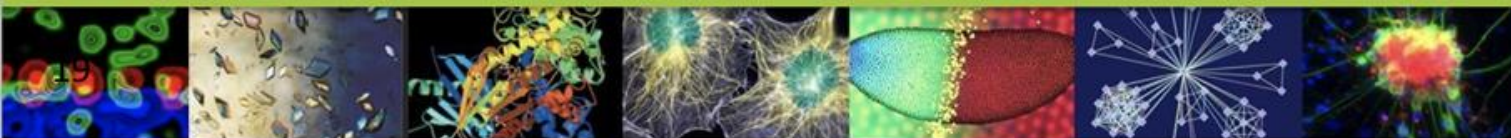
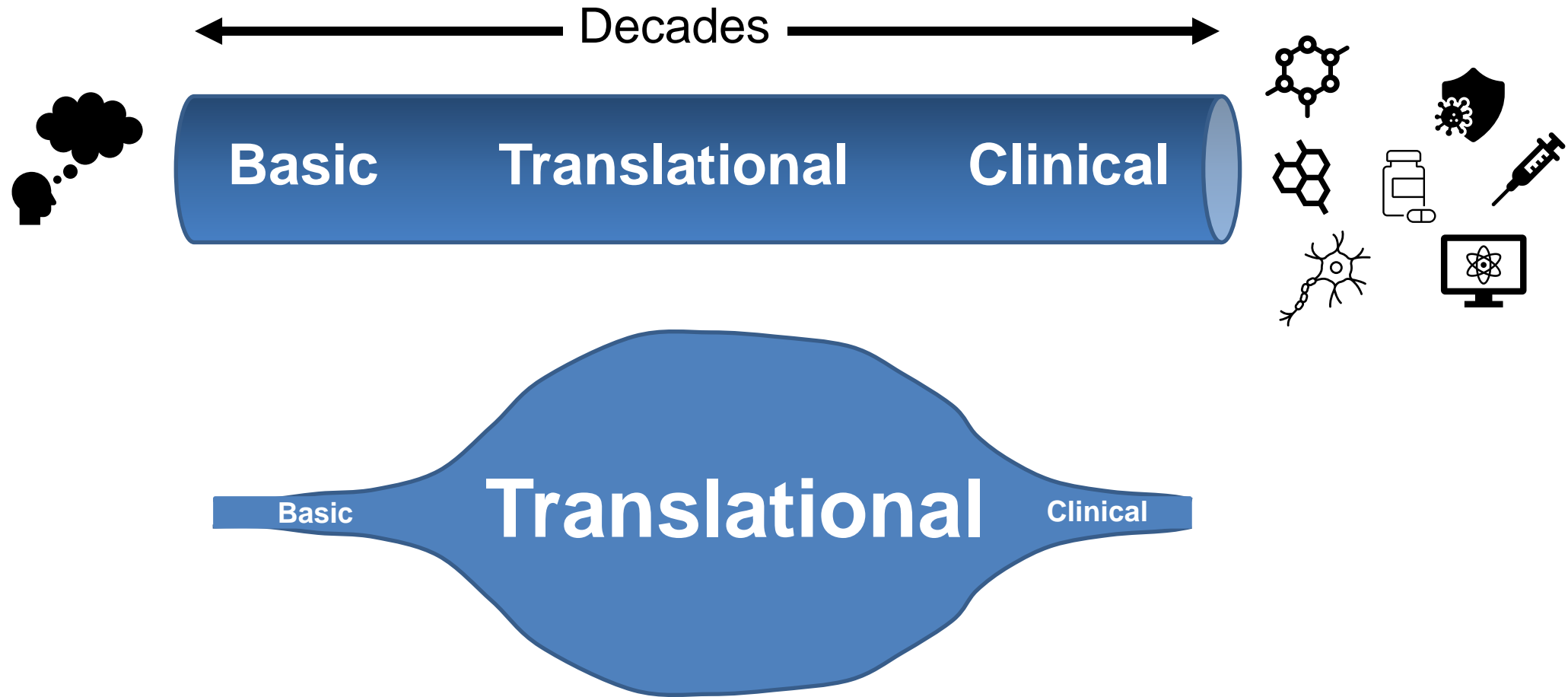
The Majority of NIGMS ESIs Are Being Funded by MIRAs



A Broadly-Focused COBRE Is Probably Better than a Narrowly-Focused One

- Broadly-focused COBREs
 - More effective in building research capacity – e.g., through hiring of sufficient junior faculty
 - Bigger pool of compelling candidates for Research Project leaders - more sustainable program with stronger position for renewal
 - Broader appeal to students and postdocs
 - Stronger rationale for securing institutional support from department chairs and deans – align with institutional strategic goals

The IDeA State Biomedical R&D Pipeline



Questions or Comments?

