Krishan K. Arora, Ph.D.

Program Director

Division for Research
Capacity Building

National Institute of General Medical Sciences

NIH and IDeA Program Update

IDeA Central Region Conference
June 13, 2019
Outlines of Presentation

• NIH
  o The Common Fund Programs
  o Data Science Initiative

• NIGMS
  o MIRA Program
  o Lab to Marketplace – SBIR/STTR Programs

• IDeA Program
  o Regional Technology Transfer Accelerator Hubs for IDeA States
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
Vision

• Address **emerging scientific opportunities and pressing challenges**

• Accelerate the pace of discovery and improve translation of research findings into medical and health interventions

• Function as “**venture capital space**” for high-risk, innovative endeavors (limited-term investments)
The Common Fund
Programs

Transformative
Exceptionally high and broadly applicable impact

Unique
Provide new solutions to specific challenges

Synergistic
Add value and enable missions of Institutes and Centers

Cross-Cutting
Address complex issues requiring trans-NIH teams

Catalytic
Must achieve a goal with deliverables within 5-10 years
High-Risk, High-Reward Research Program

• Created to accelerate biomedical, behavioral and social science discoveries by supporting exceptionally creative scientists proposing highly innovative, impactful research in line with the NIH-mission

• Four annual funding opportunities available now

• Application formats and review processes very different from NIH standard

NIH DIRECTOR’S PIONEER AWARD
• All career stages
• Single PI
• $3.5M over 5 years

RFA-RM-19-005
Applications due 9/6/19

NIH DIRECTOR’S NEW INNOVATOR AWARD
• Early Stage Investigators
• Single PI
• $1.5M over 5 years

RFA-RM-19-006
Applications due 8/26/19

NIH DIRECTOR’S TRANSFORMATIVE RESEARCH AWARD
• All career stages
• Single or multi-PI
• Flexible budget over 5 years

RFA-RM-19-007
Applications due 9/20/19

NIH DIRECTOR’S EARLY INDEPENDENCE AWARD
• “Skip the post-doc”
• Single PI
• $1.25M over 5 years

RFA-RM-19-008
Applications due 9/13/19

https://commonfund.nih.gov/highrisk
Data Science at NIH

- **Coordinate** access to and analysis of the many types of biological and behavioral ‘big data’ being generated by biomedical scientists

- **Develop** innovative and transformative computational approaches, tools, and infrastructures to make ‘big data’ and data science a prominent component of biomedical research

- **Enable** data sharing and utilization through the development of a new shared, interoperable cloud computing environment: *the ‘Commons’*

https://datascience.nih.gov/strategicplan
### Making Data *FAIR*

<table>
<thead>
<tr>
<th>Findable</th>
<th>must have unique identifiers, effectively labeling it within searchable resources.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessible</td>
<td>must be easily retrievable via open systems and effective and secure authentication and authorization procedures.</td>
</tr>
<tr>
<td>Interoperable</td>
<td>should “use and speak the same language” via use of standardized vocabularies.</td>
</tr>
<tr>
<td>Reusable</td>
<td>must be adequately described to a new user, have clear information about data-usage licenses, and have a traceable “owner’s manual,” or provenance.</td>
</tr>
</tbody>
</table>
Strategic Plan for Data Science: Goals and Objectives

https://datascience.nih.gov
**Science & Tech Research Infrastructure for Discovery, Experimentation and Sustainability Initiative**

- First **STRIDES** agreement: Google Cloud (July 2018)
- Second **STRIDES** agreement: Amazon Web Services (Oct. 2018)
- Other Transaction mechanism
- Additional partnerships anticipated

**FAIR Data: Move/Access to high priority data sets in cloud service providers**

**https://datascience.nih.gov/strides**
Enhancing Biomedical Workforce

- **2019 Graduate Data Science Summer Program (GDSSP)**
  - The Office of Intramural Training & Education and the Office of Data Science Strategy
  - A summer program to give Masters level students in data science the opportunity to participate in mentored internships at NIH.
  - Applications are open mid-December.
  - For more information, please visit: [https://www.training.nih.gov/data_science_summer](https://www.training.nih.gov/data_science_summer)
National Institute of General Medical Sciences (NIGMS) Mission

- Supports basic and translational research
- Provides leadership for the training of next generation of scientists
- Develops and increases workforce diversity
- Promotes capacity building in research infrastructure and networking
National Institute of General Medical Sciences (NIGMS)

Divisions at NIGMS

- Training, Workforce Development and Diversity
- Biophysics, Biomedical Technology, and Computational Biosciences
- Research Capacity Building
- Genetics and Molecular, Cellular and Developmental Biology
- Pharmacology, Physiology, and Biological Chemistry

(http://www.nigms.nih.gov)
Maximizing Investigator’s Research Award (MIRA): A Priority for NIGMS

Major Goals of the MIRA Program

- Improve the efficiency and effectiveness of its support for basic biomedical research.
- Enhance investigators’ ability to take on ambitious scientific problems creatively.
- Increase the flexibility for investigators to follow important new research directions.
- Improve the distribution of funding to improve overall scientific productivity and the chances for important breakthroughs.
- Reduce the time spent by researchers writing and reviewing grant applications.
Expansion of MIRA Program

• FOA for *established* PIs: PAR-17-094
  - Anyone with an NIGMS R01, R37, DP2 or SC1 award can apply to convert to a MIRA when their current grant is up for renewal
  - 5 years; renewable; more flexibility to follow new ideas and directions; increased stability; one NIGMS research grant per PI
  - Receipt date expired in May; FOA will be re-issued in Fall

• FOA for *Early Stage* Investigators: PAR-17-190
  - Receipt Date: October 3, 2019

• Separate review panels and criteria for *established* and *early stage* investigators
From Lab to Market:
Opportunities for SBIR/STTR,
Translational and Entrepreneurial
Resources at the NIH
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
**Congressionally Mandated Programs**

---

**SET ASIDE**

**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

**SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

---

https://sbir.nih.gov
NIH SBIR/STTR Budget Allocations FY2019

3.2% SBIR $1B
0.45% STTR $141M
Total FY19 $1.145B
NIH SBIR/STTR
3-Phase Program

Feasibility
Phase I

Discovery

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase III

Commercialization
Readiness Pilot (CRP)
Congressional authority back!
Re-implemented fall/winter
$3M for up to 3 years

Direct to Phase II
Congressional authority back!
Re-implemented.

Fast-Track

Only Some ICs Participate
Funding Opportunities Announcements (FOAs)

a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements.

NIH SBIR/STTR FOAs

2019 SBIR and STTR
Omnibus/Parent Grant
Solicitations for the NIH, CDC, and FDA, Clinical Trial Not Allowed and Clinical Trial Required

- SBIR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-272)
- STTR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-270)
- SBIR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-273)
- STTR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-271)
- 2019 Program Descriptions and Research Topics Document
  - (2.31 MB) (614 KB)
- 2019 SBA approved topics list for budget walvers
  - (554 KB) (72 KB)
- NIH SBIR/STTR Grant Forms

https://sbir.nih.gov/funding

Next receipt date: September 5

Standard Due Dates:
- January 5
- April 5
- September 5
NIH Institutes/Centers: Small Business Core Activities

GUIDANCE
• Help applicants prepare for application, resubmission, and discuss funding options

CENTRAL OVERSIGHT
• Administer all SBIR/STTR awards at the institute

OUTREACH
• Attend conferences and workshops & visit state based organizations and universities to raise awareness of the program

NETWORKING
• Facilitate connections between awardees and potential strategic partners (programs/external partners)

FUNDING
• Seed emerging technology areas by developing targeted funding opportunities and Omnibus interest topics

ENTREPRENEURSHIP
• Provide entrepreneurship training, as well as webinars on key commercialization-related topics
NIGMS- funded:
Regional Technology Transfer Accelerator Hubs
for IDeA States
A new initiative in response to Congressional directive

One shared Accelerator for each IDeA region to provide infrastructure and build an entrepreneurial culture at the IDeA institutions

Will provide training, mentoring, consulting services in:

- Entrepreneurship
- Technology transfer
- Intellectual property protection and marketing
- Small business finance and management
- Business development skills
- Partnerships
<table>
<thead>
<tr>
<th>IDeA Region</th>
<th>Program Name</th>
<th>Small Business Concern</th>
<th>Major Academic Partnering Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>DRIVEN: Accelerating Medical Entrepreneurship in the Northeast</td>
<td>CELDARA MEDICAL, LLC, Lebanon, New Hampshire</td>
<td>University of Vermont, Burlington, Vermont</td>
</tr>
<tr>
<td>Central</td>
<td>The Sustainable Heartland Accelerator Regional Partnership (SHARP) Hub</td>
<td>BBC ENTREPRENUERIAL TRAINING AND CONSULTING, LLC, Chelsea, Michigan</td>
<td>University of Kansas Medical Center, Kansas City, Kansas</td>
</tr>
<tr>
<td>Western</td>
<td>ASCEND, Accelerating Solutions for Commercialization and Entrepreneurial Development in the Mountain West IDeA States</td>
<td>VIRTICI, LLC, Seattle, Washington</td>
<td>University of New Mexico Health Sciences Center, Albuquerque, New Mexico</td>
</tr>
<tr>
<td>Southeast</td>
<td>Southeast Xlerator Network</td>
<td>XLERATEHEALTH, LLC, Louisville, Kentucky</td>
<td>University of Kentucky, Lexington, Kentucky</td>
</tr>
</tbody>
</table>
Regional Technology Transfer Accelerator Hubs for IDeA States

- **Western Region**: "ASCEND"
- **Central Region**: "SHARP"
- **Northeast Region**: "DRIVEN"

States are color-coded for their respective regions:
- **Green** for Western Region
- **Purple** for Central Region
- **Orange** for Northeast Region

There is a note for **Southeast Xlerator Network**.
Fostering Biomedical Entrepreneurship in IDeA States

Regional Technology Transfer Accelerator Hub

Entrepreneurship Ecosystem

Skills Development, Mentoring, Education, Training & Outreach

Biomedical Research and Innovations

Commercialization

Patient Needs
Thank you!

Email: arorak@nigms.nih.gov