The Webinar Will Begin Shortly

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- To save the chat, you should have **chat cloud storage** enabled on your Zoom account.
  - To save the chat manually, click on the chat icon 💬
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  - This will save your chat record to your local Zoom recording location on your computer. The default Documents folder is Zoom/Folder [Meeting name, date, time]
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Small Business Funding and Support to Advance Translational Science Innovation

July 21, 2022

ncats.nih.gov/smallbusiness

NIH National Center for Advancing Translational Sciences

Hosts

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NCATS Office of Strategic Alliances

ncats.nih.gov/smallbusiness

The SBIR and STTR programs support NCATS' mission to **transform the translational science process so that new treatments and cures for disease can be delivered to patients more efficiently.** These programs serve as an engine of innovation, offering grants, contracts and technical assistance to small businesses and research organizations focused on advancing translational research and technologies that will improve disease prevention, detection and treatment.

ARROWHEAD CENTER®
NM FAST

NMSU Arrowhead Center NM Fast Program

https://arrowheadcenter.org/program/nm-fast/about-nm-fast/

NM FAST (funded in part through a collaborative agreement with the Small Business Administration under the FAST program) provides SBIR/STTR proposal development assistance and support to business across the state of New Mexico. NM FAST provides a full suite of resources, including proposal development and compliance documentation, videos highlighting each agency and their focus on innovation, and multi-week cohort-based accelerators focused on a variety of SBIR/STTR agencies, to ensure that clients can submit complete and compelling proposal packages.

New Mexico Bioscience Authority

https://www.nmbioscience.org/

The New Mexico Bioscience Authority was created in 2017 by the state legislature as an official state entity and the state's first public-private partnership with the mission to increase awareness and support for New Mexico's bioscience sector by attracting capital investors, influencing policy and assisting in infrastructure and business development. From funding, to incentives, to community readiness and labor initiatives, the NM Bioscience Authority connects all the potential collaborators: universities, research & development, technology transfer, entrepreneurs, funders, elected officials and workforce to grow the bioscience industry in New Mexico.

Featured Speakers

Mayra A. Alvarez Lopez, M.S.
Program Analyst
Office of Strategic Alliances
National Center for Advancing
Translational Sciences
National Institutes of Health

Del Mackey, M.B.A.
Senior Economic Officer
NM Fast Program Manager
New Mexico State University
Arrowhead Center

Stephanie Tofighi, MSPP
Executive Director
New Mexico Bioscience Authority

Monique LaRocque, M.P.H.
Executive Vice President
Ogilvy Health | FKH

MODERATOR

Agenda

Introductions and Objectives

NMSU Arrowhead Center NM Fast Program

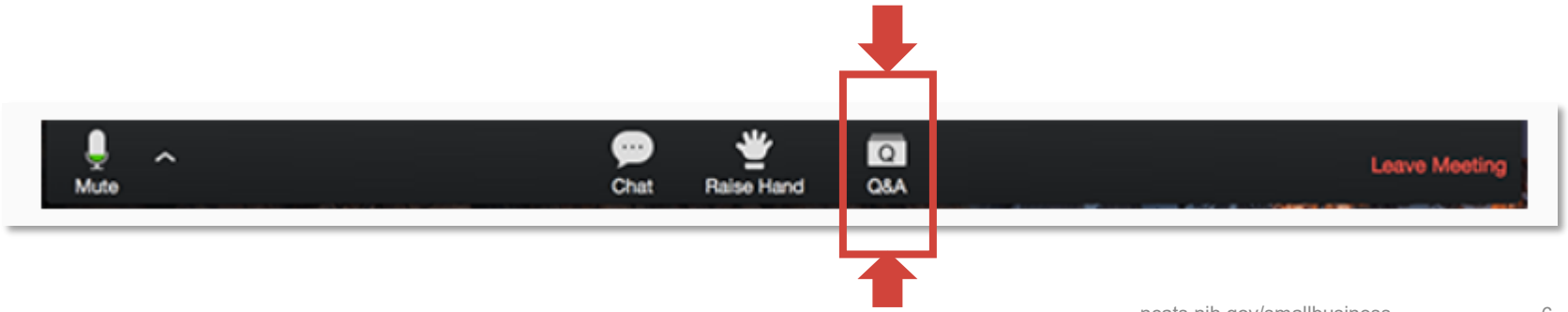
New Mexico Bioscience Authority

NCATS SBIR & STTR Programs

- Program Overview
- Opportunities and Resources

Moderated Q&A

- Please use the Q&A function to submit questions at any time during the presentation



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Del Mackey, M.B.A.
Senior Economic Officer
NM Fast Program Manager
New Mexico State University Arrowhead Center

NM FAST at Arrowhead Center

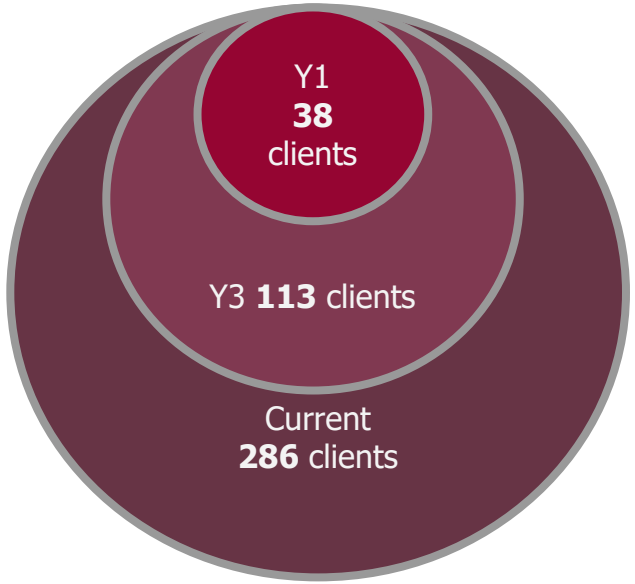
NM FAST: SBIR/STTR Story

New Mexico's source for SBIR/STTR proposal development programming and assistance, built from the ground up

NM FAST was created through New Mexico State University's Arrowhead Center, which serves as the economic development engine for the university

Arrowhead resources include experiential entrepreneurship education for K-16+ students and community members, business startup and development assistance, IP guidance and management, and a business and research park

Funding through the SBA's FAST grant allowed Arrowhead to fill a critical need within the State of NM - providing underserved small businesses access to SBIR/STTR proposal development assistance through the NM FAST program



2015 — Pre-NM FAST

No organization/program providing SBIR/STTR assistance in the State of New Mexico

Oct 2015 — NM FAST Launches

Emphasis placed on first-time applicants, underserved and rural participation; workshops in key "metro" areas; work to build program from the ground up

Oct 2016 — Year 2 Funding

Expansion of program to more rural areas with smaller "clusters" of population; launch of FAST CAST videos/podcast

Oct 2017 — Year 3 Funding

Build-out of Resource Library; creation of proposal resource documents; first year hosting annual Innovation Summit

Oct 2018 — Year 4 Funding

Expansion of Resource Library including Quick-Start Guides and Proposal Templates; launch of SBIR accelerator

Oct 2019 — Year 5 Funding

Continuation of ACSA and expansion into more agencies (NIH, NSF); more engagement with federal labs and RIs

Oct 2020 — Year 6 Funding

Expansion of ACSA cohorts via other funding streams; build-out of Canvas courses; continuation of assistance.

Oct 2021 — Year 7 Funding

More Canvas course development; NM CERG DOE ACSA cohort added; continuation of other assistance.

Present — Future of NM FAST

Continuation of program focus on traditionally underserved businesses; more digital media tools and resources; expansion of video library; expansion of funding and revenue streams.

NM FAST Assistance

NM FAST helps clients navigate the programs and de-mystify SBIR/STTR confusion points

- Free SBIR/STTR proposal development assistance (e.g., topic and agency matching, budget assistance, proposal writing assistance, etc.)
- Proposal review
- Tailored services for each client
- Micro-grants (up to $2,000) available to help with proposal development
- Free workshops and engagement activities held throughout the state
- SBIR/STTR tools and resources available on website: https://arrowheadcenter.nmsu.edu/program/nm-fast/
- Monthly SBIR/STTR newsletter and agency blasts for each solicitation
- Video podcast series
- Multi-week SBIR/STTR accelerators
- Annual SBIR/STTR Innovation Summit

"The NM FAST team has been outstanding. The support package is tailored to the company, providing critical expertise and knowledge to the company. It truly is hands on engagement." – NM FAST Client

Living Library & Website

Our always-on digital resources ensure applicants get the answers they need when they need them.

- Agency “Quick-Start” Guides
- YouTube Channel: Archive of prior workshops, structured video playlists for each agency, videos on various proposal components, etc. https://www.youtube.com/c/NMFAST
- Compliance Matrices: Bird’s-eye view of solicitation requirements
- Checklists: Final verification that all requirements have been met
- Templates: Proposal, executive summary, budget justifications, letters of support
- Solicitation Guide (updated solicitation schedule available on website)
- 18 agency guides translated into Spanish
- Documents and resources updated every release to provide the most up-to-date tools for successful proposal creation https://arrowheadcenter.org/program/nm-fast/nm-fast-resources/

ARROWHEAD CENTER® | NM FAST | NM STATE

Funded in part by the Small Business Administration.

Agency	Program	Phase (P)	Open	Close
DHS	SBIR	P-I/P-II	December	January
DoD	SBIR/STTR	P-I/P-II	January	February
			May	June
			September	October
DoE	SBIR/STTR	P-I	August	October
			December	February
DoE	SBIR/STTR	P-II	October	December
			March	April
DOT	SBIR	P-I/P-II	February	March
EPA	SBIR	P-I	June	July
HHS*	SBIR/STTR	P-I/P-II	May	Sept/Jan/April
IES	SBIR	P-I	January	March
NASA	SBIR/STTR	P-I	January	March
NIST	SBIR	P-I/P-II	February	April
NOAA	SBIR	P-I	December	February
NSF**	SBIR/STTR	P-I/P-II	December	March
			March	June
			June	September
			September	December
USDA	SBIR	P-I	July	October
	SBIR	P-II	December	March

*These are general dates for the HHS SBIR/STTR programs. The solicitation open and close dates for specific NIH institutes may vary.
** NSF has moved to a “window” submission period. Windows run consecutively and cover an entire year.

Upcoming Events

Mesas to Mountains SBIR Summit:

- Online 2-day event – October 11th and 12th (tentative)
- First day will focus on SBIR/STTR; second day will focus on partnerships and intellectual property
- Panel sessions, virtual meetings, and booths to visit
- Stay tuned for more details: https://arrowheadcenter.org/program/nm-fast/mesas-to-mountains/mesas-to-mountains-summit/

New Mexico SBIR/STTR Innovation Summit:

- December 14th in Albuquerque
- Full day event with panels, one-on-one sessions, booths, and networking opportunities
- Stay tuned for more details: https://arrowheadcenter.org/program/nm-fast/innovation-summit/

Thank You!

Contact:

delmacke@nmsu.edu

Apply for assistance at:

https://arrowheadcenter.org/program/nm-fast/

Stephanie Tofighi, MSPP
Executive Director
New Mexico Bioscience Authority




NM Bioscience Authority

Presenting on behalf of the New Mexico Bioscience Authority:

July 21, 2022

Stephanie Tofighi, MSPP
Executive Director
NM Bioscience Authority

What Is Bioscience?

Five Industries Make Up Bioscience Sector:

1. Agricultural feedstock and chemicals
2. Bioscience-related distribution
3. Drugs and pharmaceuticals
4. Medical devices and equipment
5. Research, bioinformatics, testing and medical laboratories

NEW MEXICO BIOSCIENCE AUTHORITY

New Mexico Bioscience Authority

Connecting Researchers, Entrepreneurs, and Investors Across the State to Grow the Economy

History

- State agency created through legislation in 2017 with the vision to grow a robust bioscience industry throughout the state.
- 13-member board represents all sectors of New Mexico including the three Research Universities, EDD, Spaceport, and industry

Mission

To increase awareness and support for New Mexico's bioscience sector by attracting capital investors, influencing policy and assisting in infrastructure and business development. The NMBSA connects all necessary elements of: Research & Development, Technology Transfer, Investment and Funding and Workforce.

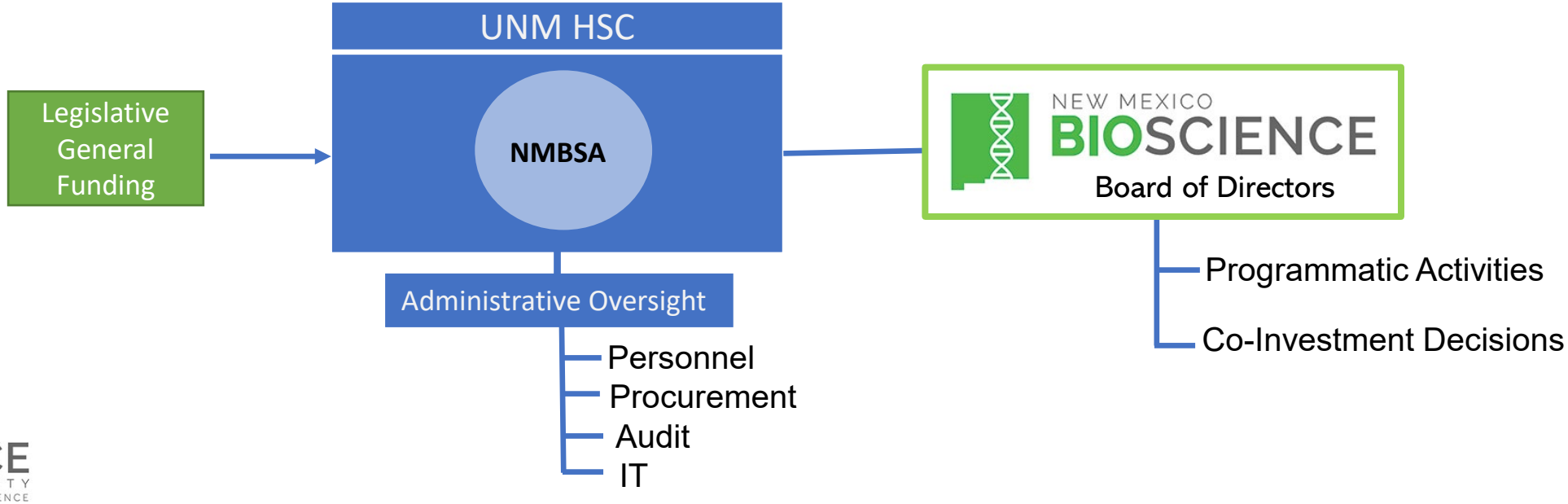
Vision

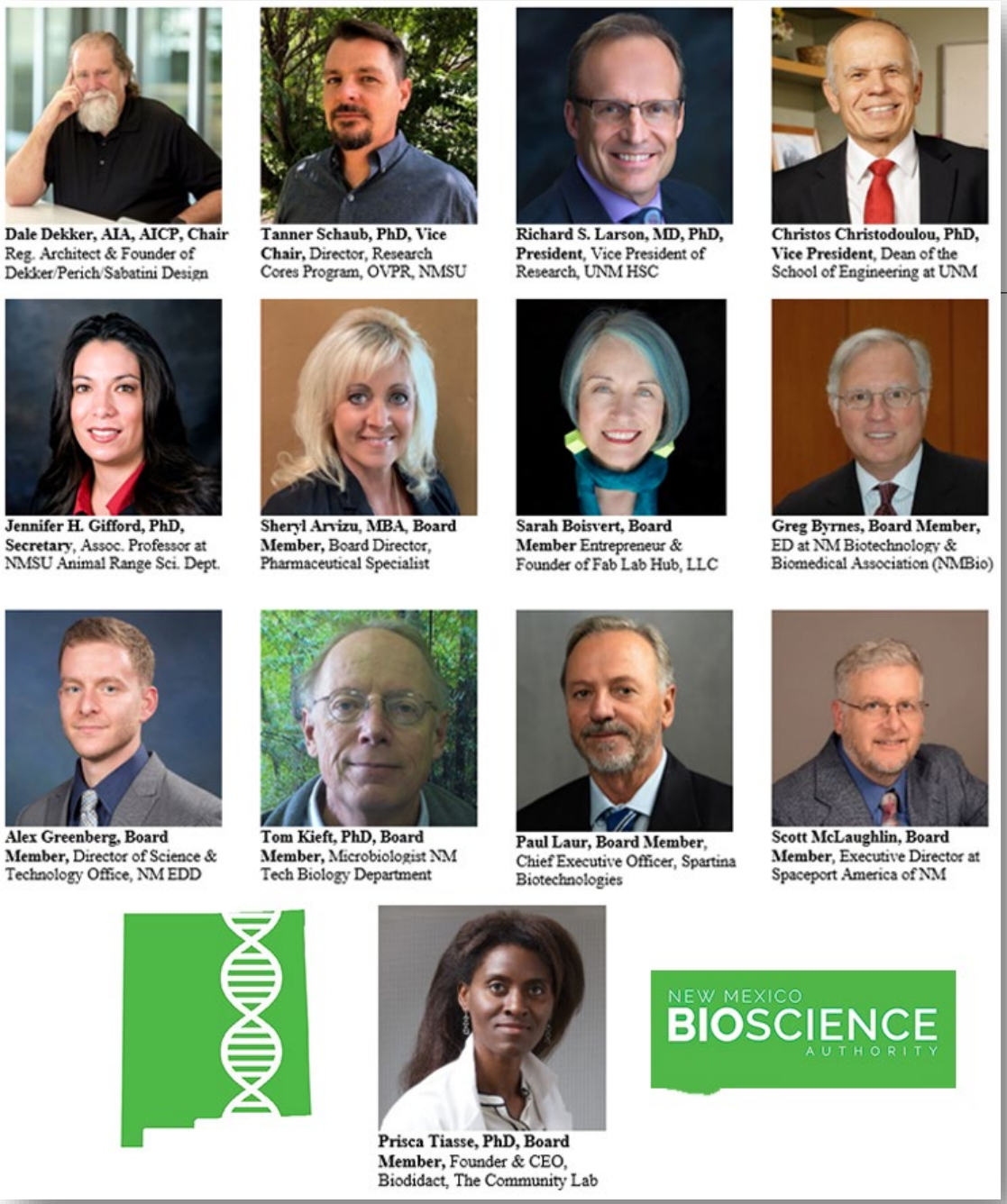
To grow a robust bioscience industry in New Mexico.

NEW MEXICO BIOSCIENCE AUTHORITY

Organization of NM Bioscience Authority

- 13-person board (appointed by Governor, Speaker of the House, Senate Pro-Tempore, and University Presidents)
- The authority is administratively attached to and is considered an affiliated organization of the UNM Health Sciences Center to assure conformity with state procurement rules, statutes, and guidelines and minimize costs.





NM Bioscience Authority Board of Directors

- 2 members appointed by UNM President
- 2 member appointed by NMSU President
- 1 member appointed by NMT President
- Secretary of EDD or Designee
- Executive Director of SpacePort Authority or Designee
- 4 members appointed by Speaker of the House and Senate Pro-Tempore
- 2 members appointed by Governor

NM Bioscience Authority Staff

Stephanie Tofighi, MSPP
Executive Director

Ryan Cangiolosi, MBA, MACCT
Strategy & Policy Director

Sterling J. Nichols III, BS
Program Specialist

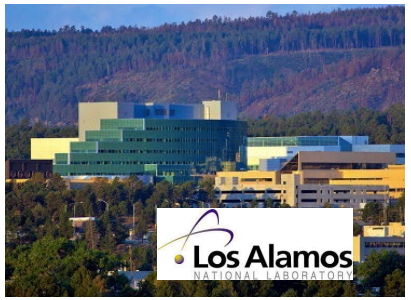
NEW MEXICO BIOSCIENCE AUTHORITY

Current NMBSA Initiatives

- **Community Readiness Program** – partners with municipalities & counties throughout the state to identify and certify zones as being ready to accept bioscience businesses
- **Co-Investment Program** – partners with professional investment firms to invest in start-up businesses in New Mexico or business relocating to New Mexico
- **SBIR/STTR Bioscience Business Accelerator Program** – provides training and mentoring to small businesses, researchers, and inventors looking to submit to the federally funded SBIR/STTR programs
- **Centralization of Statewide Resources** – website directs bioscience inventors, entrepreneurs, and investors to resources throughout the state that can help them effectively commercialize, expand, or invest effectively

NM Bioscience Authority's SBIR/STTR Bioscience Business Accelerator

- The BSA's bioscience business accelerator expands a federally funded UNM based bioscience business accelerator primarily geared toward the commercialization of biomedical innovation.
- Includes SBIR/STTR grant training, mentoring, workshops, and network facilitation to support the commercialization of bioscience innovation
  - Statewide mission to train university and research institution faculty and staff to work effectively with entrepreneurs to start bioscience businesses.
  - Latest events:
    - NIH SBIR/STTR training cohort led by Arrowhead Center's NM FAST
    - Panel discussion on How to Improve Academic/Industrial Collaborations in the Bioscience Sector at UNM's Team Research Symposium.



Upcoming Events

Los Alamos National Lab DisrupTECH event:

- Presenting on our Bioscience Business Accelerator program
- August 3rd
- https://www.lanldisruptech.com/

NEW MEXICO BIOSCIENCE AUTHORITY

Get Connected

- Check out our website at https://www.nmbioscience.org/
- Follow us on social media on Twitter @NewMexicoBSA and on LinkedIn @New_Mexico_Bioscience_Authority
- Sign up to our listserv at https://www.nmbioscience.org/contact-us/
- Contact ED Stephanie Tofighi at stofighi@salud.unm.edu or Program Specialist Sterling Nichols at snichols@salud.unm.edu

Mayra A. Alvarez Lopez, M.S.

Program Analyst
Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institutes of Health

What Does the National Center for Advancing Translational Sciences (NCATS) Do?

1 of 27

Institutes and Centers at the National Institutes of Health (NIH).

Conducts and supports research on the science and operation of translation to allow more treatments to get to more patients more quickly.

Focuses on what is common across diseases and the translational process.

NCATS

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

TRANSLATIONAL SCIENCES

NCATS Scientific Initiatives

Clinical Translational Science

- Clinical and Translational Science Awards
- Rare Disease Clinical Research Network
- New Therapeutic Uses program

Preclinical Translational Science

- NCATS Chemical Genomics Center
- Therapeutics for Rare and Neglected Diseases program
- Bridging Interventional Development Gaps program

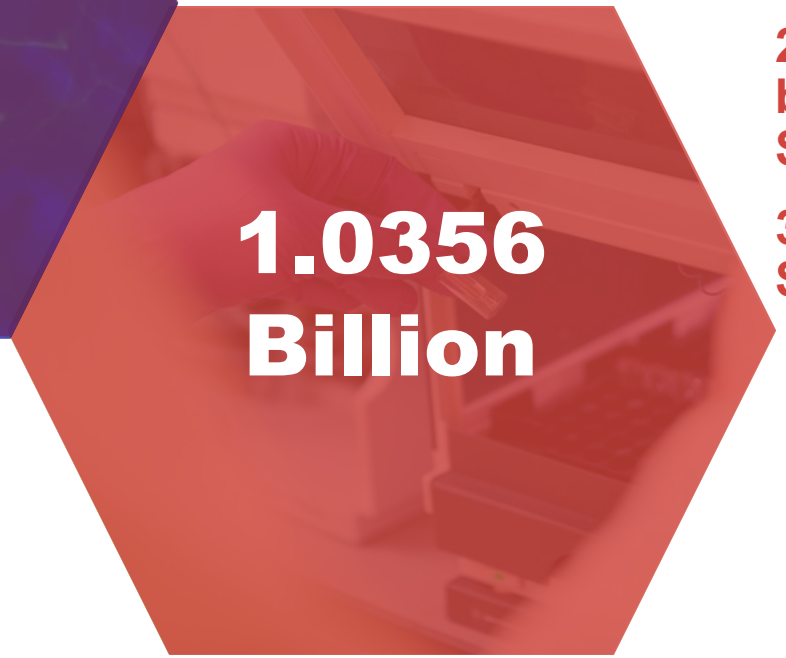
Re-engineering Translational Sciences

- Toxicology in the 21st Century
- Microphysiological Systems (Tissue Chip) program
- Office of Rare Diseases Research

SBIR and STTR:
One of the Largest Sources of Early-Stage Financing

41.68 Billion

2021 NIH budget for basic & applied biomedical science



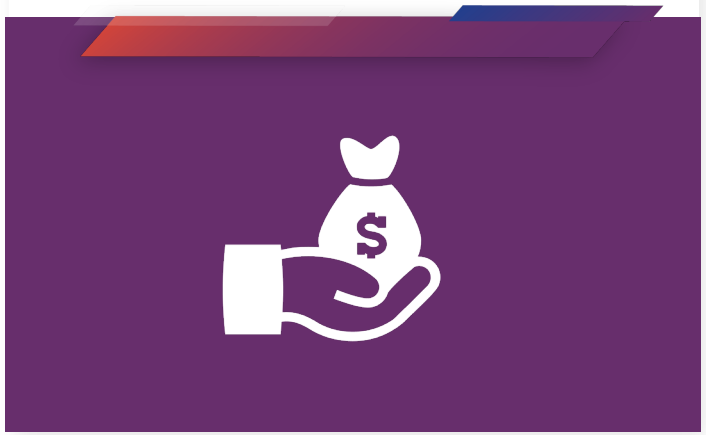
2021 NIH funds for small businesses (SBIR & STTR)

3.65% Set-aside for SBIR/STTR support

The Benefits

NCATS SMALL BUSINESS PROGRAMS (SBIR/STTR)

Stable and predictable. Not a loan. Funds don't have to be repaid.



Non-dilutive. IP rights are retained by the small business.

Technical assistance to advance and commercialize technologies for public good.

Projects undergo NIH's rigorous scientific peer review process, which awardees leverage to attract other funding and collaborations.

SBIR and STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award is always made to the small business

NIH SBIR/STTR Is a Three-Phase Program

Phase I Feasibility Study

Budget Guide: $275,766 for SBIR and STTR *($325K Waiver)*
Project Period: 6 months (SBIR); 1 year (STTR)

Phase II Full Research/R&D

$1,838,436 for SBIR and STTR, over two years *($2M)*

Fast Track combines Phase I and Phase 2
Direct to Phase 2 – allows to skip Phase 1

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA
Funding Varies (~$1M per year) for up to 3 years

Phase III Commercialization

NIH, generally, not the "customer"
Consider partnering and exit strategy

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Funding Overview

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are some of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow U.S.-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

Omnibus Solicitation	• Investigator-initiated grant funding • Standard Deadlines: April 5, September 5, January 5 • **PHS 2022-2 Omnibus Solicitation grants are now available**
Grant Solicitations in Targeted Areas	• Grant to advance a particular technology/research area • Due dates may vary
Contract Solicitation	• Contract opportunity to advance areas of high research interest • Typically due in October or November

Translational Science and Research Areas of Interest

SBIR and STTR programs support NCATS' **mission to transform the translational science process** so that **new treatments and cures** for disease can be **delivered to patients more efficiently.**

TOPICS OF INTEREST

1. Preclinical Drug Discovery & Development
2. Biomedical, Clinical & Health Research Informatics
3. Clinical, Dissemination & Implementation Research

2022-2023 DEADLINES:

September 6
January 5
April 5

Targeted Funding Opportunities for 2022

- **Development of Highly Innovative Tools and Technology for Analysis of Single Cells**
  - **SBIR:** PA-20-047 (R43/R44 Clinical Trial Not Allowed)
  - **STTR:** PA-20-025 (R41/R42 Clinical Trial Not Allowed)
  - Next Deadline: Sep 6, 2022

- **Notice of Special Interest (NOSI): Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health**
  - NOT-EB-21-001
  - Next Deadline: Sep 6, 2022

- **Notice of Special Interest (NOSI): Innovative Technologies for Research on Climate Change and Human Health (Clinical Trial Optional)**
  - **SBIR:** NOT-ES-22-010
  - **STTR:** NOT-ES-22-009
  - Next Deadline: Sep. 6, 2022

- **Basket Clinical Trials of Drugs Targeting Shared Molecular Etiologies in Multiple Rare Diseases (U44 Clinical Trial Required)**
  - SBIR: RFA-TR-22-029
  - Next Deadline: Nov. 18, 2022

- **NHLBI SBIR Phase IIB Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 Clinical Trial Optional)**
  - SBIR: RFA-HL-23-008
  - Next Deadline: Feb. 28, 2023

Application Process Timeline

Due Dates	Scientific Review	Council Review	Award Date (Earliest)
SEPTEMBER 5	OCTOBER/NOVEMBER	JANUARY/FEBRUARY	MARCH/APRIL
JANUARY 5	FEBRUARY/MARCH	MAY/JUNE	JULY
APRIL 5	JUNE/JULY	AUGUST	SEPTEMBER OR DECEMBER

Special Designations

- Encouraging participation in innovation and entrepreneurship by socially and economically disadvantaged small businesses (SDB) and women-owned small businesses (WOSB).
- What is a **Socially and Economically Disadvantaged Small Business** (SDB)?
  - The firm must be 51% or more owned and control by one or more disadvantaged person or persons.
  - The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged.
  - The firm must be small, according to SBA's **size standards**.
  - Small businesses must self-certify by registering in the **System for Award Management**.
- What is a **Women-Owned Small Business** (WOSB)?
  - A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be U.S. citizens).
  - The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry.
  - SBCs self-certify on the Sam.gov.

APPLICANT ASSISTANCE PROGRAM (AAP)

AAP is a FREE Application preparation ASSISTANCE program.

PROGRAM GOAL	AAP PROVIDES	AAP DOES NOT PROVIDE
Provide a **mentor** for applicants with great technology, but little NIH experience and limited NIH experience in their network.	Phase I SBIR/STTR application preparation support and review	Grant writer
Application portal opens August 5th *Outreach webinar for potential AAP applicants: August 5th* *Q&A/Office Hours for potential AAP applicants: September 15th* *AAP application portal closes: September 22nd*	Specific Aims page review and advice	Research plan development
https://sbir.cancer.gov/aap	Submission process coaching	Small business registration or NIH application submission services

Administrative Supplements to Promote Diversity (PA-21-345)

- Provides financial support for SBIR/STTR awardees to hire early-career scientists to **enhance the diversity of the NIH-supported workforce**
- Allows candidate to receive
  - Entrepreneurial training
  - Scientific training
  - Real-world experience
- Covers the following expenses
  - Salary Support
  - Travel
  - Supplies
- Eligibility Criteria
  - Must have an active SBIR/STTR award
  - Candidate **must** be a U.S. Citizen or a permanent resident

I-Corps at NIH™ (PAR-22-073)

- Launched at the NIH in 2014 as a program based on the Lean Startup Methodologies
- Promotes customer discovery experience by requiring participants to conduct ~100 interviews over eight weeks
  - Content from interviews helps refine proposed business model
  - “You cannot commercialize something that nobody wants
- Open to current Phase I and early stage Fast-Track SBIR/STTR awardees
- Two receipt dates per year
  - **Next due date November 15th, 2022**
- Selected companies may receive up to $55K for course registration and travel expenses

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NCATS Additional Resources: Technical and Business Assistance (TABA) Program

- Applicants can request additional funding for assistance making better technical decisions, solving technical problems, minimizing risks, and developing and commercializing new products
  - Phase I has a cap of **$6,500 per year.**
  - Phase II has a cap of **$50,000 for the life of the project.**

- TABA supports companies in areas critical to success in the competitive health care marketplace, such as access to technologies or support on product sales, intellectual property protections, market research, and planning

TABA Needs Assessment for Phase I SBIR/STTR

About the Program: The NIH TABA Program helps small businesses identify and address their most pressing product development needs. The Needs Assessment Report provides a FREE, third party, unbiased assessment of your project's progress in four technical and business areas that are critical to success in the competitive healthcare marketplace:

- Market Needs/Competitive Advantage
- Intellectual Property/Barriers to Entry
- Business Model Profitability
- Manufacturing, Regulatory, and/or Clinical Plan

Eligibility: Must be a Phase I NIH SBIR or STTR (grant, contract, or Fast-Track)

- Is active or was active within the past two years AND
- Was not awarded TABA funding within the Phase I award budget AND
- Has not already received a TABA Needs Assessment Report or NICHE Assessment for the same Phase I project

Applications are accepted on a monthly basis.

NCATS Additional Resources: Crossing the "*Valley of Death*" with the NCATS Therapeutic Development Branch (TDB)

- Medicinal chemistry lead optimization
- Evaluation of functional activity, potency, pharmacokinetics (PK), pharmacodynamics (PD), and efficacy
- Biomarker development
- Definition and optimization of dose and schedule for *in vivo* activity
- Development and implementation of pharmacological assays
- Chemical and biologics process research and development
- Manufacturing of bulk substance (GMP and non-GMP)
- Development of suitable formulations
- Development of analytical methods
- Production and stability studies of dosage forms
- Range-finding initial toxicity
- Investigational New Drug (IND)-directed toxicology, with correlative pharmacology and histopathology
- Planning of clinical trials (Phase 1 and/or Phase 2)
- Regulatory and IND filing support
- Natural history and patient-finding studies

NCATS Additional Resources: Bridging Interventional Development Gaps (BrIDGs)

Model: Collaboration between Division of Preclinical Innovation (DPI) and extramural labs (Formerly NIH-RAID Program)

Projects

- Enter with clinical candidate identified
- Any disease eligible
- Gap analysis followed by data generation using DPI resources and expertise to generate data necessary for IND filing
- Exit at or before IND
- Milestone driven
- Therapeutic modalities: small molecules, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins

Eligible Applicants

- Academic (U.S. and Ex-U.S.), Non-Profit, SBIR-eligible businesses

NCATS Additional Resources: Therapeutics for Rare and Neglected Diseases (TRND) Program

Model: Comprehensive drug development collaboration between DPI and extramural labs with disease-area/target expertise

Projects

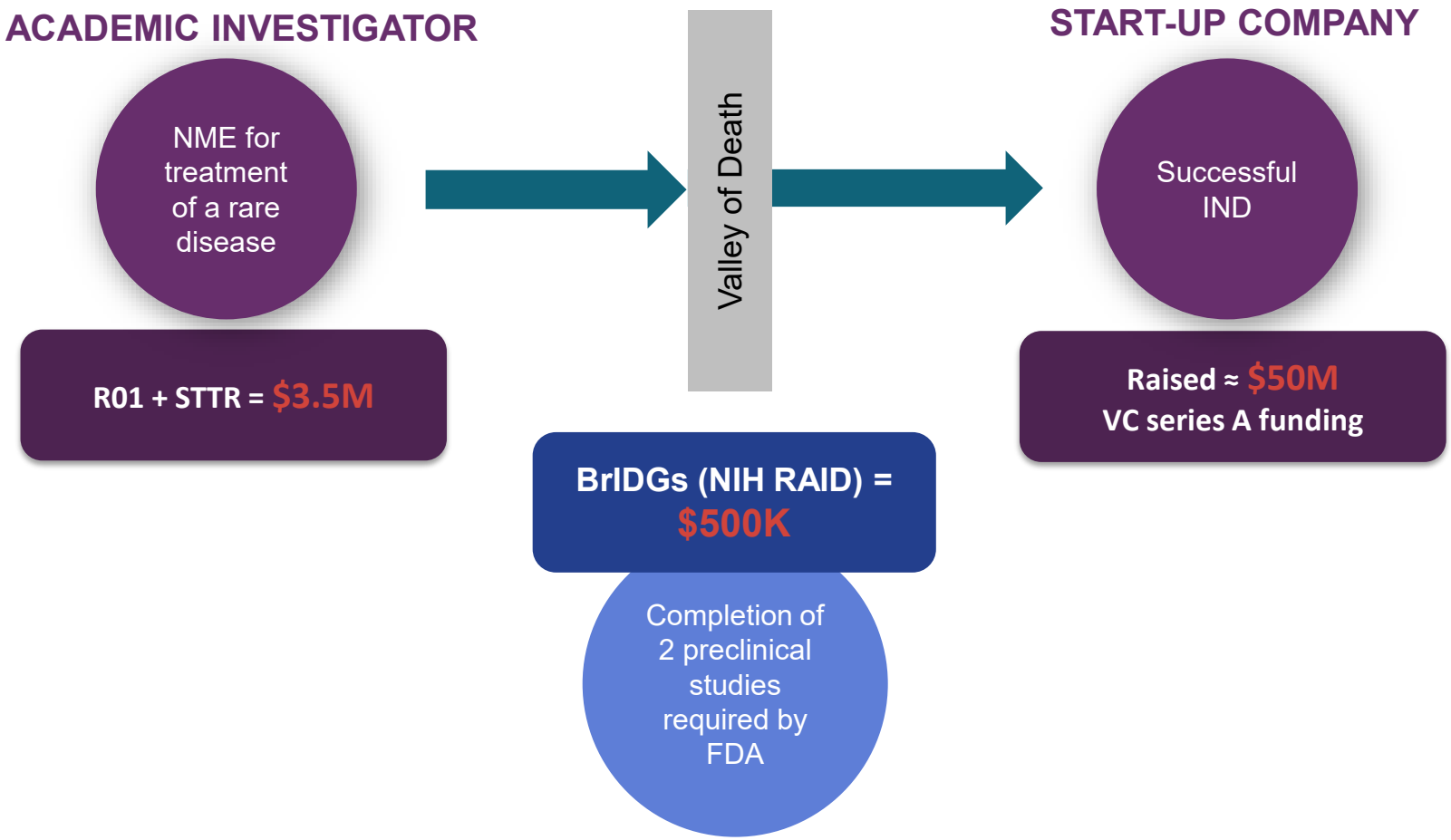
- May enter at various stages of preclinical development
- Disease must meet FDA orphan or WHO neglected tropical disease criteria
- Taken to stage needed to attract external organization to adopt to complete clinical development/registration, max Phase 2a
- Milestone driven
- Therapeutic modalities: small molecules, proteins, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins
- Aims to de-risk technology and develop new generally applicable platform technologies and paradigms

Eligible Applicants

- Academic, Nonprofit, Government Lab, Biotech/Pharma
- Ex-U.S. applicants accepted

TRND/BrIDGs Project De-Risking Model

MINIMUM TIME AND FUNDING; MAXIMUM IMPACT



Connect with NCATS

Website: ncats.nih.gov

Facebook: facebook.com/ncats.nih.gov

LinkedIn: linkedin.com/company/nih-ncats/

Twitter: twitter.com/ncats_nih_gov

YouTube: youtube.com/user/ncatsmedia

E-Newsletter: ncats.nih.gov/enews

Listserv: bit.ly/1sdOI5w

Navigate through the NCATS SBIR/STTR website using the QR code above

Questions?

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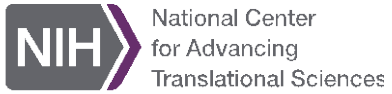
THANK YOU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