

The NIH SBIR/STTR Phase I Program

Del Mackey

Arrowhead Center, NM FAST

November 17, 2021



BE BOLD. Shape the Future.



NM Bioscience Authority

Presenting on behalf of the New Mexico Bioscience Authority:

November 17, 2021

Stephanie Tofighi, MSPP
Executive Director
NM Bioscience Authority

What is Bioscience?

Six Industries Make Up Bioscience Sector:

1. Agricultural feedstock and chemicals including biofuels
2. Bioscience-related distribution
3. Drugs and pharmaceuticals
4. Medical devices and equipment
5. Research and bioinformatics
6. Testing and medical laboratories

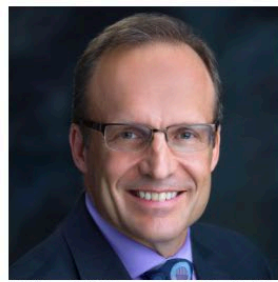




Dale Dekker, AIA, AICP, Chair
Registered Architect and Founder of
Dekker/Perich/Sabatini Design Firm



Sheryl Arvizu, Vice Chair, Board
Director, Pharmaceutical Specialist



Richard S. Larson, MD, PhD,
President, Executive Vice Chancellor,
Vice Chancellor for Research UNM HSC



**Christos Christodolou, PhD, Vice
President**, Dean of the School of
Engineering at UNM



Suzanne Quillen, RN, MPA,
Secretary, Vice President of Healthcare
Innovation for Ernest Health



Greg Byrnes, Board Member,
Executive Director at the New Mexico
Biotechnology & Biomedical Association



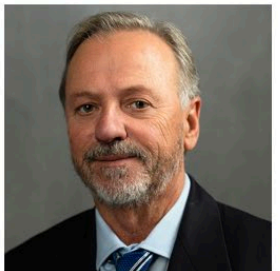
**Jennifer H. Gifford, PhD, Board
Member**, Assoc. Professor in Animal
Range Sciences Dept. at NMSU



Alicia Keyes, Board Member,
Cabinet Secretary, New Mexico
Economic Development



Tom Kieft, PhD, Board Member,
Microbiologist NM Tech Biology
Department



Paul Laur, Board Member,
Chief Executive Officer,
Spartina Biotechnologies



Scott McLaughlin, Board Member,
Executive Director at Spaceport America
of New Mexico



**Tanner Schaub, PhD, Board
Member**, Director, Research Cores
Program, OVPR, NM State University

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



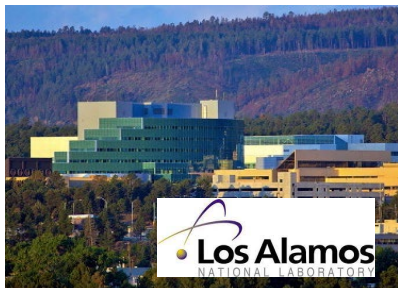
Ryan Cangiolosi, MBA, MACCT
Strategy & Policy Director



Sterling J. Nichols III, BS
Program Specialist

NM Bioscience Authority's SBIR/STTR Bioscience Business Accelerator

- The BSA's bioscience business accelerator will expand a currently federally funded UNM based bioscience business accelerator primarily geared toward the commercialization of biomedical innovation.
 - Six NM researchers from UNM, NMSU, and NMT have completed training since April 2021 with three preparing SBIR submissions now.
- BSA program will include SBIR/STTR grant training, mentoring, workshops, and network facilitation to support the commercialization of all bioscience innovation
 - Statewide mission to train university and research institution faculty and staff to work effectively with entrepreneurs to start bioscience businesses.
 - Focus will be on training to write federal grants (e.g., SBIR/STTR) and networking to form entrepreneur-university partnerships.



Contact Information

Stephanie Tofighi, stofighi@salud.unm.edu

Ryan Cangiolosi, rcangiolosi@salud.unm.edu

Sterling Nichols, snichols@salud.unm.edu

<https://www.nmbioscience.org/>

Presentation Outline

Part I – Brief Overview of the SBIR/STTR Programs

Part II – The NIH SBIR/STTR Programs

Part III – Elements of a Strong Proposal

Part IV – The NM FAST Program

Part V – Q&A



BE BOLD. Shape the Future.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

“To support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy...one small business at a time.”

Goals:

1. Meet federal R&D needs by providing research dollars to small businesses
2. Increase private-sector commercialization of innovations derived from federal R&D funding
3. Stimulate technological innovation
4. Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons
5. Foster technology transfer through cooperative R&D between small businesses and research institutions (STTR)

Benefits:

1. Provides funding to move from invention to innovation
2. Interested in innovations with commercial potential
3. Largest source of non-dilutive funding
4. Validates idea and allays technical risk, which helps secure outside funding for development
5. Can move between programs (SBIR to STTR; STTR to SBIR) and between agencies (NSF to NIH, etc.) between phases

Participating Agencies

SBIR

STTR

Department of Agriculture
(USDA)

Department of Commerce
(DoC)
NIST, NOAA

Department of Defense
(DoD)

Department of Education
(ED)

Department of Energy
(DOE)

Department of Health and
Human Services
(HHS)
NIH, CDC, FDA

Department of Homeland
Security
(DHS)

Department of
Transportation
(DOT)

Environmental Protection
Agency
(EPA)

National Aeronautics and
Space Administration
(NASA)

National Science
Foundation
(NSF)

SBIR/STTR Nuance

- Small businesses can work with Research Institutions to develop the innovation
 - The business will always be the main awardee; the Research Institution will be the sub
 - The business has to do technical work under the project; it can't just be project management
- SBIR is very business-focused
 - Geared more towards solving a technical problem/challenge with launching a commercial solution
 - The business can sub out up to 1/3 of the budget and the work
 - PI has to be majority employed by the Small Business Concern (SBC)
- STTR tends to be more research-focused
 - Can be earlier stage validation of research being performed
 - The business can sub out up to 60% of the work and budget
 - PI can be majority employed by the RI (except for NSF)

Presentation Outline

Part I – Brief Overview of the SBIR/STTR Programs

Part II – The NIH SBIR/STTR Programs

Part III – Elements of a Strong Proposal

Part IV – The NM FAST Program

Part V – Q&A

NIH SBIR/STTR Overview

- NIH SBIR/STTR program is run out of the Health and Human Services (HHS) agency
 - 24 out of the 27 Institutes and Centers (IC) across NIH participate
 - Also offers opportunities from Centers for Disease Control and Food and Drug Administration
- NIH is pretty “aggressive” in supporting your innovative idea
 - They have multiple complementary opportunities to support you through the entire SBIR/STTR project
- NIH has multiple funding streams for SBIR/STTR
 - Three solicitations a year for “Omnibus” topic areas
 - Rotating targeted solicitations for crisis areas; contracts for specific technology needs

NIH SBIR/STTR Overview

- NIH funds technologies that improve health and save lives
 - Each of the NIH ICs focuses on a different mission and research priority
 - If it is a health-tech/biotech that solves illness, improves well being, aids healthcare, enables new tools, improves current tools, etc., NIH might fund it
- NIH is similar to DoD in one key facet; each IC can have differing levels of funding and periods of performance
 - Based on what the IC considers priorities and what you are creating
 - Vital to talk with the IC program manager before creating your proposal
 - The “standard” for Phase I is \$259,613/6 months; Phase II is \$1,730,751/24 months
- NIH also has Fast-Track and Direct Phase II for some ICs

NIH SBIR/STTR Overview

- The breadth and depth of NIH SBIR/STTR funding covers pretty much any area of health that you can think of
 - Each IC is typically named for the area of health, the disease, or the malady they want to cure
 - NIDA covers areas related to substance abuse, including nicotine
 - NIEHS covers areas related to how the environment impacts health
 - NHGRI not only covers areas related to genome research, but the ethical, legal, and social implications of this research
 - NCCIH looks at ways to offer “alternative care” in complement to traditional care
 - NLM covers areas related to research data and research tools for health

Other Agency Opportunities

- One thing to keep in mind, NIH is not the only agency that funds health innovations
 - NSF funds anything related to science and tech; the only thing they don't fund in health is drug discovery
 - USDA funds some specialized areas of health tech, mainly as it relates to impacts in rural communities
 - DoD and NASA fund health innovations, but based on the application of the technology more than the technology itself

Presentation Outline

Part I – Brief Overview of the SBIR/STTR Programs

Part II – The NIH SBIR/STTR Programs

Part III – Elements of a Strong Proposal

Part IV – The NM FAST Program

Part V – Q&A



NIH SBIR/STTR Phase I - Proposal

- Phase I is about validating the feasibility of the idea and addressing a critical technical problem/challenge that is keeping you from moving forward
- Projects are typically \$259,613 for 6 months
 - Again, individual ICs have varying requirements and waivers based on topics
 - Don't just search for the best "bang for your buck"; make sure it aligns directly with your goals
- If this is your first award, you can either do a standard Phase I submission, a Fast-Track, or Direct Phase II
 - For a Fast-Track, you are writing the Phase I and Phase II at the same time and submitting at the same time; you still do all of the activities, but there is no "lag" between the Phases
 - A Direct Phase II is if you have already done all of the activities you would normally do to establish feasibility in a Phase I; these are very rigorous though

NIH SBIR/STTR Phase I - Contents

- Don't think you can just take a proposal submitted to another agency and copy it over for NIH; NIH has some key differences in their proposal packages that are very dissimilar from other agencies
 - Your technical narrative is a 6-page Research Strategy
 - You have a very short Project Summary and Project Narrative; 30 lines and three sentences, respectively
 - A 5-page Biosketch for all Senior/Key Persons at a minimum
 - A 1-page Specific Aims (this is something you will want to develop first to use as an introduction with program managers)
 - Budget and budget justification
 - Various forms to complete

Phase I – Specific Aims

- Your Specific Aims is kind of an introduction into what you are doing
 - You will want to provide a synopsis of the problem and why there is a current gap in the market
 - You will want to cover what your solution is, what it will look like, and why you think it will work
 - You will want to outline a solid 3 or so Aims (think Objectives) that you will do during the Phase I and how those are going to establish the idea is feasible
- This document is a 1 pager that is an overview of the project
 - This is the perfect document to send to NIH Program Managers, potential partners, and targets for Letters of Support

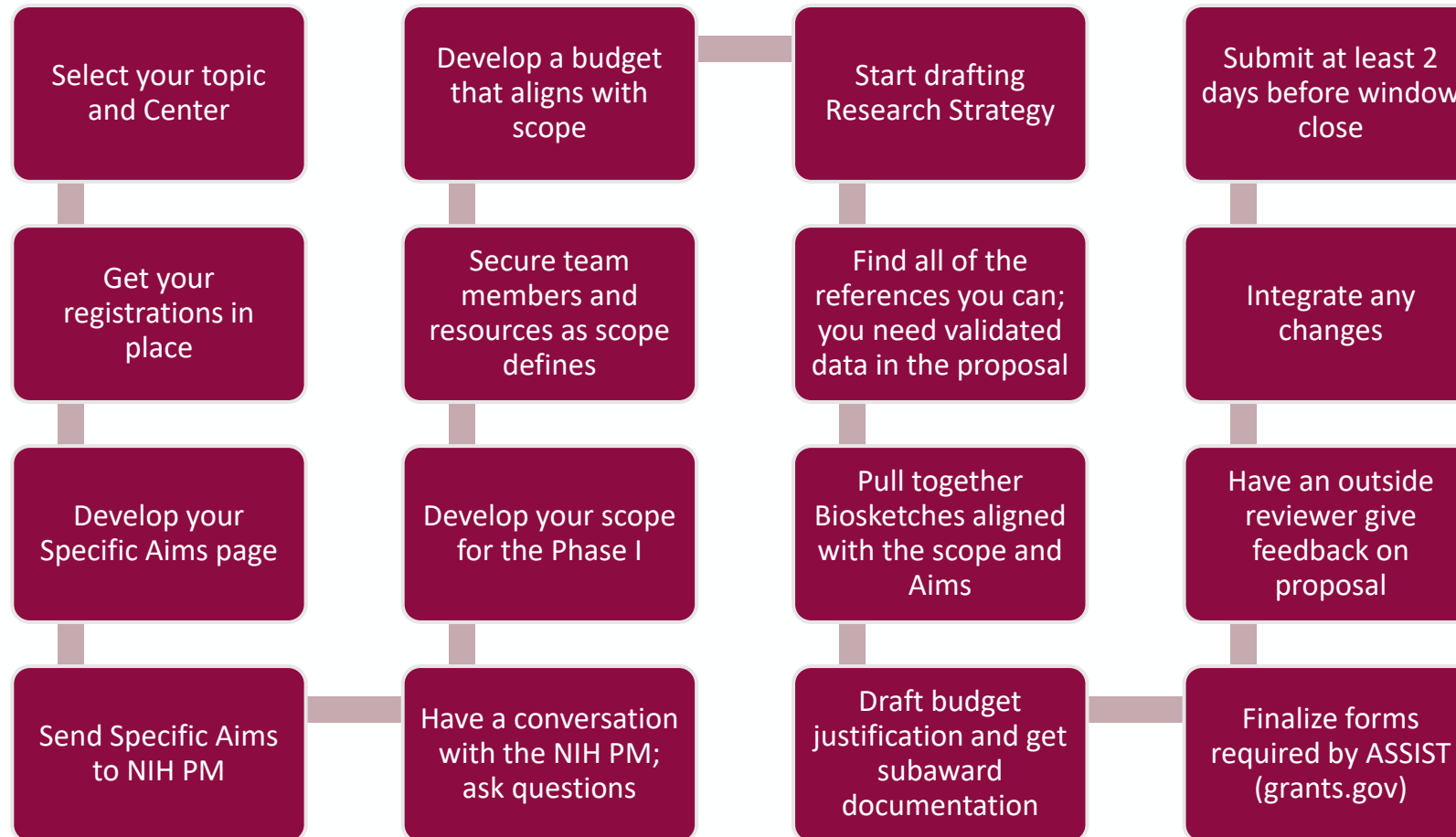
Phase I – Research Plan

- The Research Strategy is a 6-page document that discusses the need, the background, the activities, and the outcomes from your proposed project
 - There are three sections here:
 - Significance – summary of the problem and the research done to date
 - Innovation – summary of what your solution will be and why you think you are getting it “right”
 - Approach – essentially your project plan
- For a good Research Strategy:
 - In the Significance, focus on how pervasive the problem is and how you will change people’s lives; in the Innovation, focus on how your potential solution is revolutionary and why you figured out a way to do it that no one else has; in the Approach, don’t forget to have milestones that discuss how you will know that you have succeeded with your research

Phase I – Biosketches

- Biosketches for NIH are up to 5 pages in length
- Each Key/Senior Person on your team needs a biosketch
 - If the person is specifically named because of their expertise in an area, or their research acumen, then you need a biosketch for them
 - You can also include biosketches from partners that will be part of the effort, senior researchers for subawardees, etc.
- The biosketch is pretty standard in form, fit, function to other agencies
 - The key difference is the Personal Statement at the top of the biosketch
 - This is a statement, usually around a half page, that states exactly why you care about bringing forward a solution to this problem

Phase I – Process



Niche Assistance Program (NAP)

- Must have an active HHS SBIR/STTR Phase I or Fast-Track award
- Designed to “jump-start” commercialization activities during the award period
 - Provides market insight and data on the intended solution(s)
 - Assesses the different applications of the solution and then provides an in-depth report on the solution with the largest depth/breadth of commercial application
 - Awardees are matched with a commercial specialization firm to find this data and provide this report; awardees aren’t just given tools then told to figure it out
- The data from this report feeds directly into a Phase II submission

I-Corps at NIH

- Must have an active NIH Phase I award
- Based on the NSF I-Corps program
 - An 8-week program focused on business development and customer identification
 - Teaches you how to split the market, focus on a customer segment, find out the actual pain points you are trying to address, determine a true value proposition, and provides the resources to develop the business model
 - Keeps people from falling into the “Field of Dreams” fallacy
- This goes a long way to verifying the customer and discovering the need/competitive advantage for a Phase II application

Presentation Outline

Part I – Brief Overview of the SBIR/STTR Programs

Part II – The NIH SBIR/STTR Programs

Part III – Elements of a Strong Proposal

Part IV – The NM FAST Program

Part V – Q&A

NM FAST Activities & Assistance

NM FAST offers NM small businesses:

- Free SBIR/STTR proposal development assistance (e.g., topic and agency matching, budget assistance, proposal writing assistance, etc.)
- Proposal package review
- Tailored services for each client
- Micro-grants (up to \$2,000) available to help with proposal development and/or conference travel
- Free workshops and engagement activities held throughout the state (from March 2020-present, webinars in lieu of in-person events due to COVID-19 restrictions)
- 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 series: <https://bit.ly/2D3UV4M>
- Multi-week SBIR/STTR accelerators
- Annual SBIR/STTR Innovation Summit
- Canvas integration of SBIR/STTR curriculum and tools

“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



BE BOLD. Shape the Future.

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.
- 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)
- Documents and resources updated every release to provide the most up-to-date tools for successful proposal creation

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	July
			September	October
DoE	SBIR/STTR	P-I	August	October
			December	February
DoE	SBIR/STTR	P-II	October	January
			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	November	January
NIST	SBIR	P-I/P-II	January	April
NOAA	SBIR	P-I	October	January
NSF**	SBIR/STTR	P-I/P-II	December	March
			March	June
			June	September
			September	December
USDA	SBIR	P-I	August	October
	SBIR	P-II	February	May

*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.

Listed dates are valid as of October 2020 All dates above are subject to change at the agency level due to continuing resolutions, federal budget availability, or other mitigating factors. To stay up-to-date on the latest solicitation openings please visit our website at <http://arrowheadcenter.nmsu.edu/nmfast>. Copyright © 2020 by Arrowhead Center. All rights reserved.

In Summary, NM FAST...

- **Assists** in identifying appropriate agency(s) and topic area(s)
- **Provides** how-to information on agency registrations and electronic proposal submission
- **Helps** guide proposal preparation, including assessments of technical objectives, commercialization plan, research hypotheses, and creation of supporting documents
- **Provides** access to a suite of SBIR resources
- **Reviews** proposal drafts, with feedback
- **Offers** micro-grants for proposal development support

New Mexico SBIR/STTR Innovation Summit

- **December 15th, 8:30 – 4:30 MT**
- Full day of informative panels, presentations, and sessions on topics such as commercialization, differences between grants and contracts, and building a strong proposal
- Attendees can schedule one-on-one sessions with federal program managers, support organizations, and decision-makers
- Expo hall will feature booths from various organizations across the country that help businesses navigate the SBIR/STTR process
- Can schedule a one-on-one with NCATS SBIR/STTR staff
- **Event is virtual and free!**

**Contact:**

Dana Catron, dderego@nmsu.edu

For more information:

<https://arrowheadcenter.nmsu.edu/program/nm-fast/innovation-summit/>

To register:

<https://sbirinnovationsummit.vfairs.com/>

Presentation Outline

Part I – Brief Overview of the SBIR/STTR Programs

Part II – The NIH SBIR/STTR Programs

Part III – Elements of a Strong Proposal

Part IV – The NM FAST Program

Part V – Q&A

Thank You!

Contact:

Del Mackey, delmacke@nmsu.edu

Apply for assistance at:

arrowheadcenter.nmsu.edu/program/nm-fast