JAN 10, 2024 | NON-DILUTIVE FUNDING SUMMIT

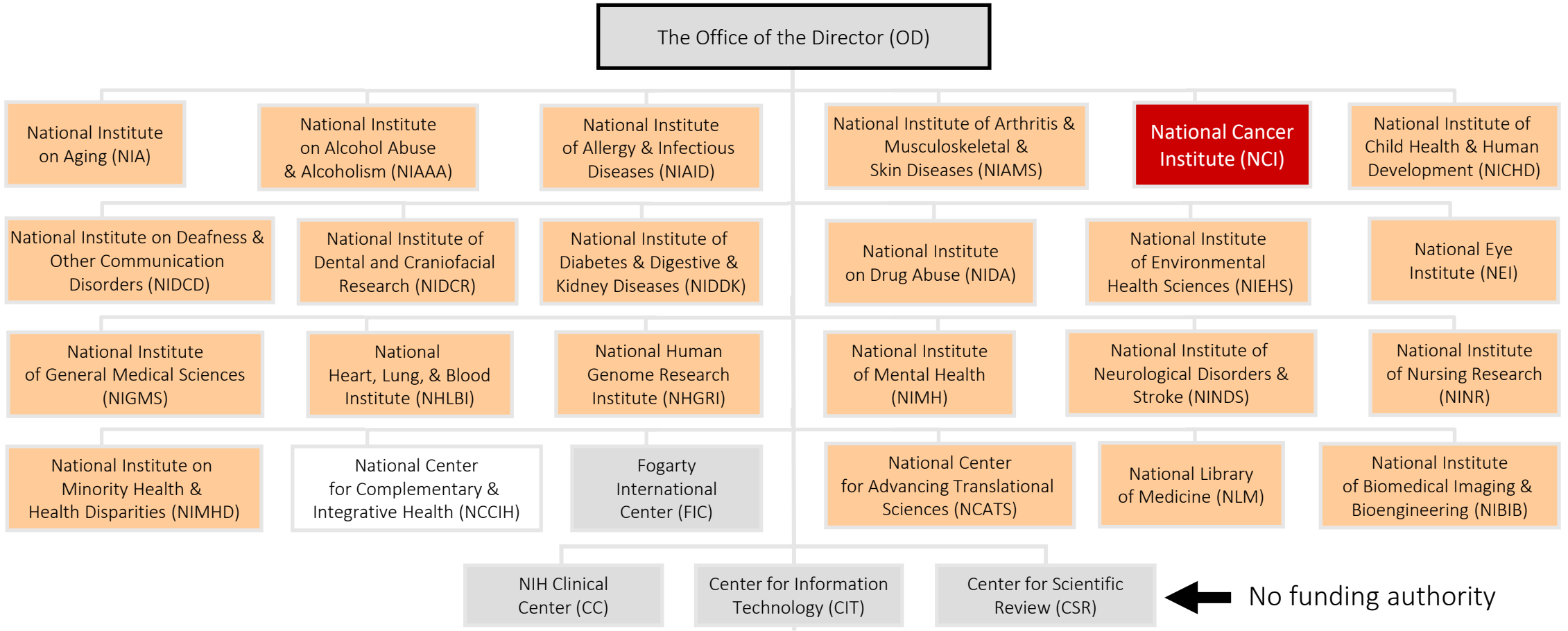
FUNDING & COMMERCIALIZATION RESOURCES FOR CANCER TECHNOLOGIES

BRITTANY CONNORS, PMP
DIRECTOR OF INVESTOR RELATIONS
SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE

SBIR
DEVELOPMENT CENTER

ABOUT THE SBIR/STTR PROGRAMS

27 INSTITUTES & CENTERS AT THE NIH



CONGRESSIONALLY MANDATED PROGRAM

		Set Aside for FY23
SBIR SMALL BUSINESS INNOVATION RESEARCH	Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization *Federal agencies with an extramural R&D budget > $100M*	**$178M (3.2%)**
STTR SMALL BUSINESS TECHNOLOGY TRANSFER	Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization *Federal agencies with an extramural R&D budget > $1B*	**$25M (0.45%)**
	Total	**$203M for NCI** **$1.3B for NIH**

ELIGIBILITY

Applicant must be a Small Business Concern (SBC)

Organized for-profit U.S. business (based in the U.S. and work performed in the U.S.)

500 or fewer employees, including affiliates

> 50% U.S.- owned by individuals and independently operated

OR

> 50% owned & controlled by another (one) business concern that is > 50% owned & controlled by one or more individuals

OR

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (SBIR ONLY)

The award is ALWAYS made to the small business concern

WHY SEEK SBIR FUNDING?

Provides seed funding for innovative technology development //

Not a Loan
No repayment is required
Doesn't impact stock or shares in any way (i.e., non-dilutive.)

IP rights retained by the small business //

NIH does not request intellectual property for the SBIR- or STTR-funded technologies.

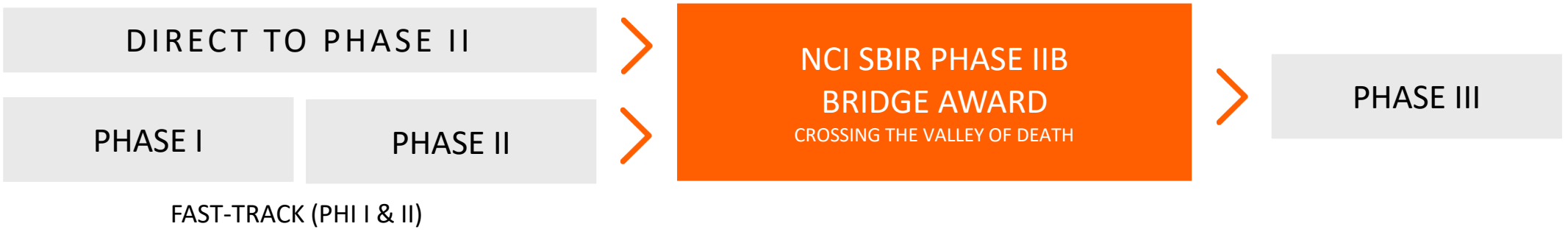
Provides recognition, verification, and visibility //

Every application is rigorously assessed by NIH Peer Review system.

Helps attract additional funding or support //

In addition to funding, we provide commercialization resources to help advance your project.

NCI SBIR'S THREE-PHASE PROGRAM



- Proof-of-Concept
- Up to $400,000 over 6 to 12 months

- Research &
- Development
- Commercialization plan required
- Up to $2M over 2 years

- Technology validation & clinical translation
- Follow -on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- $4M over 2-3 years

- Commercialization stage
- Use of non-SBIR/STTR funds

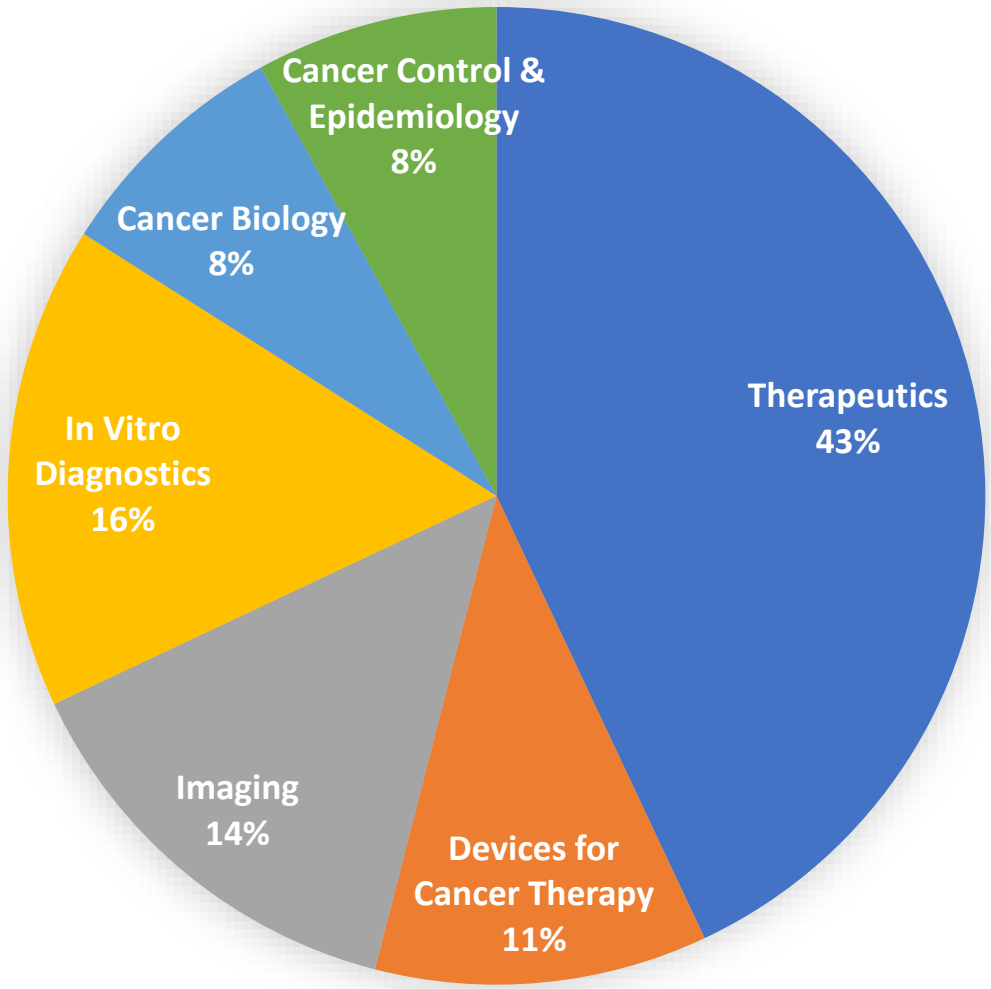
CRITICAL DIFFERENCES

SBIR		STTR
Permits research institution partners (e.g., universities)	PARTNERSHIP	Requires research institution partners (e.g., universities)
Small business may outsource ~33% of Phase I activities and 50% of Phase II activities	DIVISION OF LABOR	Minimum 40% of the work should be conducted by the small business (for profit), and minimum of 30% by a U.S. research institution (non-profit)
The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period	PI INVOLVMENT	PI primary employment not stipulated (min.10% effort to project)

The award is ALWAYS made to the small business concern.

NCI SBIR/STTR PORTFOLIO (n=475)

- $203M in FY23 for SBIR/STTR awards
- 86% Grants, 14% Contracts



FUNDING OPPORTUNITIES

GRANTS VS. CONTRACTS

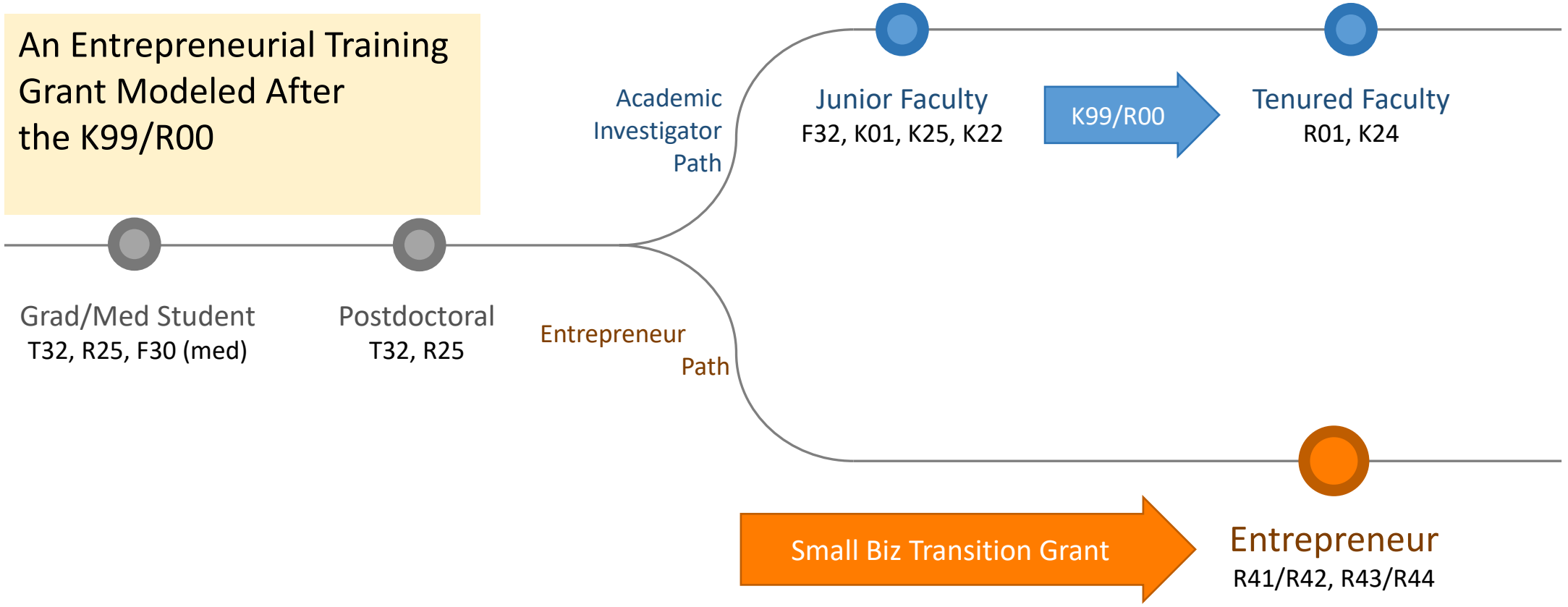
GRANTS		CONTRACTS
Investigator-defined within the mission of NIH	Scope of the proposal	Defined by the NIH (focused)
NIH Center for Scientific Review (CSR)	Peer Review Locus	NCI DEA (target 50% business reviewers)
May speak with any Program Officer	Questions	MUST contact the contracting officer
3 times/year for Omnibus	Receipt Dates	Only ONCE per year
NO	Set-aside of funds for particular areas?	YES
Based on score during peer review	Basis for Award	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
One final report (Phase I); Annual reports (Phase II)	Reporting	Kick-off presentation, quarterly progress & final reports

FUNDING OPPORTUNITIES

TITLE	SBIR FOA	STTR FOA	RECEIPT DATES
Omnibus Solicitation	PA-23-230 (General) PA-23-231 (Clinical Trial)	PA-23-232 (General) PA-22-233 (Clinical Trial)	Standard Receipt Dates January 5; April 5; September 5
Notice of Special Interest for Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	NOT-CA-21-062	NOT-CA-21-062	
Notice of Special Interest: Utilization of Cohorts and Prospective Study Designs for Liquid Biopsy Assay Validation for Early Detection of Cancers	NOT-CA-23-004	NOT-CA-23-004	
Notice of Special Interest: SBIR Technology Transfer	NOT-NS-22-017		
Notice of Special Interest: NCI Entrepreneurial Education Programs to Facilitate Commercialization of Cancer Relevant Technologies			January 25, May 25, September 25
Small Business Transition Grant for Early Career Scientists	No SBIR	Coming Soon	August 2024 (anticipated)
NCI SBIR Concept Award (Contract)	Coming Soon	No STTR	August 2024 (anticipated)
NCI SBIR Phase IIB Bridge	Coming Soon	No STTR	August 2024 (anticipated)
Contract Solicitation	Coming Soon	No STTR	Fall 2024

SMALL BUSINESS TRANSITION GRANT

An Entrepreneurial Training Grant Modeled After the K99/R00



SMALL BUSINESS TRANSITION GRANT

FAST-TRACK

Phase I STTR

TRAINING

- SBC PI: Postdoc
- Mentoring plan required including a Technical and a Business Mentor

TECHNICAL

- PI preps technology to move to SBC
- I-Corps at NIH required

BUDGET: $400K (12 months)

Transition

PERSONNEL

- PI moves to SBC

Phase II SBIR

TRAINING

- Same PI (non-transferrable)
- Mentoring continues

TECHNICAL

- Most research conducted at SBC site
- Small pivots allowed

BUDGET: $2M (2 years)

SMALL BUSINESS CONCEPT AWARD

- Phase I SBIR Contract Funding ($300K)
- Focus is on innovation
- Disruptive technologies to address rare and pediatric cancer
- Short applications (~20 pages vs. 50)
- Special review criteria with focus on innovation
- Fund experiments to de-risk early-stage technologies
- Make awards rapidly (within six months)
- Awardees are expected to enroll in the NIH I-Corps Program
- Previous Solicitation: 75N91023R00034 | 2024 TBD

Phase IIB Bridge Award

Phase II
Grants
Contract

PHASE I

PHASE II

NCI SBIR PHASE IIB BRIDGE AWARD
CROSSING THE VALLEY OF DEATH

COMMERCIALIZATION

$4,500,000 over 2-3 years (next deadline anticipated August 2024)

Phase II awardees from any federal agency with projects relevant to NCI mission are eligible to apply

Applicants are required to raise third party funds (≥ 1:1 match).

Supports technology validation and clinical translation to accomplish critical milestones toward commercialization

- Bridge Award recipients leveraged $65M in NCI funding with **$358M in follow on funding** (>5:1 third party matching funds to NCI funding).
- Supported and resulted in 17 clinical trials, 19 product launches, BLA submission, FDA Breakthrough and Orphan Designations, merger & acquisitions, and more!

https://sbir.cancer.gov/small-business-funding/grants/bridge-award

FY24 NCI SBIR CONTRACT TOPICS

- Ultra-Fast Dose Rate (FLASH) Radiation
- Technologies for Detecting Tumor-Derived Cell Clusters
- Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control
- Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions
- Microbiome-Based Tests for Cancer Research, Diagnosis, Prognosis, and/or Patient Management
- Organ-on-Chip for Preclinical and Translational Radiobiological Studies
- Point-of-Care Detection of Prostate Specific Antigen
- Cancer Prevention and Treatment Clinical Trials Tools for Recruitment and Retention of Diverse Populations
- Cloud-Based Multimodal Data Analysis Software for the Cancer Research Data Commons
- Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies
- Automated Software for Point-of-Care Testing to Identify Cancer-Associated Malnutrition

https://sbir.cancer.gov/small-business-funding/contracts/current-solicitation

ADMINISTRATIVE SUPPLEMENT

Phase I
Phase II
Phase IIB
Grants

PURPOSE

Funds may be available for administrative supplements to meet increased costs that are **within the scope of the approved award** but were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted.

FOA

Funding Opportunity Title	Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)
Activity Code	Administrative Supplement Additional funds may be awarded as supplements to parent awards for all activity codes.
Announcement Type	Reissue of PA-18-591
Related Notices	See Notices of Special Interest associated with this funding opportunity NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 See Notices of Special Interest related to this Funding Opportunity • **September 8, 2022** - Notice of Early Termination of NOT-OD-22-031, Research on the Health of Women of Understudied, Underrepresented and Underreported (U3) Populations (Admin Supp Clinical Trial Optional). See Notice NOT-OD-22-209 • **June 30, 2022** - Notice of Pre-Application Webinar for NOT-CA-21-100 "Administrative Supplements to Participate in

https://grants.nih.gov/grants/guide/pa-files/PA-20-272.html

BUDGET

- As appropriate
- Check with your Program Director

IMPORTANT POINTS

- Aims that help with commercialization efforts are encouraged.
- No peer review, Programmatic Review is required.
- Decisions based on merit, programmatic balance & available funds

ELIGIBILITY

- Must have an active SBIR/STTR Phase I or Phase II grant.
- Project duration shouldn't exceed the project period of the parent award.
- Applications can be submitted on a rolling basis

DIVERSITY SUPPLEMENT

Phase I
Phase II
Phase IIB
Grants

PURPOSE

Improve the diversity of the research workforce by recruiting and supporting students, post-doc fellows, and eligible investigators from groups that have been shown to be underrepresented in health-related research or in the SBIR program.

FOA

Funding Opportunity Title	Administrative Supplements to Promote Diversity in Research and Development Small Businesses-SBIR/STTR (Admin Supp Clinical Trial Not Allowed)
Activity Code	Administrative Supplement Additional funds may be awarded as supplements to parent awards using the following Activity Code(s). Note, however, that not all participating NIH Institutes and Centers (ICs) support all the activity codes listed below. Applicants must therefore consult the Table of IC-Specific Information, Requirements and Staff Contacts for more details. Administrative supplement requests may be submitted electronically for the following activity codes: R41/R42 Small Business Technology Transfer (STTR) Grant - Phase I, Phase II, and Fast-Track R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track U43 Small Business Innovation Research (SBIR) Cooperative Agreements - Phase I U44 Small Business Innovation Research (SBIR) Cooperative Agreements - Phase II
Announcement Type	Reissue of PA-18-837

https://grants.nih.gov/grants/guide/pa-files/PA-21-345.html

BUDGET

- Application budgets are limited to no more than the amount of the current parent award and must reflect the actual needs of the proposed project.

IMPORTANT POINTS

- Strongly encouraged to discuss with Program Director
- No peer review, Programmatic Review is required.
- Research objectives must be within the original scope of the peer reviewed and approved project,

ELIGIBILITY

- Must have an active Phase I or Phase II or Fast Track grant.
- The project and budget periods must be within the currently approved project period for the existing parent award.
- Applications can be submitted on a rolling basis

COMMERCIALIZATION READINESS PILOT

Aims to facilitate the transition of previously funded SBIR and STTR Phase II and Phase IIB projects to the commercialization stage by providing additional support for technical assistance not typically supported through Phase II or Phase IIB grants or contracts.

APPLICATION DUE DATES

January 5, April 5, September 5

FOA

Funding Opportunity Title	SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance (SB1, Clinical Trial Not Allowed)
Activity Code	SB1 Commercialization Readiness Program
Announcement Type	Reissue of PAR-19-334
Related Notices	See Notices of Special Interest associated with this funding opportunity • NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 • **March 14, 2022** - Notice to Extend Expiration Date for PAR-20-128. See Notice NOT-OD-22-085. • **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018. • **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181. • **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 • **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 • **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 • **November 23, 2020** - Notice of Clarification of SB1 Resubmission/Submission Policy. See Notice NOT-OD-21-027. • **June 2, 2020** - Notice of Special Interest: NIGMS Priorities for Small Business Development of Sepsis Diagnostics and Therapeutics. See Notice NOT-GM-20-028.
Funding Opportunity Announcement (FOA) Number	PAR-20-128

BUDGET

$250,000 total costs for NCI

SCOPE

- Funds can be requested for help with regulatory, reimbursement or IP Strategy.
- Design and planning for a clinical trial including administrative tasks
- Technical assistance associated with manufacturing.
- Other technical assistance offered through a third-party technical assistance provider, including market research.
- And more ….check with your Program Director

ELIGIBILITY

Must have active or completed NCI SBIR (Phase II and Phase IIB) or STTR (Phase II) awards.

REVIEW

- Peer Review with Special Emphasis Panel at CSR
- Decisions based on peer review, merit, programmatic balance & available funds

https://grants.nih.gov/grants/guide/pa-files/PAR-20-128.html

SUCCESS STORY: IMMUNOMEDICS

Trodelvy
(Sacituzumab Govitecan-hziy)
Antibody drug conjugate that is directed against Trop-2, a cell-surface protein expressed in many solid cancers.

SBIR

2012
Immunomedics received SBIR award and used it to fund the first in-human trial of Trodelvy.

FDA

April 2020
FDA approved Trodelvy for treatment of Triple Negative Breast Cancer.

GILEAD

September 2020
Gilead agreed to acquire Immunomedics for ~$21 billion

GETTING STARTED

Read the solicitation & SF424 carefully to understand the requirements.
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/sbir-sttr-forms-g.pdf

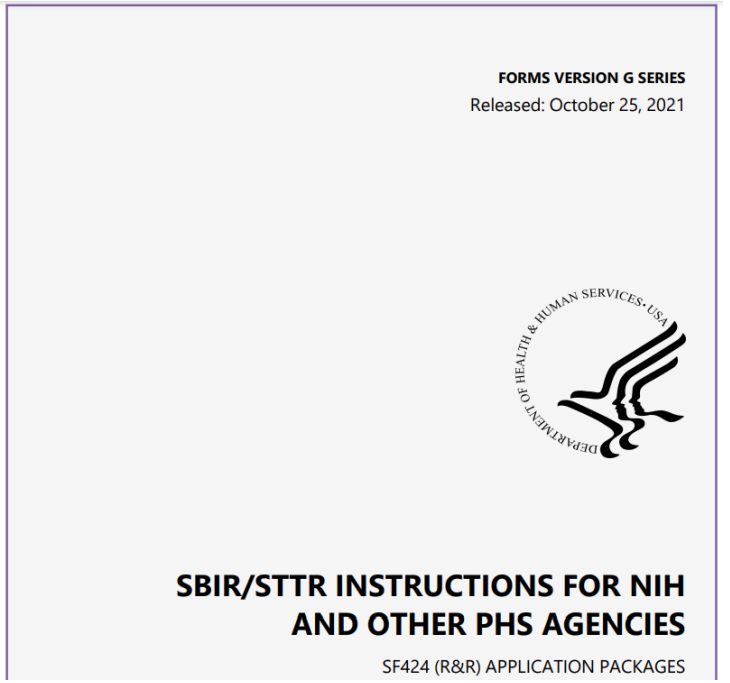
Review similar, currently-funded NIH SBIR/STTR projects.
https://projectreporter.nih.gov/reporter.cfm

Look at some sample applications.
https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

https://sbir.cancer.gov/resources/forapplicants#Sample

Check out our Peer Learning And Networking (PLAN) Videos.
How to Write a Good Specific Aims Page

First Steps for Starting a Small Business



ASSISTANCE and INITIATIVES

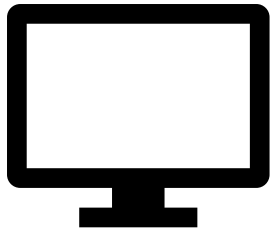
NCI SBIR/STTR ASSISTANCE

SBIR DEVELOPMENT CENTER

https://sbir.cancer.gov/resources

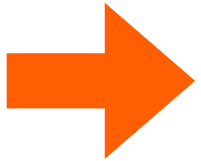
Peer Learning and Networking (PLAN) Webinar Series

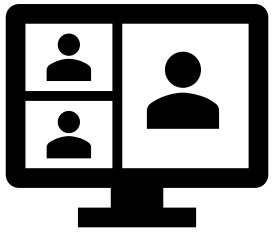
Applicants
Phase I
Phase II
Phase IIB
Grants
Contracts



Part I. Presentation

Watch pre-recorded panelist presentation on the PLAN webpage prior to joining the webinar and write down your questions.





Part II. Panel Session

Attend real-time panel session and ask your questions to the panelists and/or the moderating NCI SBIR program director.

Video Content Available Online:

- ❑ First Steps for Starting a Small Business (4 speakers)
- ❑ Implementing a Quality Management System (QMS) (6 speakers)
- ❑ How to Write a Good Specific Aims Page (4 speakers)
- ❑ Keys to a Successful IND Submission (4 speakers)

NIH Applicant Assistance Program (AAP)

FREE 10-week program that provides a mentor for applicants, who have never applied/won an SBIR/STTR award, to prepare and submit a Phase I SBIR/STTR application

One-on-one, weekly mentoring for application preparation support

Review of every application component (i.e., specific aims page, budget, etc.)

Guidance on registration and submission process

Omnibus deadlines (Jan 5, Apr 5, Sep 5)

Especially encourage businesses that are:

- Owned/run by women
- Owned/run by racial/ethnic groups underrepresented in biomedical research
- Owned/run by individuals from socially and economically disadvantaged backgrounds
- Located in NIH IDeA states

https://sbir.cancer.gov/small-business-funding/application-process/applicant-assistance

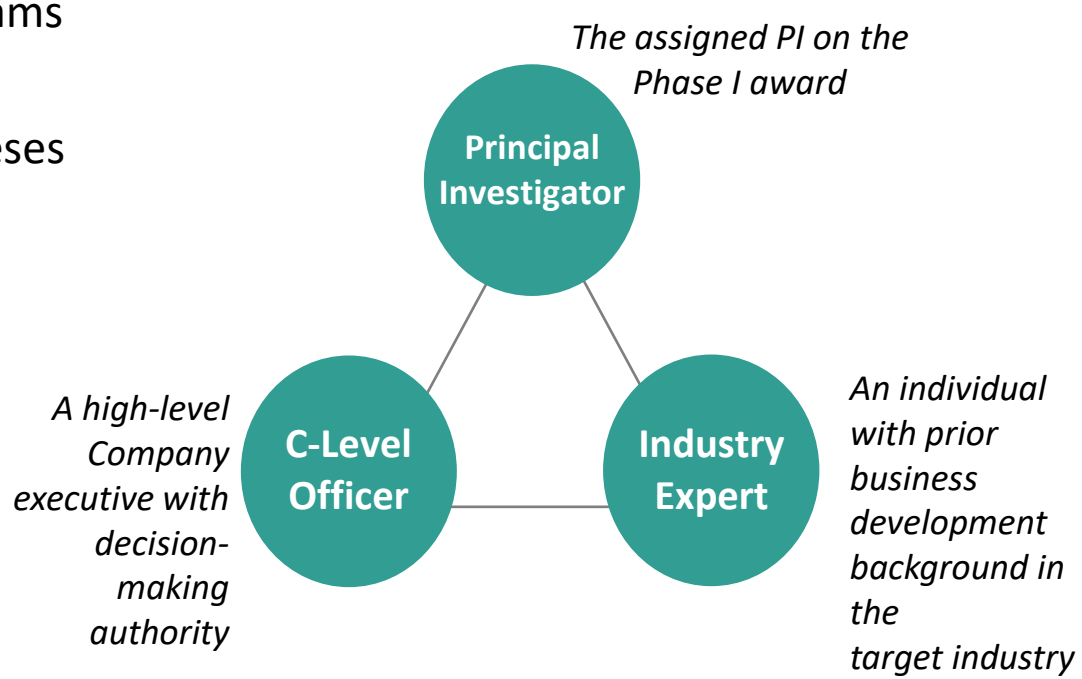
I-CORPS at NIH

Phase I
Grants
Contracts

Program for SBIR/STTR *Phase I awardees* (Grants + Contracts) to help:

- Intensive *Entrepreneurial Immersion* course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the market(s) for the technology
- Teams are expected to conduct over *100 interviews* in 8 weeks
- Format is focused on *Experiential Learning*
- NCI SBIR designed, launched, and manages the program for NIH
- 24 Institutes at NIH and CDC participate

Three-member Team



For more information, please see –
https://sbir.cancer.gov/icorps

HOW NCI SBIR WORKS WITH INVESTORS

Annual portfolio review/company showcase program

Partner hosted pitch-events

Pitch Coaching ahead of NCI-sponsored conference presentations

Identifying market trends & emerging areas

Growing and Maintaining an Active Investor/Partner Network

Sharing curated NCI SBIR portfolio

Email Brittany Connors (brittany.connors@nih.gov) for more information

INVESTOR INITIATIVES PORTFOLIO SHOWCASE

Phase I
Phase II
Phase IIB
Grants
Contracts

INVESTOR REVIEW//

Current and recent NCI awardees can apply (80-110 per year)

Reviewed by pharma, MedTech and venture partners (e.g., Pfizer, J&J, OrbiMed, Merck, MPM)

ALL applicants receive constructive feedback

SUPPORT TO PITCH//

NCI matches 30-35 companies with stage and technology appropriate events

Assists with presentation fees for one individual

NCI or Industry managed company showcases

PITCH COACHING //

Selected companies receive coaching, give pitches at investor forums and conferences, and meet one-on-one with investor attendees

Industry mentoring

DIRECT INTROS//

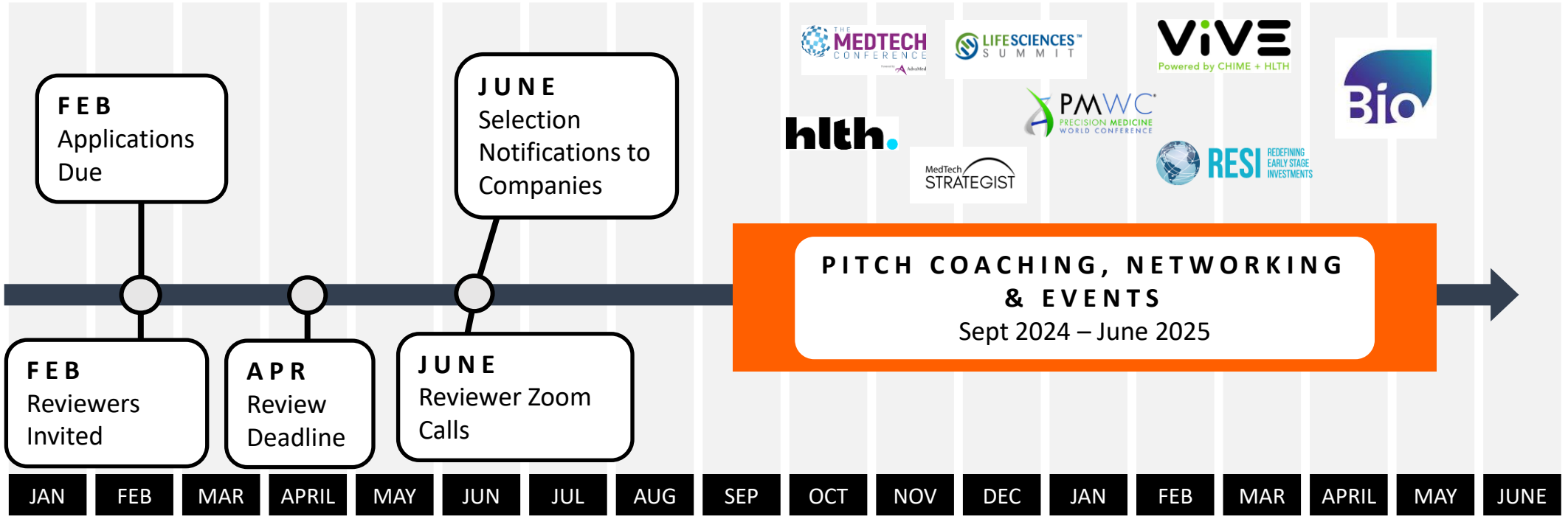
Develop a wide network of investor/strategic partners

Companies are profiled in an investor-oriented booklet shared with network

Direct introductions to SBIR awardees in NCI SBIR portfolio

PORTFOLIO SHOWCASE TIMELINE

1 APPLICATION & REVIEW CYCLE PER YEAR



TIMELINE OF 2024-2025 PROGRAM

Phase I
Phase II
Grants
Contracts

TECHNICAL AND BUSINESS ASSISTANCE (TABA)

TABA Programs help small businesses identify and address their most pressing product development needs

	Applicant requests TABA Funds (at time of submission)	OR	Applicant uses NIH-provided TABA services
Phase I	**TABA Funding** • Up to $6,500 for Phase I to use your own vendors • Request as other direct costs (must include quote) in application, on top of $400,000 budget cap		**TABA Needs Assessment** • NIH-vetted third party company prepares an unbiased assessment of areas critical to success (IP/barriers to entry; market needs/competitive advantages; regulatory, manufacturing, and/or clinical plan; business model profitability
Phase II	**TABA Funding** • Up to $50,000 across all years for Phase II to use your own vendors • Request as other direct costs (must include quote) in application, on top of $2,000,000 budget cap		**TABA Consulting Services** • NIH-vetted third party identifies vendors to provide consulting services worth up to $50,000 in one of these areas: IP, market analysis, regulatory, or reimbursement strategy and services

https://seed.nih.gov/support-for-small-businesses/technical-business-assistance-program
https://sbir.cancer.gov/commercialization/business/taba

Connecting Awardees with Regulatory Experts (CARE)

Phase I
Phase II
Phase IIB
Grants
Contracts

NCI SBIR and FDA collaborate to connect small businesses with FDA and support communications during early-stage product development.

Who Is This Program For?

- Early-stage companies that have not discussed their technology with FDA or participated in the CARE program previously

What Does It Entail?

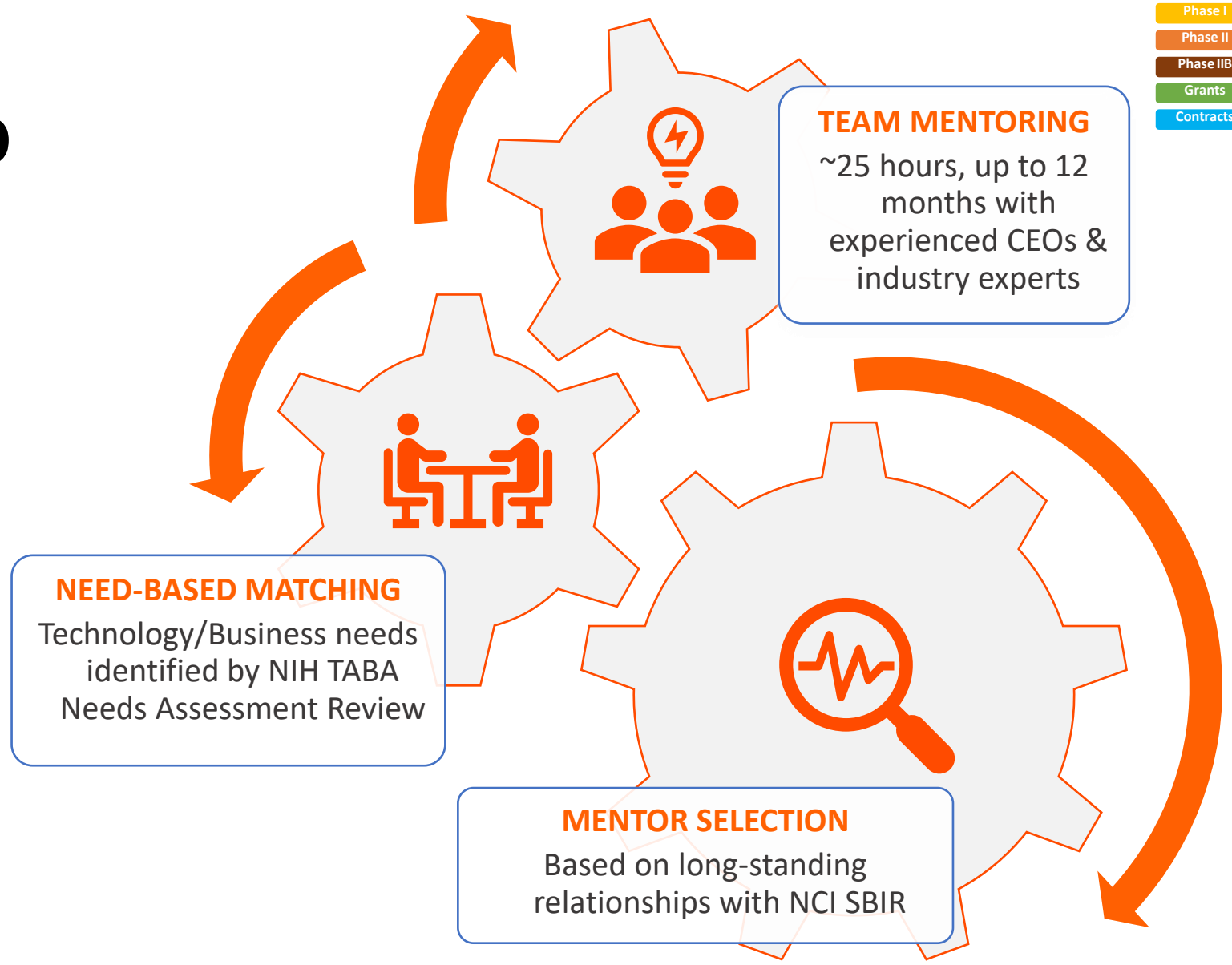
- Companies submit their application containing regulatory questions to NCI SBIR
- NCI SBIR reviews and directs to correct FDA Center
- Companies receive informal responses from discipline specific experts at the relevant FDA center

When/How Can I Apply?

- Applications are due in Feb 2024, check the program link below for up-to-date information.
- Submit your application on the CARE Program website **here**

INDUSTRY MENTORING AND ASSISTANCE PROGRAM

Provides expert guidance to NCI SBIR companies through mentorship to address their most pressing needs in technology and business development



Women's Innovation Network (WIN)

Phase I
Phase II
Phase IIB
Grants
Contracts

WIN started in 2022 and provides a forum for women entrepreneurs and scientists to:

- Hear from their peers.
- Discover real-world solutions to common challenges.
- Get leadership resources.
- Grow their network.

SESSION FORMAT

1. Panel session guest speaker
2. Breakout "Circles" with topic discussions on business and career challenges
3. Live Q&A/Reflection session with NCI SBIR Director and panelists

PARTICIPANT FEEDBACK

"Excellent networking opportunity, made concrete connections with several founders."

"The circle members answered my questions and provided value suggestions to the problems I have. More importantly, after meeting with them, I feel that I finally found a group of people in the entrepreneur field that I belong to."

Katharine Ku
Chief Licensing Advisor to Wilson, Sonsini, Goodrich and Rosati

Melinda Richter
Founder and Global Head of J&J Innovation (JLABS)

Julie Grant
General Partner at Canaan Partners

Nicky King
Managing Partner at Hat Trick Communications

Phase I
Phase II
Phase IIB
Grants
Contracts

EXECUTIVE ROUNDTABLE

- Platform for founders/CEOs/other C-Level Executives of NCI SBIR-funded startups to mentor and advise each other on real-life startup issues.
- 4 ongoing cohorts
- 2-3 hours once every 1-2 months

- New cohort coming soon

- Networking
- Ongoing Mentoring & Advice
- Potential Partnerships

- In person (pre-COVID) or Virtual

- C-Level Executives of all awardees
- 10-12 participants per cohort

REACH OUT TO A PROGRAM DIRECTOR

Michael Weingarten, MA
Director
NCI SBIR Development Center

https://sbir.cancer.gov/about/contact-staff

Greg Evans, PhD
Lead Program Director
Cancer Biology, E-Health, Epidemiology, Research Tools

Jonathan Franca-Koh, PhD, MBA
Lead Program Director
Cancer Biology, Biologics, Small Molecules, Cell Based Therapies, Phase IIb Bridge

Monique Pond, PhD
Lead Program Director
Biologics, Small Molecules, Therapeutic Devices, Digital Health, Regulatory Resources

Melissa Li, PhD
Program Director
Biologics, Small Molecules, Digital Health, AAP

William Bozza, PhD
Program Director
Therapeutics, Biologics, Small Molecules, Regulatory (CMC), Concept Award, PLAN Webinar

Sarra Djemil, PhD
Program Director
Therapeutics & Mentoring

Jian Lou, PhD
Program Director
In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investor Initiatives

Linda Zane, PhD
Program Director
Therapeutics, Diagnostics, Research Tools

Swamy Tripurani, PhD
Program Director
Therapeutics, Biologics, Small Molecules, diagnostics, devices, and Regulatory (CMC and Nonclinical))

Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics, Biologics, Resources Workshop

Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

Saroj Regmi, PhD
Program Director
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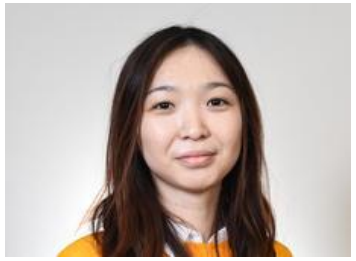
Director of Investor Relations

Lisa Yeom, MA
Communications Manager

Julienne Willis
Program Specialist



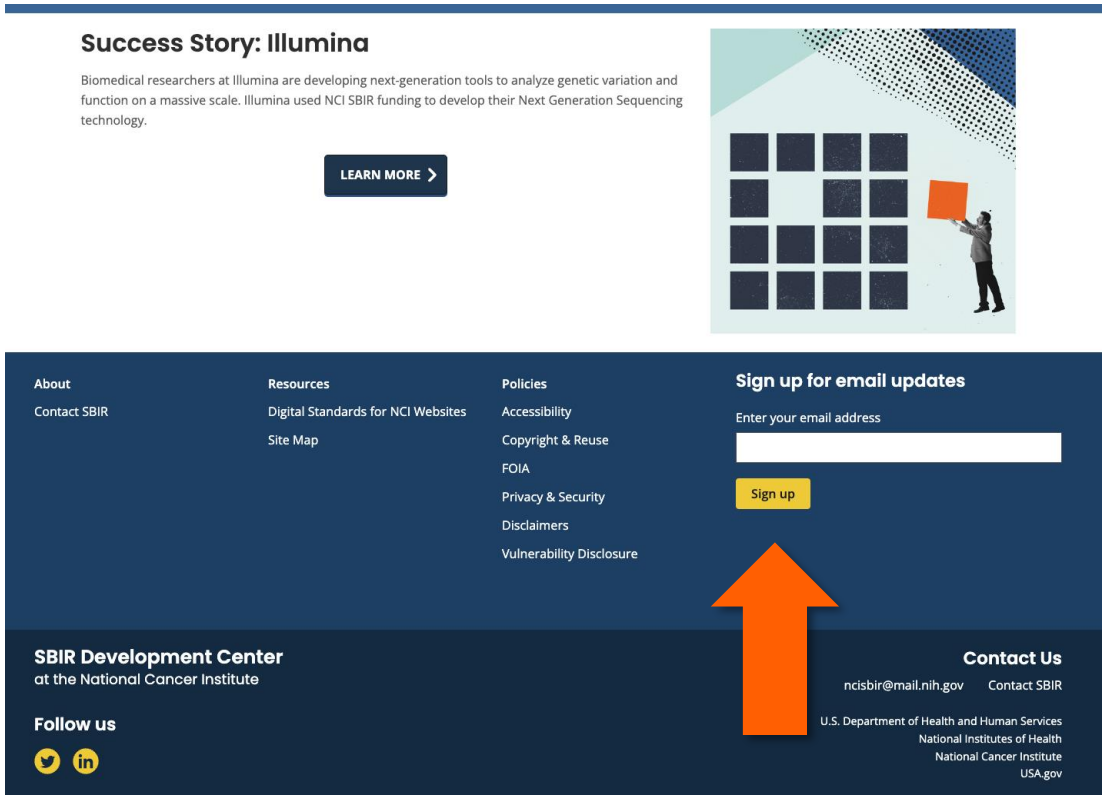
Kehui Zhang
Program Analyst

Bryce Geiling
Communications Coordinator

Janelle Azore
Communications Specialist

Jordan Robbins, JD
Program Specialist

Need More Help? Stay In Touch!



- **Sign up for our mailing list for the latest updates on** https://sbir.cancer.gov/
- **Discuss your project and/or other available resources with your Program Director**
- **Check out awardee resources** https://sbir.cancer.gov/commercialization/awardee-resources
- **Attend in-person and virtual events** https://sbir.cancer.gov/events
- **Follow and engage with us on social media**
  - https://www.linkedin.com/company/nci-sbir-development-center/
  - https://twitter.com/ncisbir

THANK YOU & QUESTIONS

NCI SBIR DEVELOPMENT CENTER
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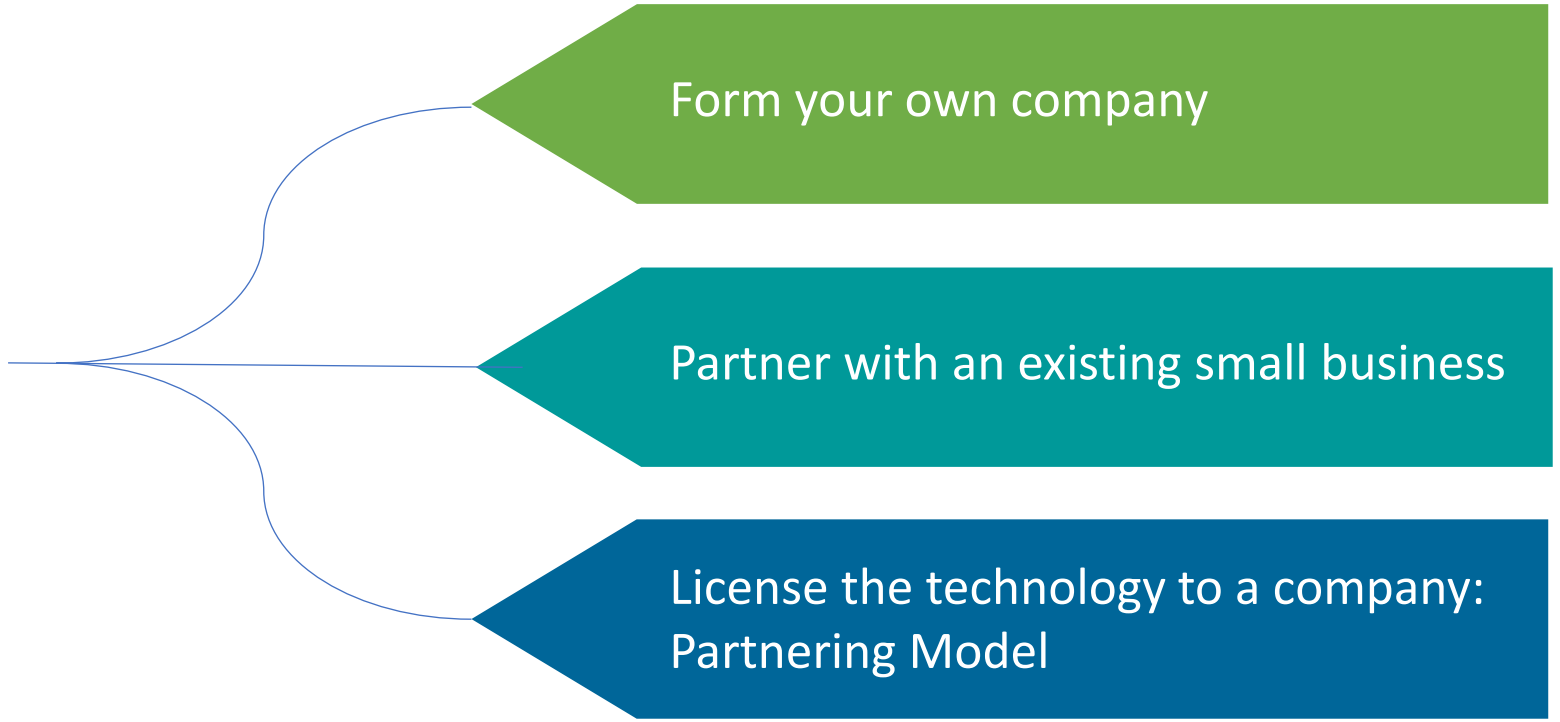
240.276.5300

Getting Started

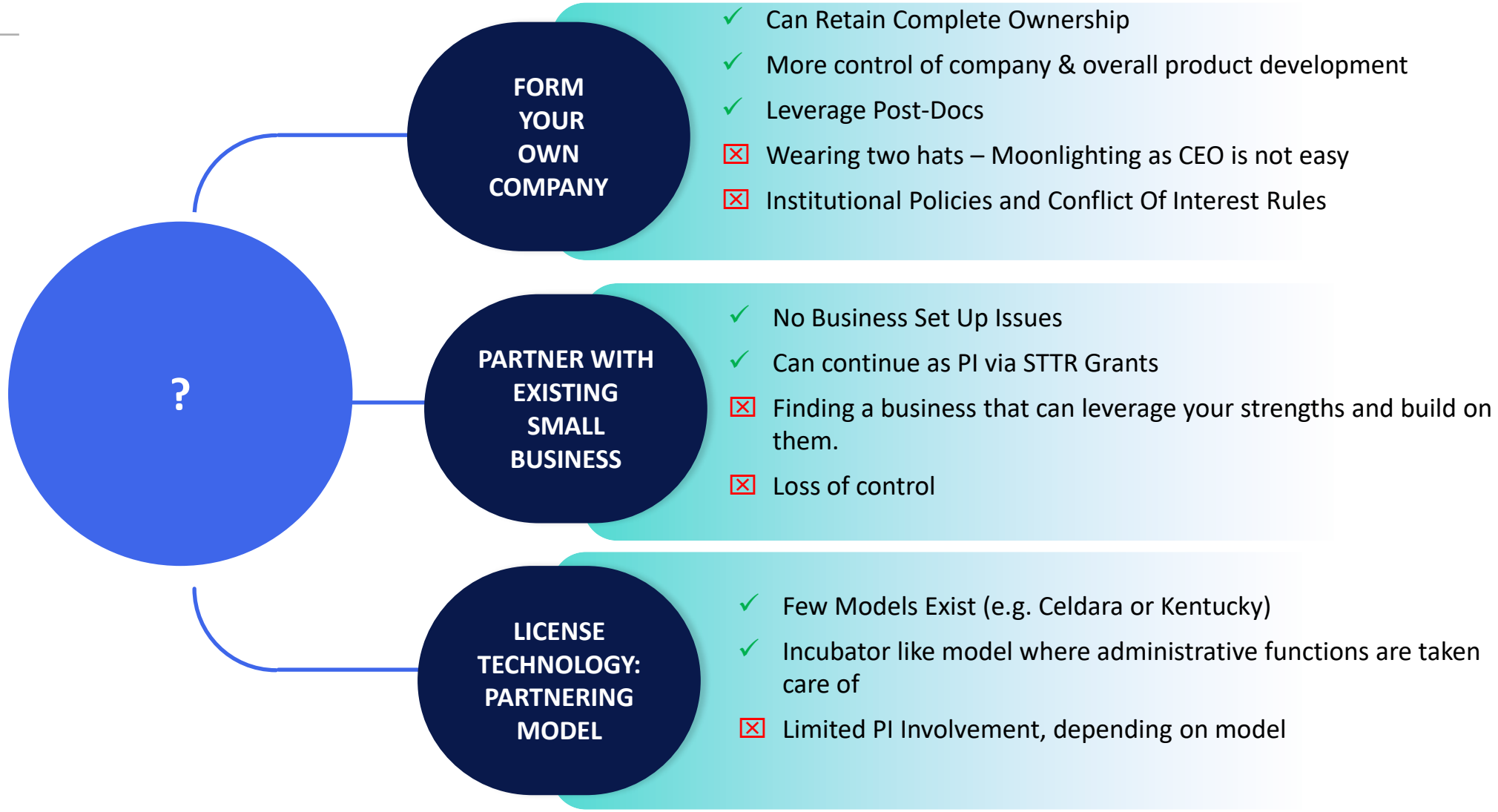
William Bozza, PhD
PROGRAM DIRECTOR
NCI SBIR DEVELOPMENT CENTER

COMMERCIALIZE YOUR TECH WITH SBIR

More than one way to SBIR/STTR funding!



TECHNOLOGY COMMERCIALIZATION



GETTING STARTED

Read the solicitation & SF424 carefully to understand the requirements.
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/sbir-sttr-forms-g.pdf

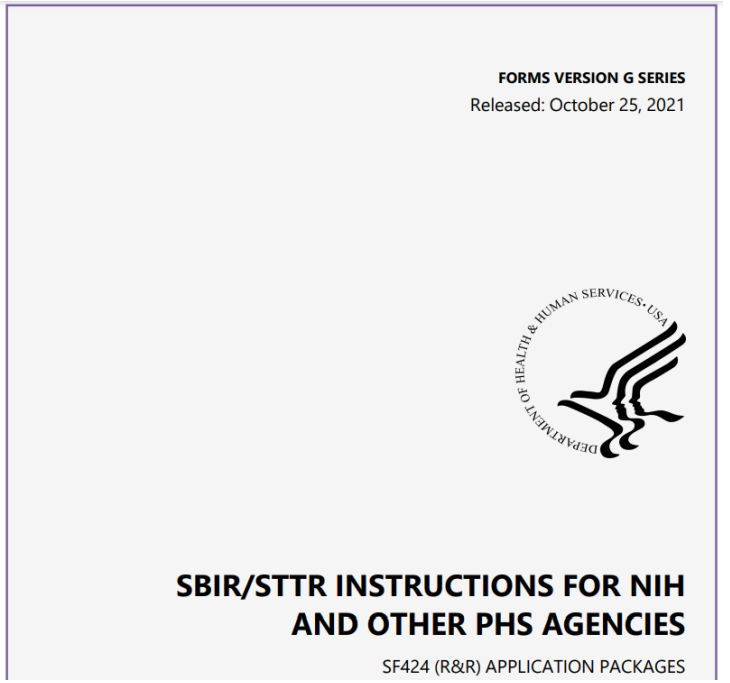
Review similar, currently-funded NIH SBIR/STTR projects.
https://projectreporter.nih.gov/reporter.cfm

Look at some sample applications.
https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

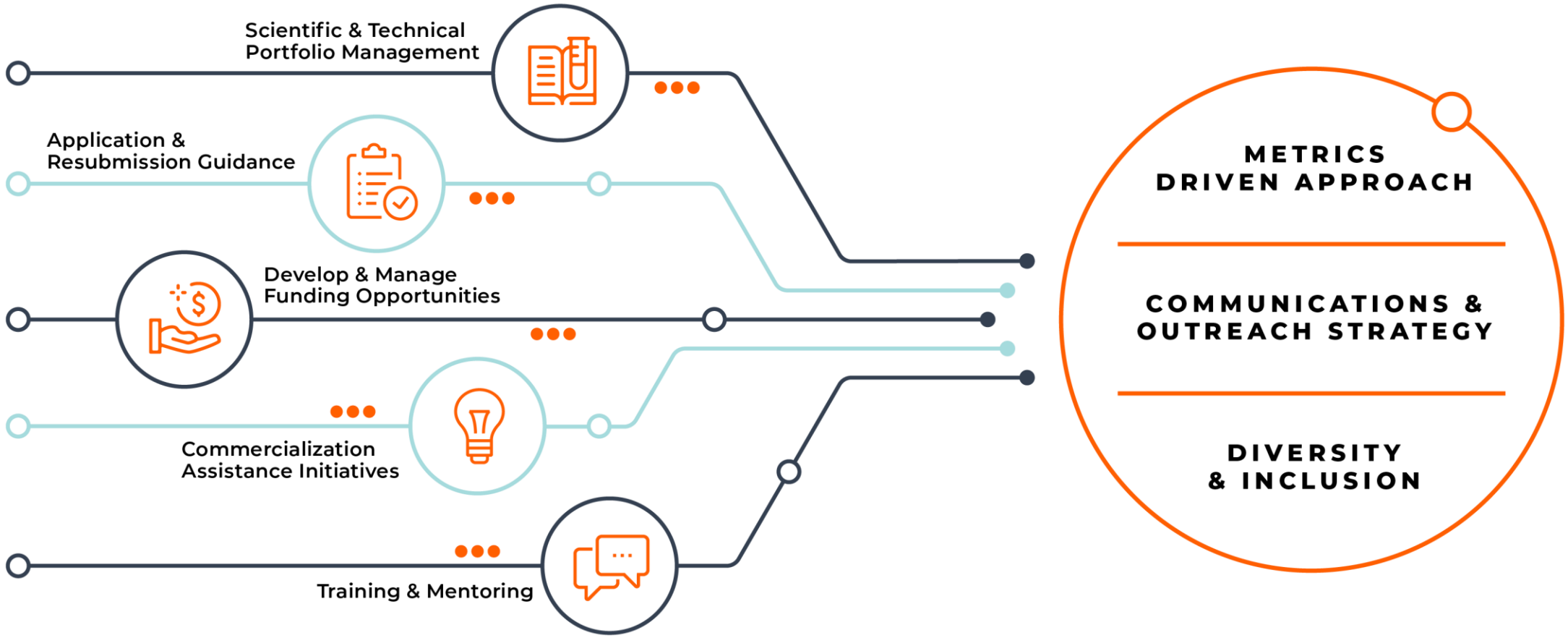
https://sbir.cancer.gov/resources/forapplicants#Sample

Check out our Peer Learning And Networking (PLAN) Videos.
How to Write a Good Specific Aims Page

First Steps for Starting a Small Business



NCI SBIR CORE ACTIVITIES



REACH OUT TO A PROGRAM DIRECTOR

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Director
NCI SBIR Development Center

https://sbir.cancer.gov/about/contact-staff

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Melissa Li, PhD
Program Director
Biologics, Small Molecules, Digital Health, AAP

William Bozza, PhD
Program Director
Therapeutics, Biologics, Small Molecules, Regulatory (CMC), Concept Award, PLAN Webinar

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Swamy Tripurani, PhD
Program Director
Therapeutics, Biologics, Small Molecules, diagnostics, devices, and Regulatory (CMC and Nonclinical))

Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics, Biologics, Resources Workshop

Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

Saroj Regmi, PhD
Program Director
Therapeutics, Diagnostics, Imaging, Digital Health, Investor Initiatives, Small Business Transition Grant, I-Corps

Application Tips

William Bozza, PhD
PROGRAM DIRECTOR
NCI SBIR DEVELOPMENT CENTER

WHAT IS THE NCI LOOKING FOR?

Innovative solution to significant **unmet clinical need**

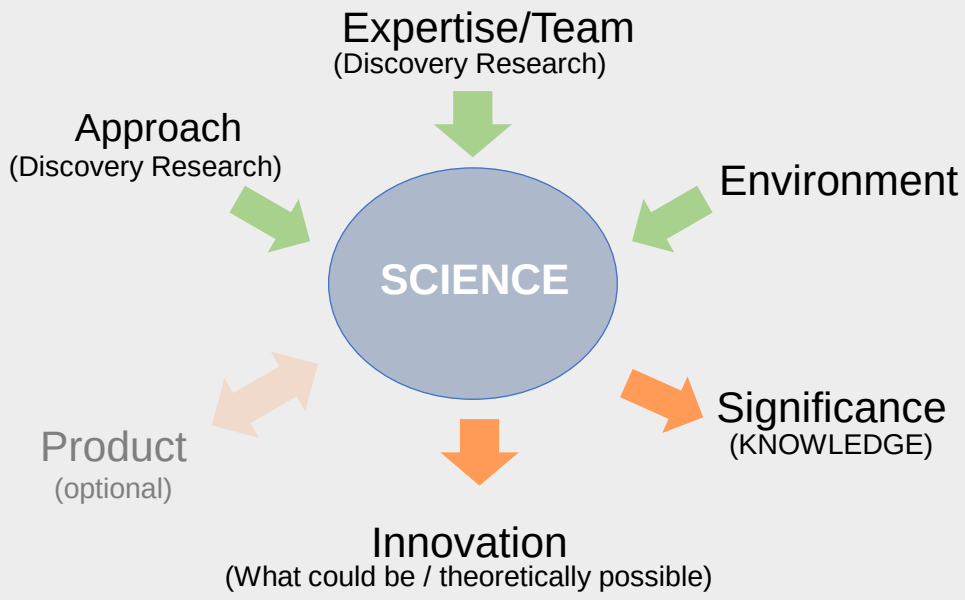
Leverage the expertise of the company/founder

Solution that has **significant commercial potential**

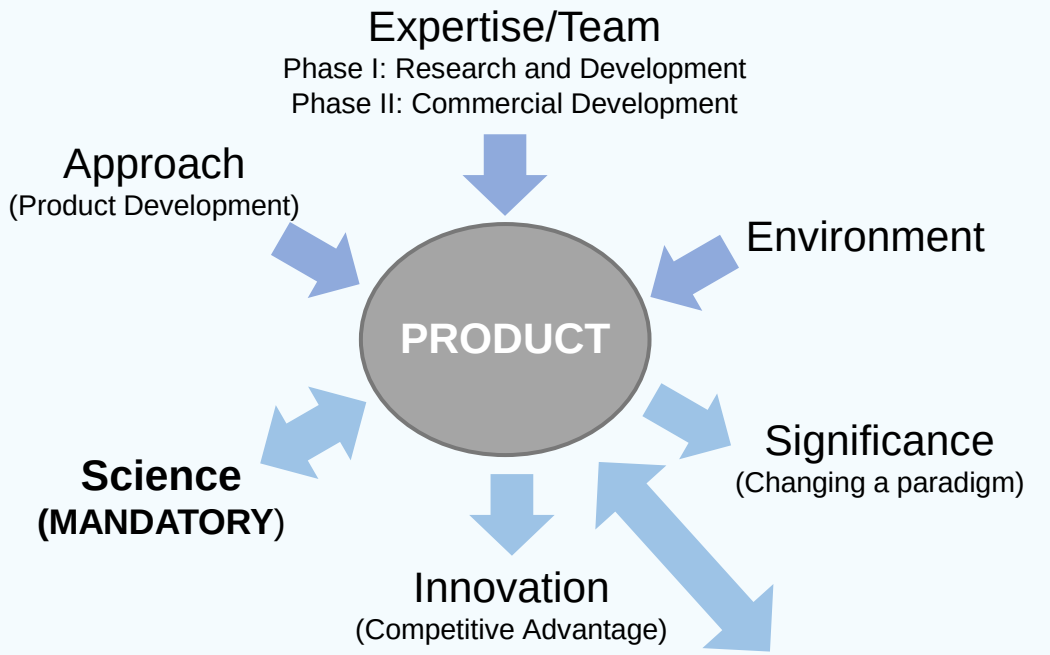
Translate federally funded research into the clinic.

PRODUCT FOCUSSED SCIENCE IS ESSENTIAL FOR SBIR

ACADEMIC GRANT



SBIR/STTR GRANT



TIP #1. START EARLY

- **Strong proposals take time to develop**
  - Refining your product
  - Gain access to equipment, facilities, other resources
  - Assemble a strong scientific team
  - Obtain letters of support from collaborators

- **Complete the administrative registrations**
  - Five Required registrations (https://sbir.nih.gov/infographic)
  - Send specific aims to Program at least a month before

COMPLETE REQUIRED REGISTRATIONS

1. **Employer Identification Number** (EIN) – The NIH requires both the EIN and a DUNS number prior to the issuance of a funding award. The EIN base for the organization is the IRS Tax ID number, for individuals it is their social security number, both of which are nine-digit numbers.

2. **Dun and Bradstreet Universal Numbering System** (DUNS) – All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin SAM, SBA Company, and eRA Commons registrations.

3. **System for Award Management** (SAM) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration.

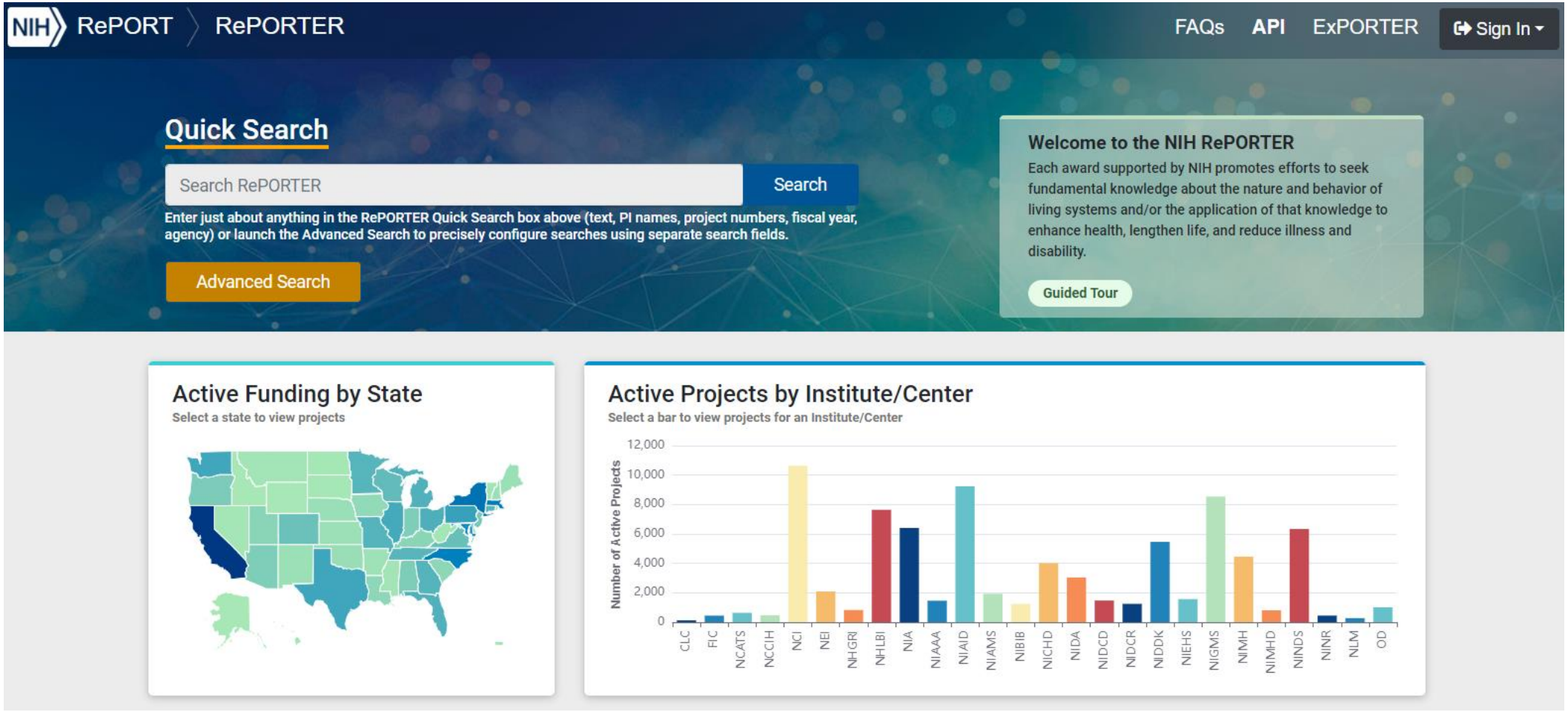
4. **Grants.gov** – Grants.gov is a federal-wide portal to find and apply for federal grant funding. It is used by all 26 federal grant-making agencies.

5. **eRA Commons** – eRA Commons is NIH's Electronic Research Administration system that allows applicants, grantees, and NIH staff to access, share and transmit application/grant information.

6. **SBA Company Registry** – All applicants are required to register at the SBA Company Registry prior to application submission and attach proof of registration to their application.

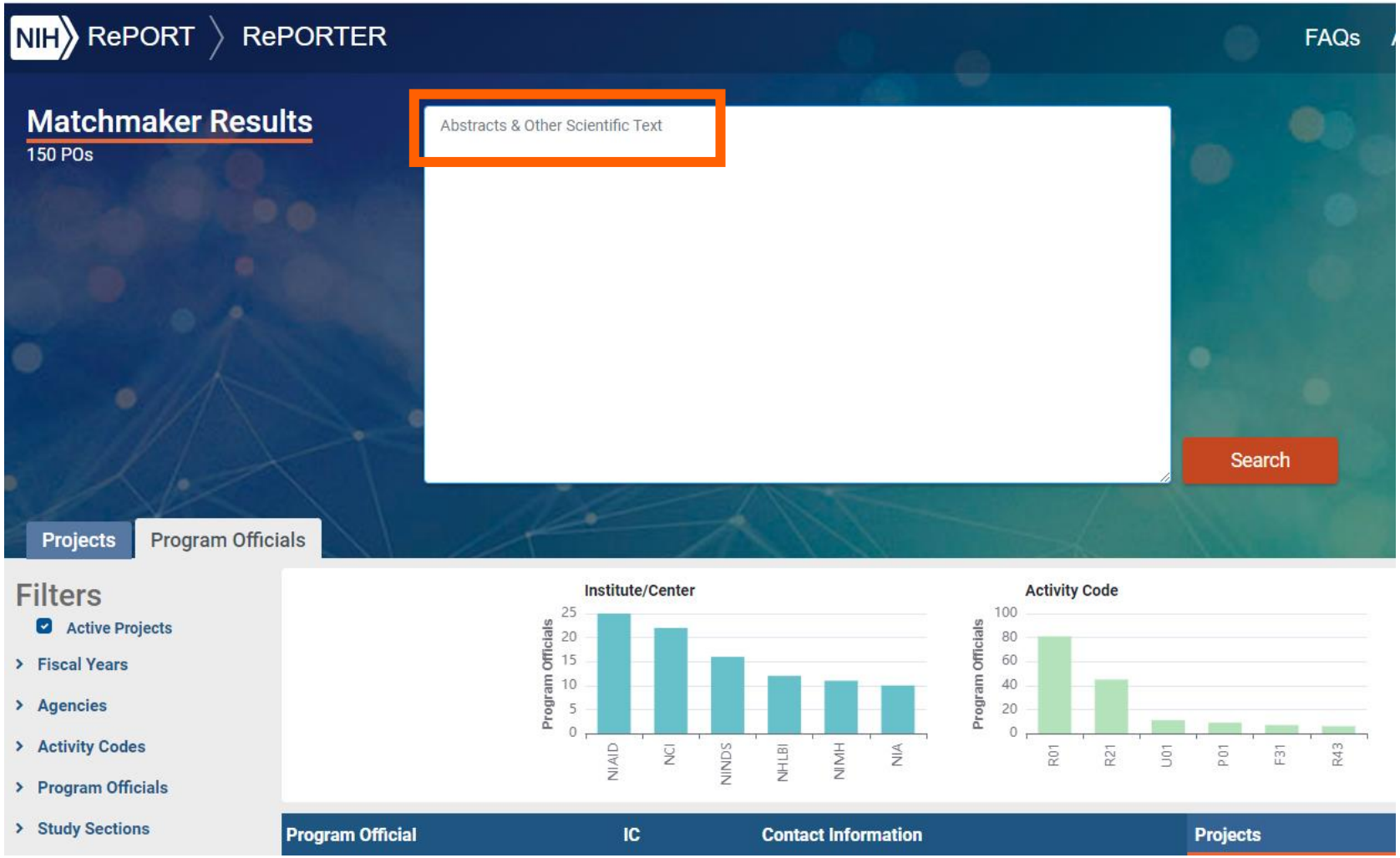
Helpful Tools: NIH Project Reporter

Search using key words what NIH has previously funded



https://projectreporter.nih.gov/reporter.cfm

Helpful Tools: NIH Matchmaker



Enter your abstract and find:

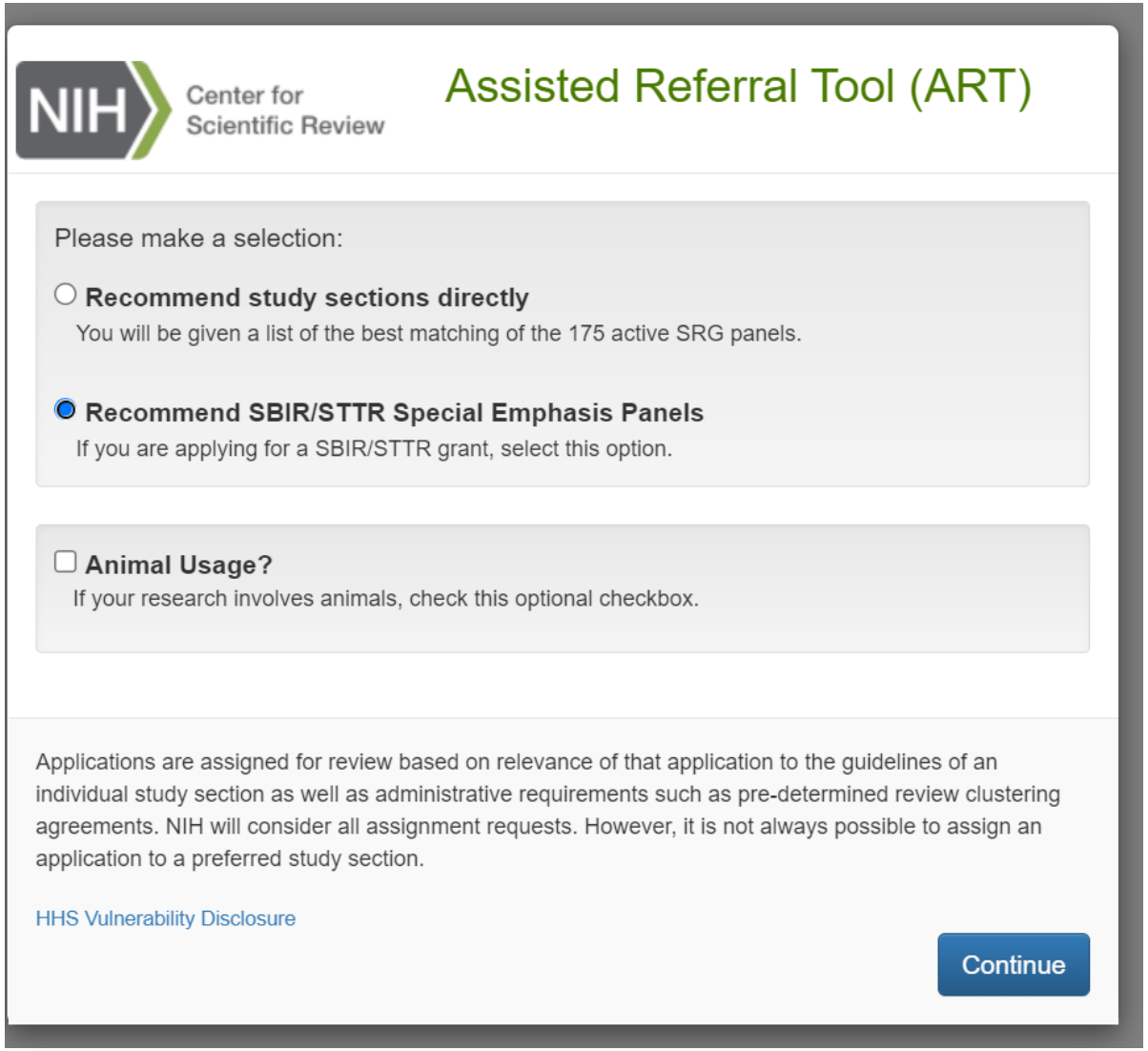
- The best IC
- The best study section
- Similar projects
- PDs who manage a similar portfolio

https://projectreporter.nih.gov/reporter_matchmaker.cfm?source=RPCO&new=1

Helpful Tools: Assisted Referral Tool (ART)

Check out SBIR study sections
https://public.csr.nih.gov/StudySections/SmallBusinessAndTechnologyTransfer

Assisted **R**eferral **T**ool to recommend SBIR/STTR Special Emphasis Panels (Similar to Matchmaker)
https://art.csr.nih.gov/ART/

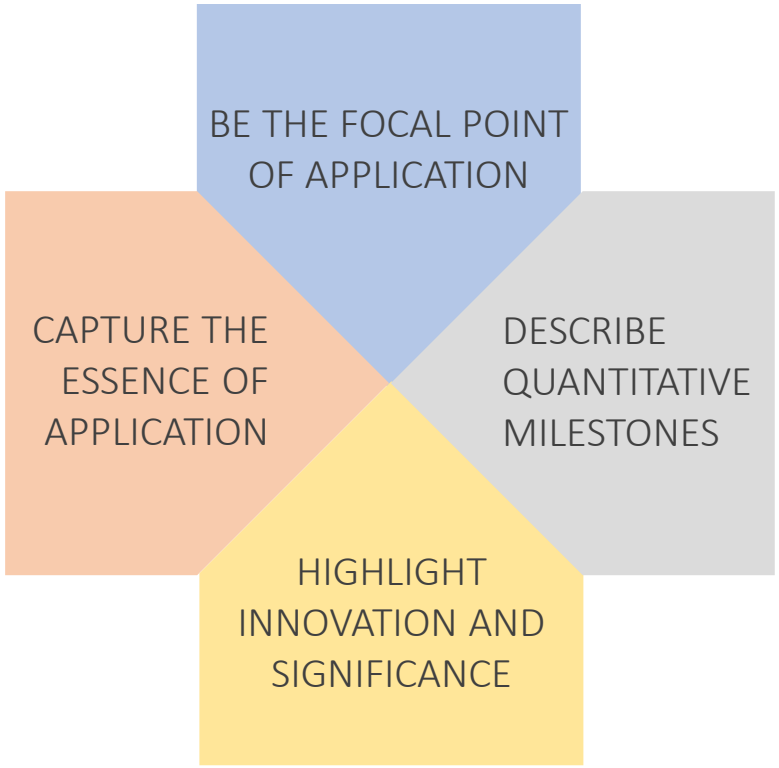


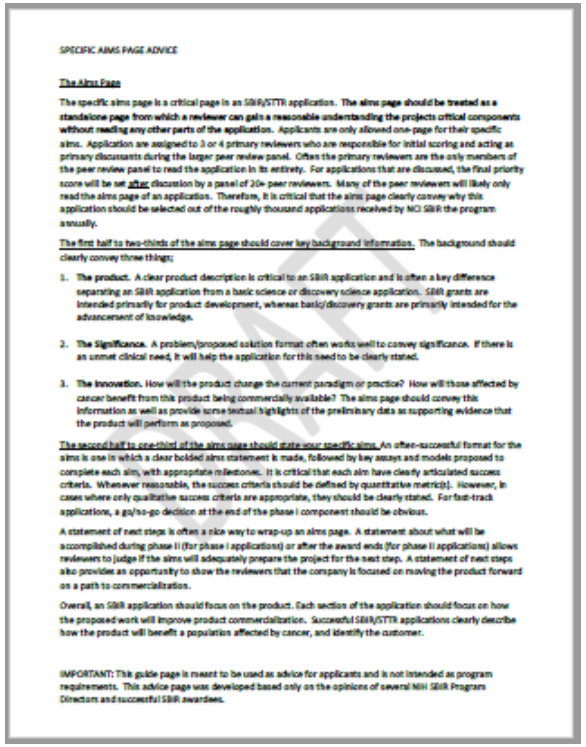
TIP #2: REFINE YOUR PRODUCT VISION

- **Start informal discussions to clarify the product vision**
  - Technical experts, potential customers, investors, commercialization partners, and other stakeholders
- **Seek help from others with experience and insights**
  - Current/prior SBIR grantees
  - Academic collaborators with grant writing experience
  - Professional grant writers*
  - **Engage with SBIR program staff for the most up-to-date information on agency priorities, current NIH policies, etc.**
- **Carefully consider the study design**
  - Identify strategies to mitigate risk
  - Present alternative approaches if problems are encountered

TIP #3. KNOW THE APPLICATION COMPONENTS

SPECIFIC AIMS





SPECIFIC AIMS PAGE ADVICE

The Aims Page

The specific aims page is a critical page in an SBIR/STTR application. **The aims page should be treated as a standalone page from which a reviewer can gain a reasonable understanding the projects critical components without reading any other parts of the application.** Applicants are only allowed one-page for their specific aims. Application are assigned to 3 or 4 primary reviewers who are responsible for initial scoring and acting as primary discussants during the larger peer review panel. Often the primary reviewers are the only members of the peer review panel to read the application in its entirety. For applications that are discussed, the final priority score will be set after discussion by a panel of 20+ peer reviewers. Many of the peer reviewers will likely only read the aims page of an application. Therefore, it is critical that the aims page clearly convey why this application should be selected out of the roughly thousand applications received by NCI SBIR the program annually.

The first half to two-thirds of the aims page should cover key background information. The background should clearly convey three things:

1. **The product.** A clear product description is critical to an SBIR application and is often a key difference separating an SBIR application from a basic science or discovery science application. SBIR grants are intended primarily for product development, whereas basic/discovery grants are primarily intended for the advancement of knowledge.
2. **The Significance.** A problem/proposed solution format often works well to convey significance. If there is an unmet clinical need, it will help the application for this need to be clearly stated.
3. **The Innovation.** How will the product change the current paradigm or practice? How will those affected by cancer benefit from this product being commercially available? The aims page should convey this information as well as provide some textual highlights of the preliminary data as supporting evidence that the product will perform as proposed.

The second half to one-third of the aims page should state your specific aims. An often-successful format for the aims is one in which a clear bolded aims statement is made, followed by key assays and models proposed to complete each aim, with appropriate milestones. It is critical that each aim have clearly articulated success criteria. Whenever reasonable, the success criteria should be defined by quantitative metric(s). However, in cases where only qualitative success criteria are appropriate, they should be clearly stated. For fast-track applications, a go/no-go decision at the end of the phase I component should be obvious.

A statement of next steps is often a nice way to wrap-up an aims page. A statement about what will be accomplished during phase II (for phase I applications) or after the award ends (for phase II applications) allows reviewers to judge if the aims will adequately prepare the project for the next step. A statement of next steps also provides an opportunity to show the reviewers that the company is focused on moving the product forward on a path to commercialization.

Overall, an SBIR application should focus on the product. Each section of the application should focus on how the proposed work will improve product commercialization. Successful SBIR/STTR applications clearly describe how the product will benefit a population affected by cancer, and identify the customer.

IMPORTANT: This guide page is meant to be used as advice for applicants and is not intended as program requirements. This advice page was developed based only on the opinions of several NIH SBIR Program Directors and successful SBIR awardees.

BACKGROUND:
- Product
- Innovation
- Significance

AIMS:
- Goals-based statements
- Key assays and models
- Quantitative milestones

CONTEXT:
- These studies will get us to…
- Next we will…
- This data will be used for…

TIP #3. KNOW THE APPLICATION COMPONENTS

RESEARCH STRATEGY

- Provide background information
- Preliminary data not required (Phase I), but needed to be competitive
- Provide detailed technical plan to achieve the Specific Aims
  - Expand on quantitative milestones & success criteria
  - Describe potential pitfalls and alternative angles of attack
- Propose a project scope within the budget and time constraints
  - Timeline/GANTT chart is a good idea

OTHER APPLICATION COMPONENTS

BIOSKETCHES	Bio-sketches for all senior/key personnel (<4 pages each)
FACILITIES	Provide description of facilities and equipment relevant to this grant.
BUDGET	Provide budgets for each project period & sub-contractors.
TITLE/ABSTRACT	CSR uses this to assign IC and Study section.
HUMAN/ANIMAL STUDIES	Complete VAS or Human Subjects section Check if you have an NIH defined clinical trial.
COMMERCIALIZATION PLAN	Important Element of Phase II; Program views it seriously.
LETTERS OF SUPPORT	Necessary from consultants and collaborators Helpful endorsements from clinicians, end-users, investors.

TIP #4: UNDERSTAND PEER REVIEW PROCESS

- Application is submitted to NIH (not the institute)

- Study section assigned is in Commons at least 30 days before review.
  - Finding the appropriate Study Section: https://public.csr.nih.gov/StudySections/SmallBusinessAndTechnologyTransfer
  - Use G.600-PHS Assignment Request Form, to request Study section, suggested review expertise, conflicted reviewers with rationale.

- Get Review Experience
  - https://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm

TIP #4: UNDERSTAND PEER REVIEW PROCESS

INVESTIGATOR

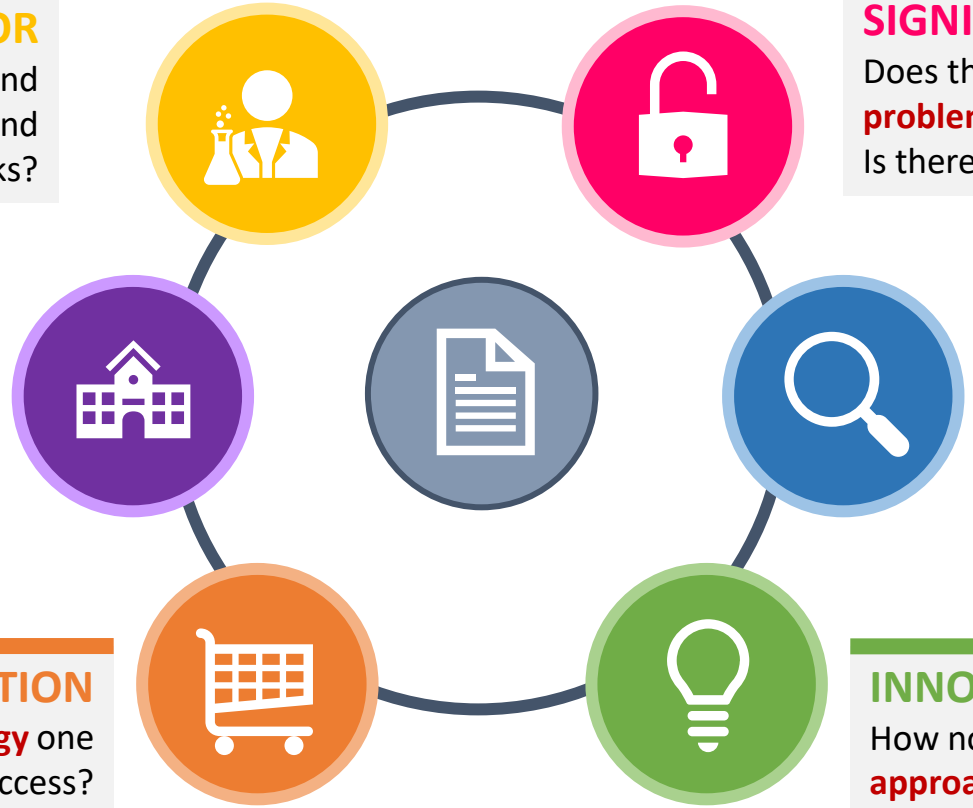
Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

SIGNIFICANCE

Does the product address an important **problem**, and have commercial potential? Is there a market pull for the product?

ENVIRONMENT

Does the **scientific environment** contribute to the probability of success? **Facilities**? Independence?



APPROACH

Are **design and methods** well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

COMMERCIALIZATION

Is the company's **business strategy** one that has a high potential for success?

INNOVATION

How novel is the **technology/product** and **approaches** proposed to test feasibility?

SUMMARY STATEMENT

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 10/20/2016
Revised Date:

PROGRAM CONTACT:
Christopher Beisel
240-292-1096
cbeisel@niaid.nih.gov

Application Number: 1 R43 AI132075-01

Principal Investigators (Listed Alphabetically):

BAILEY-KELLOGG, CHRIS
BROOKS, BENJAMIN DELBERT (Contact)
COHEN, GARY H
EISENBERG, ROSELYN J

Applicant Organization: WASATCH MICROFLUIDICS

Review Group: ZRG1 IMST-K (14)
Center for Scientific Review Special Emphasis Panel
Small Business: Computational, Modeling, and Biodata Management

Meeting Date: 10/13/2016
Council: JAN 2017
Requested Start: ~~07/01/2017~~

RFA/PA: PA16-302
PCC: M34
Dual PCC: P146SS
Dual IC(s): GM

Project Title: High-throughput, multiplexed characterization and modeling of antibody:antigen binding, with application to HSV
SRG Action: Impact Score:18
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
1	[redacted]	[redacted]
TOTAL	[redacted]	[redacted]

SUMMARY STATEMENT: INTERPRETING SCORES

higher throughput than traditional structural studies, this approach promises to better drive discovery and development of vaccines and therapeutic antibodies.

CRITIQUE 1:

Significance: 2

Investigator(s): 1

Innovation: 2

Approach: 1

Environment: 2

Overall Impact: Antibodies are a major class of therapeutic agents, and a critical determinant of the functional effect of binding of an antibody to its target antigen is mediated by the specific residues involved in the binding epitope. Currently, antibodies are typically developed with little structural insight into the residues involved in the binding epitope. The investigators propose to address this limitation of current technologies by developing a faster and more efficient approach to identify specific residues involved in antigen:antibody binding through an integrated solution combining multiplex surface plasmon resonance (SPR) with computational modeling. The investigators will implement and leveraged two elegantly complementary approaches: antibody vs. antibody binning to identify clusters of similar antibodies, and antibody vs. antigen binding to identify candidate residues at the binding epitope.

The proposal builds upon current independent approaches for SPR and modeling, and will validate the platform using the herpes simplex virus (HSV) glycoprotein D (gD) antigen bound with a collection of

SUMMARY STATEMENT: REVIEW TEAM

MEETING ROSTER
Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW
Small Business: Computational, Modeling, and Biodata Management
ZRG1 IMST-K (14)
10/13/2016

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OAKLAND, CA 94618

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RESEARCH SCIENTIST
ROCHE TISSUE DIAGNOSTICS
DIGITAL PATHOLOGY
PALO ALTO, CA 94304

TIP #5. KNOW COMMON PITFALLS

The reviewers just didn't understand my proposal.

- Improve your presentation.
  - ✓ Check for spelling or grammatical errors, make sure figures are clearly labeled, avoid jargon.
- Present key data in the application.
  - ✓ Reference publications to save space, but show the most important figures!
- You are the expert in your area, but you have to convince reviewers

TIP #5. KNOW COMMON PITFALLS

Reviewers did not think my technology is significant.

- Consider reviewer comments from their point of view and their knowledge of current clinical practice (or relevant sector/customer segment)
- Address reviewer comments in an evidence-based fashion
- Be specific and quantitative when providing data to support your claims
- Obtain additional letters of support from stakeholders who can confirm the magnitude of the problem **AND** the potential impact of your solution

TIP #5. KNOW COMMON PITFALLS

I mentioned this on page 43, but the reviewers didn't read the proposal.

- Reviewers are reading several proposals
- Reiterate key points in different parts of the application.

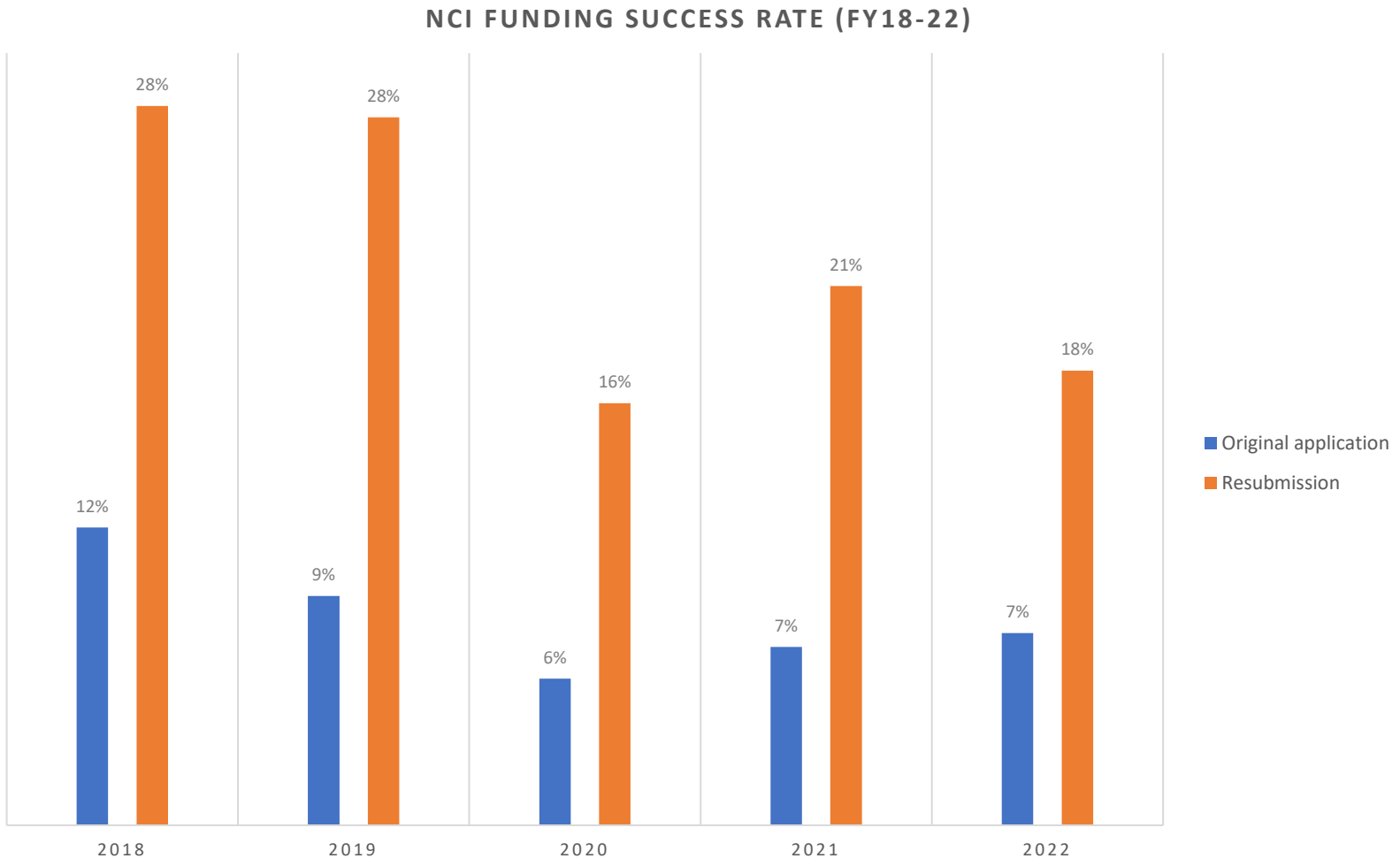
TIP #5. KNOW COMMON PITFALLS

I got a low score for investigators.

- Provide more background on your team members' qualifications
- Strengthen your team by adding collaborators and consultants
- Consider including a management plan/strategy that describes who is completing which aspects of the work, and how they are qualified
- For multidisciplinary projects, consider a multi-PI team

TIP #6. BE RESILIENT

- **You are not alone!**
- Remember the three Rs:
  - **Review** your summary statement
  - **Revise** your application
  - **Resubmit** and try again!
- Talk to your program officer.
  We are here to help!



THANK YOU & QUESTIONS

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