Dec 2024 | NCI NY Outreach

NCI SMALL BUSINESS FUNDING OPPORTUNITIES & RESOURCES

SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE

SBIR
DEVELOPMENT CENTER

CONGRESSIONALLY MANDATED PROGRAM

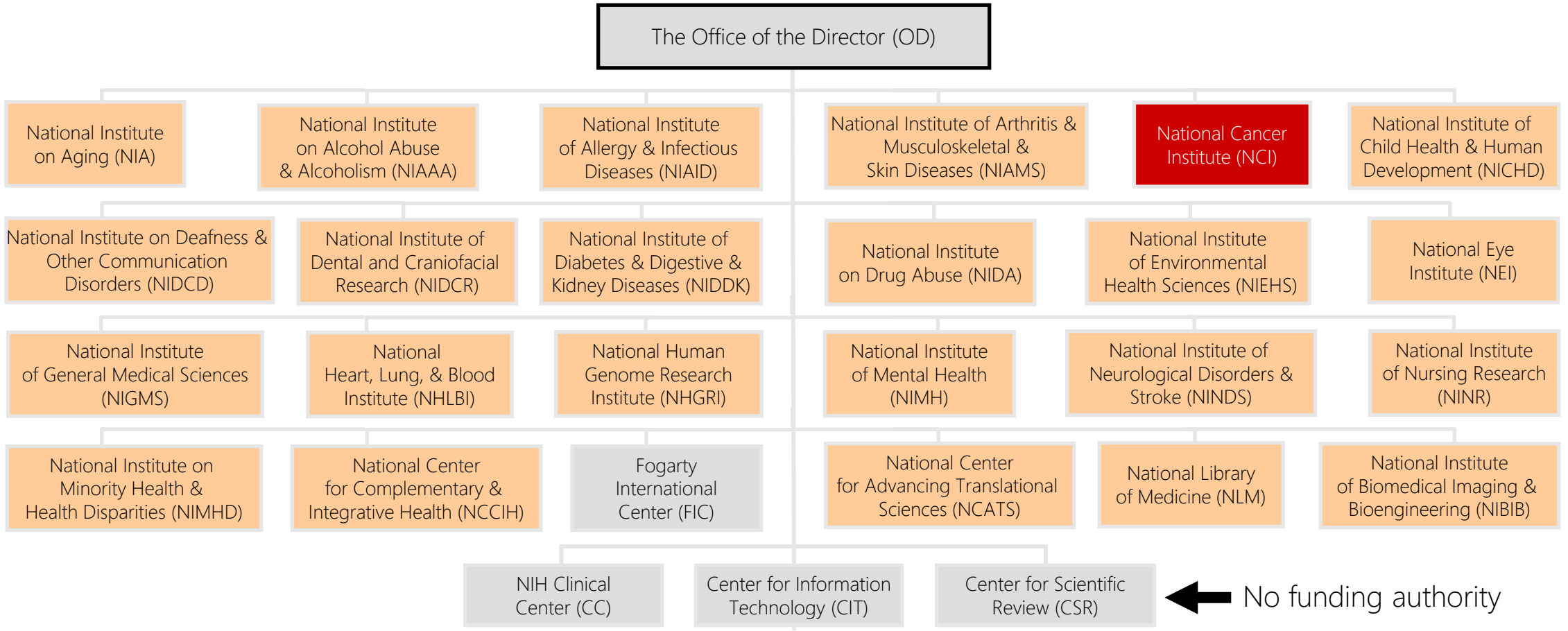
		Set Aside for FY23
SBIR SMALL BUSINESS INNOVATION RESEARCH	Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization Federal agencies with an extramural R&D budget > $100M	$178M (3.2%)
STTR SMALL BUSINESS TECHNOLOGY TRANSFER	Set-aside program to facilitate 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

SBIR PROGRAMS

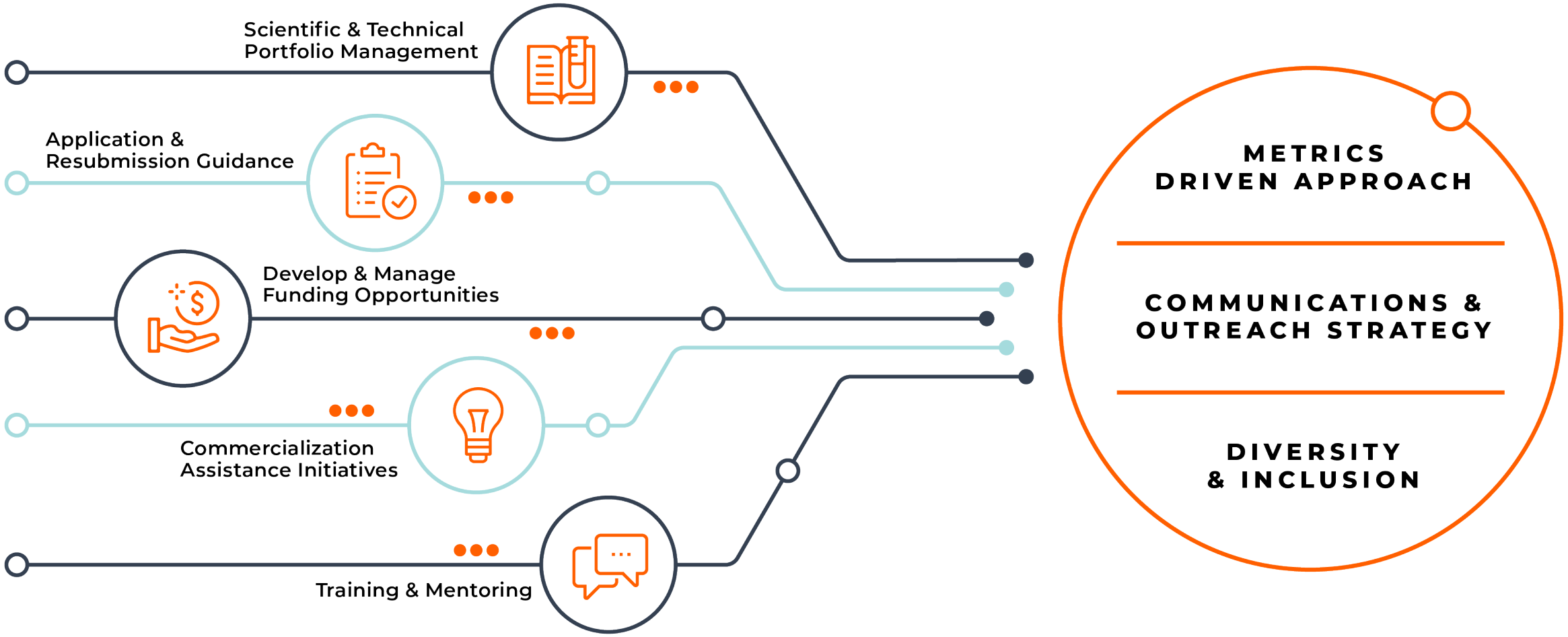
11 Federal Agencies

- Department of Defense
- **Department of Health and Human Services**
- Department of Energy
- National Science Foundation
- National Aeronautics and Space Administration
- Department of Agriculture
- Department of Homeland Security
- Department of Commerce
- Department of Transportation
- Department of Education
- Environmental Protection Agency

27 INSTITUTES & CENTERS AT THE NIH

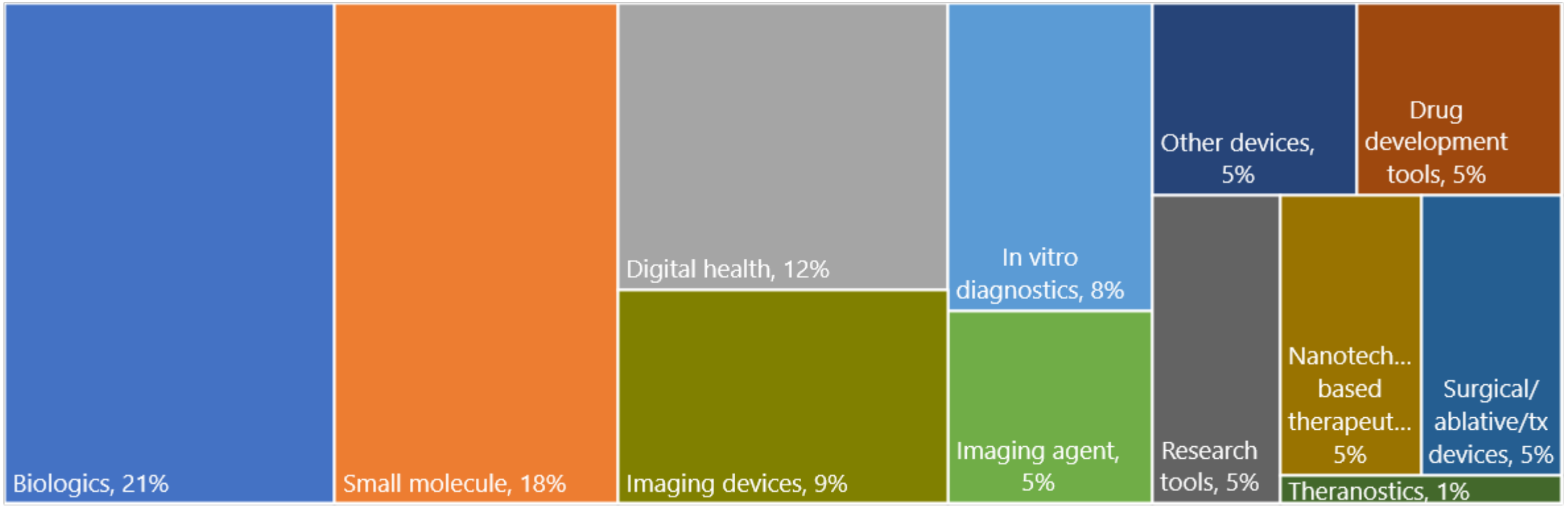


CORE ACTIVITIES



PORTFOLIO

- Technology agnostic and covers cancer prevention, diagnosis, and treatment
- 450+ active projects managed by 12 program directors
- NCI SBIR/STTR funding: ~80% grants & ~20% contracts



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

CRITICAL DIFFERENCES BETWEEN SBIR & STTR

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.

WHY SEEK SBIR/STTR 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.

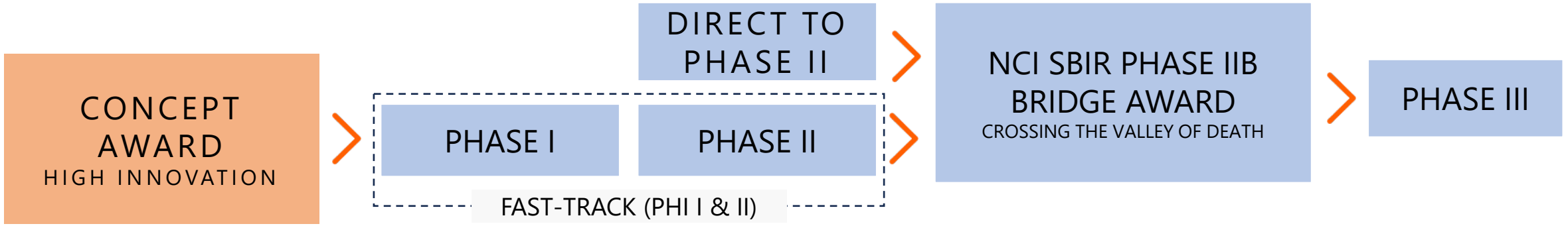
Provides recognition, verification, and visibility

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.

A $200M PROGRAM AT NCI



- High-risk, high-reward projects
- Pipeline for innovation
- Concept de-risking
- $300K – 1 year

- Proof of concept
- $400K over 1 year

- Research & Development
- Commercialization plan required
- $2.25 M over 2 years

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Matching 3rd party investor funds
- $4.5M over 2-3 years

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

~ 7 Million USD in funding per project!

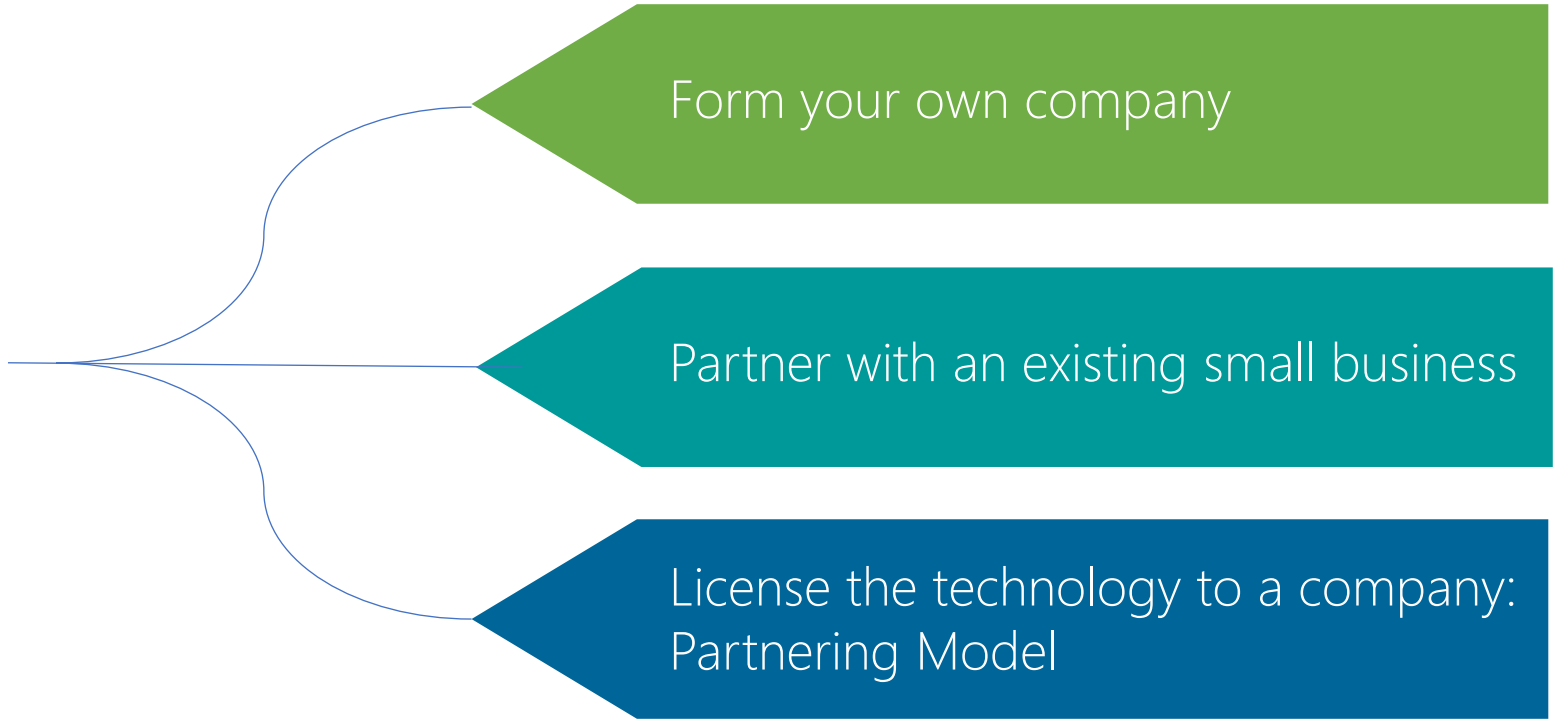
FUNDING OPPORTUNITIES

TITLE	SBIR NOFO	STTR NOFO	RECEIPT DATES
Omnibus Solicitation	PA-24-245 (General) PA-24-246 (Clinical trial required)	PA-24-247 (General) PA-24-248 (Clinical trial required)	Standard due dates (January 5; April 5; September 5)
NOSI: Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	NOT-CA-21-062	NOT-CA-21-062	
NOSI: SBIR Technology Transfer	NOT-NS-22-017	N/A	
NOSI: 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	
NOSI: RNA Delivery Technologies to Allow Specific Tissue Target Homing (RNA-DASH)	NOT-AI-24-007	NOT-AI-24-007	
Small Business Transition Grant for Early Career Scientists		RFA-CA-24-023	Aug 21, 2024
NCI SBIR Phase IIB Bridge Award	RFA-CA-24-022		Aug 21, 2024
NCI SBIR Concept Award (Contract)	75N91024R00013		Sept 23, 2024
Contract Solicitation	PHS 2024-1		Closed

* NOFO: Notice of Funding Opportunity
** NOSI: Notice of Special Interest

GO TO MARKET WITH NCI SBIR!

More than one way to SBIR/STTR funding!



FUNDING MECHANISMS

GRANTS

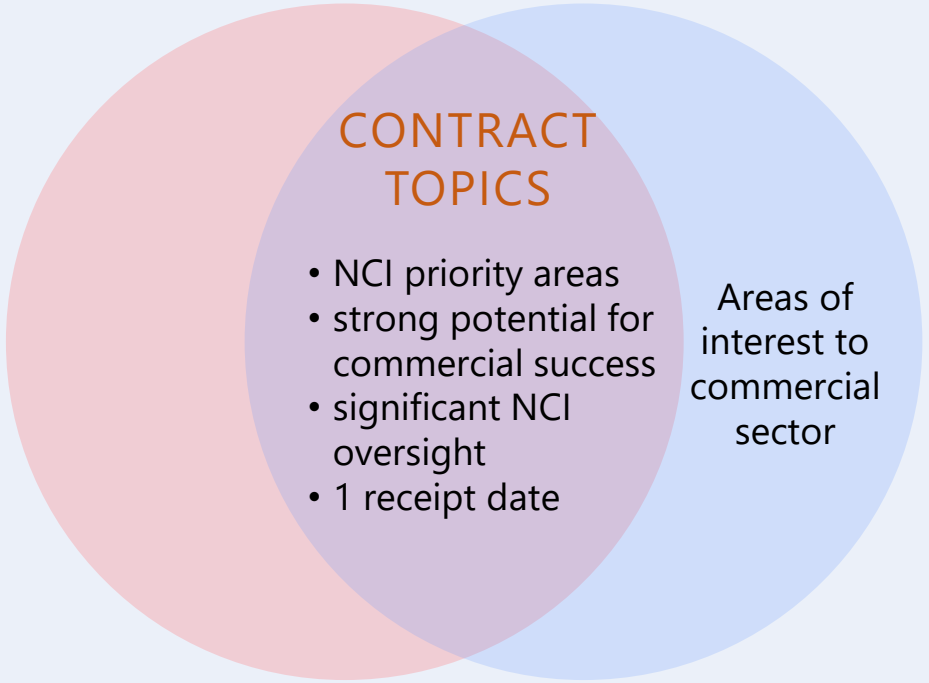
Omnibus Solicitation

- Investigator initiated
- 3 receipt dates (January, April, September)

Targeted Solicitation

- Focused/NCI gap/ priority areas
- Variable receipt dates

CONTRACTS

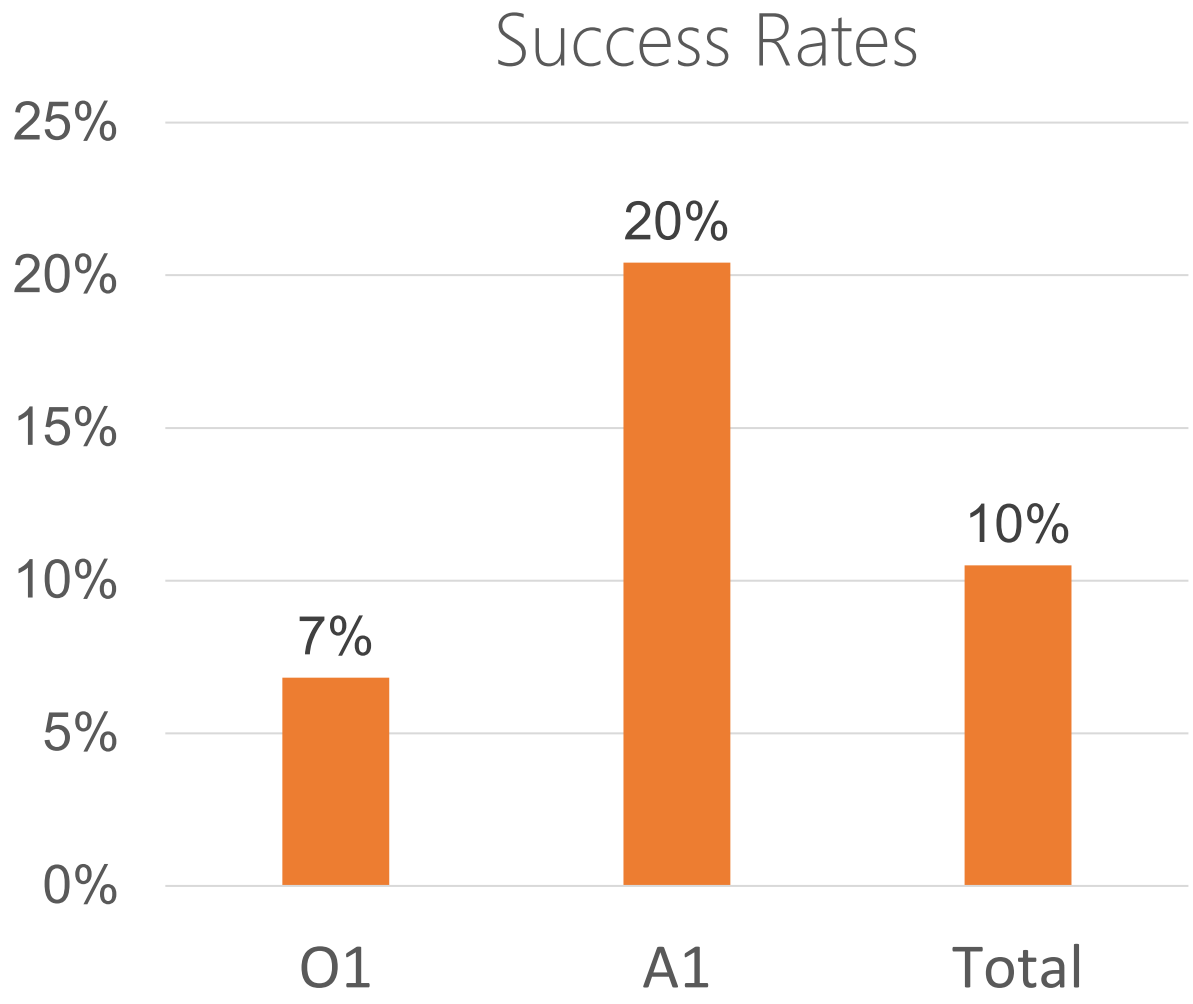


GRANTS VS. CONTRACTS

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

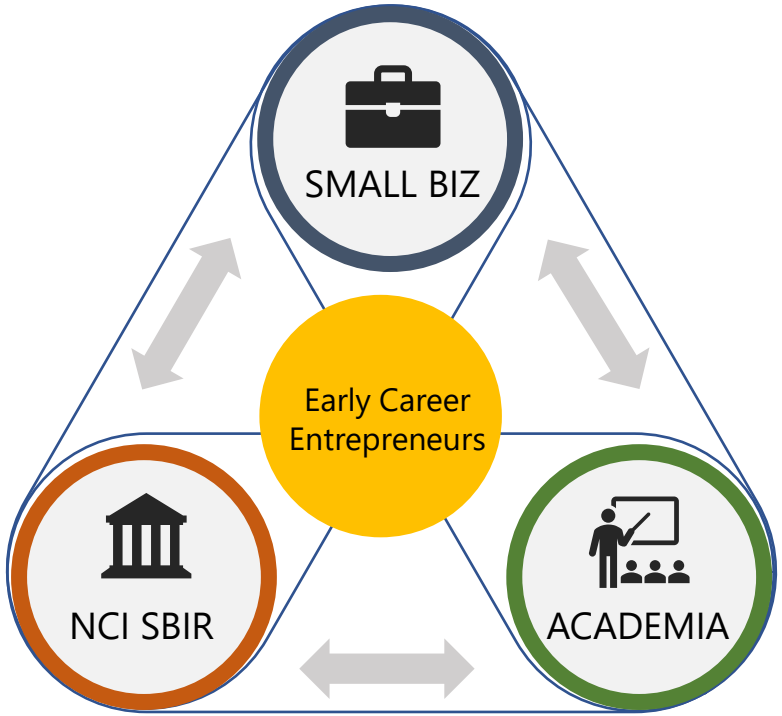
FY21 GRANTS SUCCESS RATE

Grant Type (Phase I, Phase II, Fast-Track, Phase IIB, Direct-To-Phase II)	Number of Competing Applications	Number of Competing Awards
Original Submission (O1)	1056	72
Resubmission (A1)	392	80
Total (O1 + A1)	1448	152



SMALL BUSINESS TRANSITION GRANT

Funding support for early-career academic entrepreneurs (e.g., Postdocs) to advance innovative technologies from the academic lab bench to the clinic.



- First of its kind of funding opportunity at the NIH and the NCI.
- $2.65 M Fast-track award for early-career entrepreneurs that combines a Phase I STTR & Phase II SBIR. (Maximum 10-years from terminal degree)
- Phase I STTR-only option allowed
- Mentoring team is key component of the award – critical for successful transition to product development.
- Solicitation: RFA-CA-24-023
- Deadline: Closed
- Interested companies to send letter of intent 30 days prior to deadline

SBTG awardees: *a local NY story*

Dr. Kacey Ronaldson
PI

Dr. Gordana Vunjak-Novakovic
Technical Mentor

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

Link Biosystems

Link Biosystems is creating a systemic human pre-clinical model for cancer drug development

Part of BiomedX accelerator

SMALL BUSINESS CONCEPT AWARD

Website: https://sbir.cancer.gov/small-business-funding/contracts/innovative-concept-award

Solicitation: 75N91024R00013

- Deadlines:
  - White Paper: Closed
  - Full Application: Closed

Goal

- Support high-risk/high-reward technologies in pediatric/rare cancers
- De-risk disruptive innovation
- Contract; not a Grant

Special Features

- Submission of White Paper to get Program input
- Short applications (15 pages v/s 50)
- Preliminary data are not required
- Special Review Criteria (50 % v/s 25% scoring is based on innovation)
- Make awards rapidly (within six months)
- $300K total costs
- 1 year award

Support

- Leverage NIH I-Corps Program
- Followed by another Phase I, Direct to Phase II or Fast-Track

HIGH-RISK HIGH-REWARD RESEARCH

NCI SBIR INNOVATIVE CONCEPT AWARD

Acceleration of out-of-the-box & high patient need rare/pediatric cancer technologies – from concept to clinic

OBJECTIVE

- High-risk/high-reward projects, focusing on innovation
- Transformative technologies to address rare and pediatric cancer

FUNDING

- $300K SBIR Contract (1 year) - Fund experiments to obtain initial de-risking and proof-of-concept data
- Follow-on Phase II ($3-3.5M) in FY25

APPLICATION PROCESS

- High response rate with ~100 white papers and ~50 full proposals each year
  - 23 awards ($300K) made through FY22-24
- Intra-agency coordination of 70 white paper reviewers/fiscal year

KEY ASPECTS

- 78% of awards represent indications heavily underrepresented in the portfolio
- 74% of awardees are companies new to NCI SBIR funding

Disruptive Innovation Example:

Angstrom Research

- Developing a new time-of-flight PET sensor that can result in a 10-100-fold increase in PET scan sensitivity, improving pediatric cancer diagnosis and treatment planning.
- Increased PET scan sensitivity can lead to several imaging paradigm shifts such as utilization of short half-life tracers, shortened scan durations, and reduced radiation dose.
- Faster scanning can eliminate the need for pediatric patient sedation and anesthesia.

NCI SBIR PHASE IIB BRIDGE AWARD

PHASE I

PHASE II

NCI SBIR PHASE IIB BRIDGE AWARD
CROSSING THE VALLEY OF DEATH

COMMERCIALIZATION

- Solicitation: RFA-CA-21-036 (Closed)
- Funding: $4.5 Million over the period of 2-3 years
- Eligibility: Phase II awardees from any Federal agency with cancer-focused projects
- Matching funding:
  - Awardees leverage federal funding to attract private investments and partnership with strategic partners
  - Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., ≥ 1:1 match)
- Through FY 2024, Phase IIB Bridge program has made
  - 2-6 awards/year (60 awards in total)
  - $170 Million in funding distributed
  - Companies leveraged NCI SBIR funding to secure $4 from third party for every $1 from NCI SBIR (2017 data)
  - 21 products launched including new devices, diagnostics, and research tools for cancer patients

SUCCESS STORY: *Tovorafenib*

Tovorafenib (OJEMDA)
First and only FDA-approved Type 2 RAF inhibitor for patients 6 months of age or older with pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

2003-2011 — SBIR, Takeda

Sunesis Pharmaceuticals received **SBIR award** and used it to conduct early-stage preclinical testing/discovery of tovorafenib; Takeda licensed it for clinical work in melanoma

2020-2023 — Day One BIOPHARMACEUTICALS

Day One Biopharmaceuticals licensed tovorafenib for application toward relapsed or refractory **Pediatric Low-Grade Glioma (pLGG), most common pediatric brain tumor;** Phase 2 Firefly-1 clinical study results published, demonstrating **major efficacy outcome measure of overall response rate**

2024 — FDA

FDA **accelerated approval** for patients with relapsed or refractory BRAF-altered pLGG

FY25 SBIR CONTRACT TOPICS

Program Solicitation
PHS 2025-1
[view solicitation]

Proposal Types
Phase I, Phase II, Fast-Track, Direct to Phase II

- NIH/NCI 466 - Novel Delivery Systems for RNA-based Cancer Vaccines
- NIH/NCI 467 - Development of Cancer Immunoprevention Agents
- NIH/NCI 468 - Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies
- NIH/NCI 469 - Development of Novel Therapeutics for HPV-related Precancer
- NIH/NCI 470 - Precision Nutrition Interventions to Reduce Cancer-Related Symptoms
- NIH/NCI 471 - Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention
- NIH/NCI 472 - Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer
- NIH/NCI 473 - Point of Care Detection of Antibodies Against HPV16/18 E6 and E7 Oncoproteins in Oropharyngeal Cancer
- NIH/NCI 474 - Point of Care Technologies for GI Cancer Prevention and Early Detection
- NIH/NCI 475 - Development of Digital Biomarkers and Endpoints for Clinical Cancer Care
- NIH/NCI 476 - Digital Twin Software for Optimization of Cancer Radiation Therapy
- NIH/NCI 477 - Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment
- NIH/NCI 478 - Advanced Biomaterials to Improve Cancer Modeling for Research

RESOURCES FOR SBIR APPLICANTS

ENTREPRENEURSHIP COURSEWORK

- Developed with CCT; no separate set-aside; $300K direct costs for up to 5 years
- Support development of programs that will equip the next generation of cancer researchers with entrepreneurial training

PURPOSE	Promote the development of entrepreneurial education programs to broaden the skillset of graduate students and postdoctoral researchers, as well as early-career master's, Ph.D., M.D., M.D./Ph.D., and Dr.P.H. scientists, in fields relevant to the NCI mission
REQUISITES	Courses and workshops with a broad scope: product development, commercialization, scientific communication, tech transfer, science policy, drug development, regulatory affairs, finance, marketing, business dev & research administration.
ELIGIBILITY	Broad eligibility for educational institutions. We encourage partnering with existing NIH-funded or other federally funded resources and programs, including NIH Centers for Accelerated Innovations (NCAI), NIH Research Evaluation and Commercialization Hubs (REACH) and NIGMS IDeA Regional Technology Transfer Accelerator Hubs, NSF-I-Corps, and NCATS Clinical and Translational Science Awards (CTSA).

https://grants.nih.gov/grants/guide/notice-files/NOT-CA-24-001.html

ENTREPRENEURSHIP BOOTCAMP

HISTORY

- The program originated from the NIH I-Corps initiative established by the NCI SBIR Development Center
- Recently, NIH SEED launched a new program with contributions from various ICs

GOAL

- Offer early-stage (pre-SBIR) innovators a foundational understanding of customer discovery and business model validation
- An excellent opportunity for academic innovators interested in entrepreneurship training and/or academic spinouts

MECHANICS

- Virtual bootcamp over 7 weeks, requiring about 10-20 hours per week of effort from the team
- The selected team will interview a minimum of 30 prospective customers

TOPICS COVERED

- Hypothesis development, Market segmentation, culminating in a lessons learned presentation

APPLICATION PORTAL: https://seed.nih.gov/entrepreneurial-training/bootcamp

NCI STEP | NCI SBIR/STTR Training and Entrepreneurship Program

ELIGIBILITY

- US-based small businesses
- No prior NIH SBIR/STTR awards (in last 10 years)
- Submitting a Phase I SBIR/STTR to NCI for Sept 5, 2025

STEP APPLICATION DEADLINE

- **TBD (Spring 2025)**

	STEP PROVIDES ✓	STEP DOES NOT PROVIDE ✗
Stage 1: Customer Discovery (6 weeks)	Instruction from STEP coach on conducting customer discovery interviews and business model development	Market research
Stage 2: Application Preparation and Submission (10 weeks)	Phase I SBIR/STTR application preparation support and review	Grant writer
	Specific aims page and research strategy review	Research plan development
	Phase I SBIR/STTR submission process coaching	Small business registration or NIH application submission services
Post Submission Support (5 hours)	Support on post-submission activities including summary statement review, resubmission process, and just-in-time procedures	NIH application/JIT submission services

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

MATCHUP

Facilitating connections between new scientific talent with small business SBIR/STTR awardees to apply for a Supplement.

1. Apply to MATCHUP – Email MATCHUP Program Manager (PM) Melissa Li (melissa.li@nih.gov) for an application to be screened for eligibility. (Trainees will have screener call with MATCHUP PM).

2. Partner via MATCHUP – Accepted participants are invited to online platform to identify potential partners. Matches will be introduced via MATCHUP PM.

3. Apply to Supplement – Partnered trainees and small businesses are encouraged to speak to their Program Director before applying to a Supplement.

https://sbir.cancer.gov/small-business-funding/supplement/matchup

NCI SBIR ECONOMIC IMPACT STUDY

- Phase II awards initiated from FY 1998 to FY 2010
- 444 companies
- 690 separate projects

$9.1 BILLION
in total sales to date of products and services resulting from the NCI SBIR/STTR Phase II awards

$26.1 BILLION
in total economic output nationwide

368
awards with sales, royalties, and follow-on R&D funding

$2.9 BILLION
in new tax revenues (federal, state, and local)

$8.1 BILLION
in labor income

107,918
new jobs created with an average compensation of **$75,385**

https://sbir.cancer.gov/portfolio/impact-study

NCI SBIR PATIENT IMPACT 2020-2023

36
Regulatory approvals

38
First dosed in human

21
IND/IDE applications

13
Product launches

Regulatory Approvals

Company Name	Name of Drug/Device	Indication
C4 Imaging	Sirius® positive-signal MRI Markers	Prostate Cancer
Carina Medical	INT Contour	Radiation treatment planning
Carmot Therapeutics	LUMAKRAS™ (sotorasib)	KRAS mutated metastic NSCLC
Delphinus Medical Technologies	SoftVue™ 3D whole breast ultrasound tomography	Mammograms for dense breasts
DoseOptics	BeamSite™ System	Photon external beam radiotherapy
G1 Therapeutics	COSELA™ (trilaciclib)	Chemotherapy-induced myelosuppression
Immunomedics	Trodelvy (sacituzumab govitecan-hziy)	Metastatic TNBC Metastatic urothelial cancer
Invenio Imaging	NIO Laser Imaging System	Histology of unprocessed tissue Brain tumor surgery
MacroGenics	MARGENZA (margetuximab-cmkb)	Metastatic HER-2 positive breast cancer
NView Medical	NView S1 With Nav Option	Surgical guidance for spine procedures
On Target Laboratories	CYTALUX fluorescent imaging agents	Ovarian cancer Lung Cancer
Promega Corp.	OncoMate™ MSI Dx Analysis System	Detect MSI status in CRC
Pulse Biosciences	Cell FX	Skin-ablation procedures
Quantitative Radiology Solutions	Automatic Anatomy Recognition (AAR) technology	Radiation treatment planning
RefleXion Medical	RefleXion™ X1 machine	Radiotherapy and radiosurgery
Seattle Genetics	Adcetris (brentuximab vedotin)	Pediatric classical Hodgkin lymphoma
Voximetry	Torch	Dose assessment for radiopharmaceutical therapy

BREAST CANCER

1 in 8

women will be diagnosed with breast cancer in her life time

Awareness Education
4 Funded Projects

Imaging
52 Funded Projects

6 Marketed Products

Pathology
21 Funded Projects

4 Marketed Products

Treatment
29 Funded Projects

3 Marketed Products

Quality of Life
18 Funded Projects

3 Marketed Products

Breast Cancer Funding

124
Phase II Projects

$145M
Awarded

16
Marketed Technologies

PATIENT IMPACT: BREAST CANCER

Imaging

Koning Brest CT - CT scanner that produces 3D visualization through cone beam technology
- First commercial 3-D breast CT scanner
- 10 second scan time

LumaGEM® - MBI system that delivers scans by using dual headed cadmium zinc telluride (CZT) imager
- Molecular breast imaging

MammoReader® - Computer-aided detection (CAD) system designed to analyze mammographic images
- Radiologists' second pair of eyes

TOMO™ Application - 2D anti-scatter grids for digital and film screen mammography
- Stationary anti-scatter grids

Breast Companion® - Computer-aided imaging system (CAIS) intended for ultrasound interpretation
- Ultrasound computer-aided diagnostic tool

PEM Flex Solo II - PEM Scanner designed to provide images with high resolution and high count efficiency
- Specifically developed for close-range and spot

Pathology

CELLSEARCH® - Liquid biopsy test for detecting tumor cells in peripheral blood
- First and only FDA-approved circulating tumor cell (CTC) blood test

EndoScout® - Navigation system enables MRI guided interventions
- Real time tracking during MRI scan
- Works on any type of scanner

Stereo Navigator™ - Breast-PET guided biopsy accessory used to define location and extent of breast lesions
- First FDA-cleared PET-guided biopsy tool

INFORM HER2 Dual ISH DNA Probe Cocktail - HER2 assay that determines HER2 gene status for in vitro diagnostic use
- HER2 gene amplification test with full automation
- 12 hour run time

Treatment

Zenascope™ PC1 - Tissue spectrometer enabled non-destructive and real-time monitoring of biologic tissue
- Real time measurement
- Harmless monitoring with white light

TomoTherapy® - Radiation therapy device that combines imaging and treatment delivery
- 360° radiation delivery
- CT guided patient positioning

GammaPod™ - Image-guided radiation system that provides stereotactic therapy to patients with early breast cancer
- First stereotactic radiotherapy system for breast c
- Patented vacuum-assisted cup system

Quality of Life

Walking through the Storm - 4-hour audio program aimed at enhancing quality of life via spoken-word presentations about cancer survivorship
- Distributed by public radio
- Digital copies available

ENVISION - Multi-media program focused on stress reduction for breast cancer survivors
- Up-to-date behavior medicine
- Clinically tested

PainACTION® - Interactive online program for coping with chronic pain
- Personalized medical education
- Step-by-step pain managementt guide

APPLICATION TIPS

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.

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

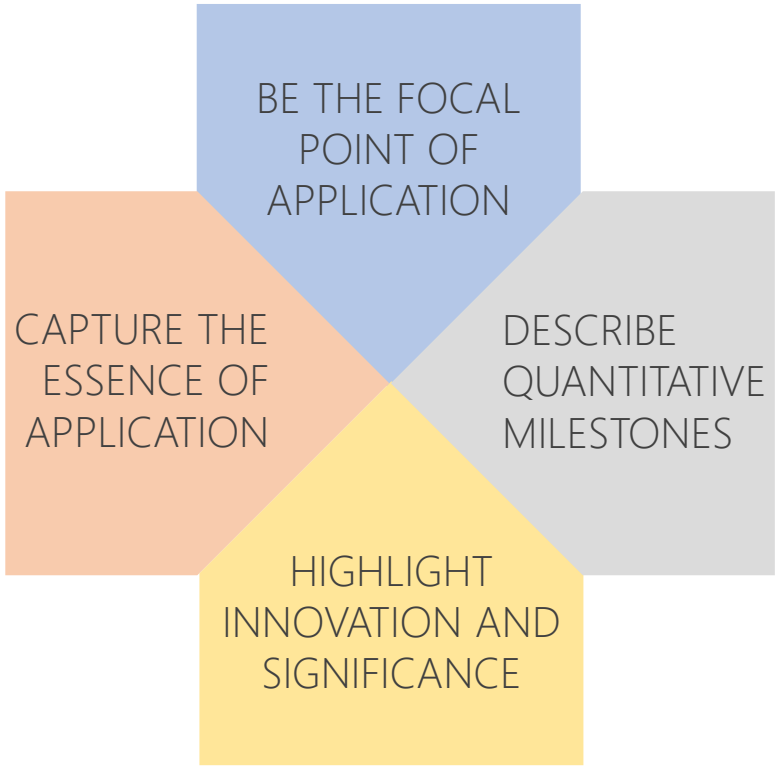
- **Complete the administrative registrations**
  - Four Required registrations (https://sbir.nih.gov/infographic)
  - Send specific aims to Program at least a month before

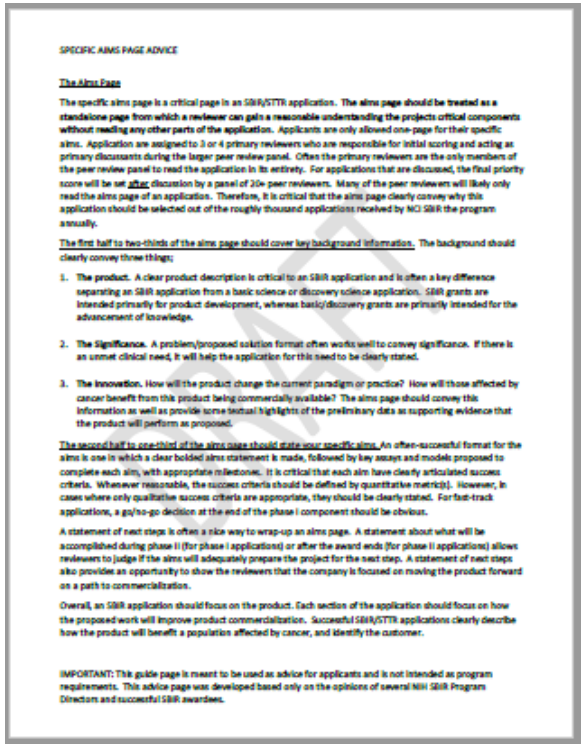
TIP 2: REFINE YOUR PRODUCT VISION

- **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 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 4: UNDERSTAND PEER REVIEW

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

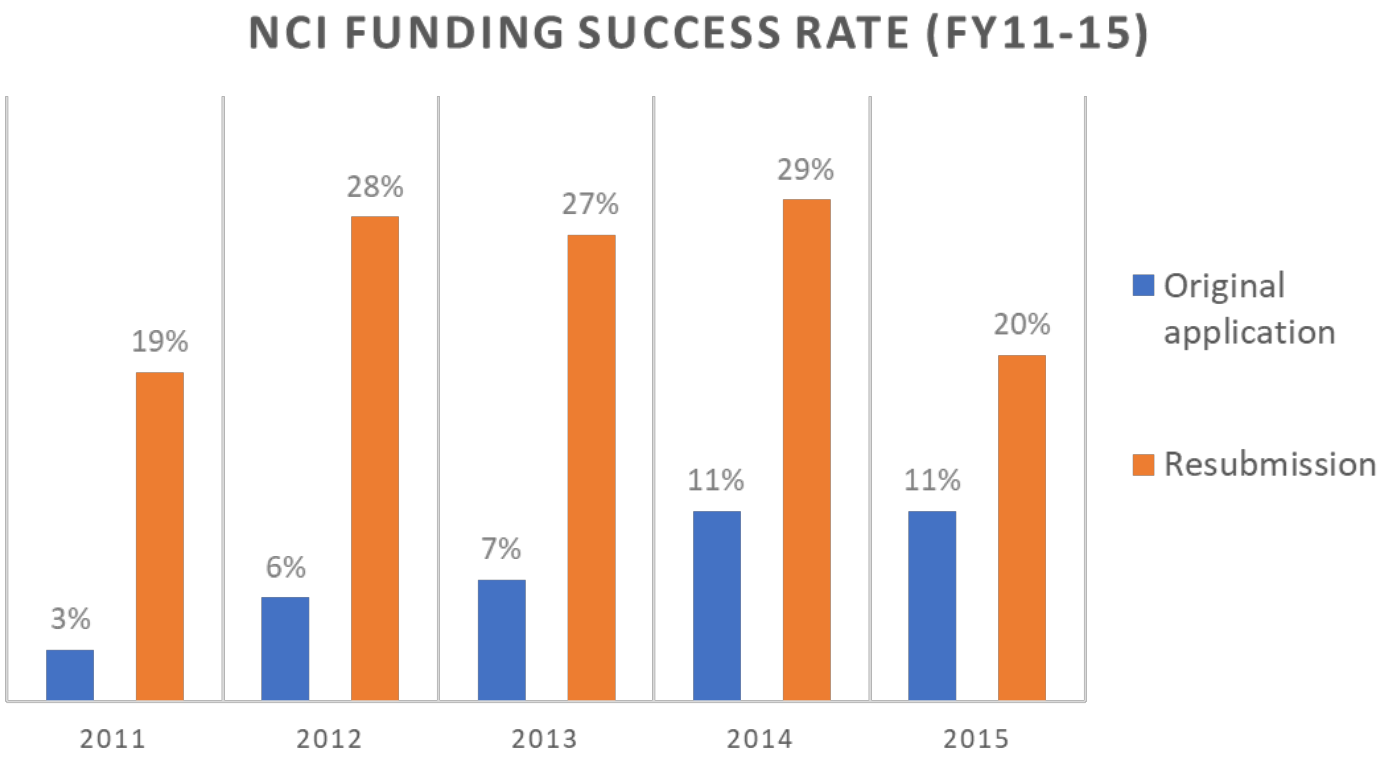
Is the company's business strategy one that has a high potential for success?

INNOVATION

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

TIP 5: 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!



REACH OUT TO A PROGRAM DIRECTOR

Michael Weingarten, MA
Director

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

William Bozza, PhD
Program Director

Therapeutics, Biologics, Small Molecules, Regulatory (CMC), Concept Award, PLAN Webinar

Sarra Djemil, PhD
Program Director

Therapeutics & Mentoring

Melissa Li, PhD
Program Director

Biologics, Small Molecules, Digital Health, AAP

Jian Lou, PhD
Program Director

In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investor Initiatives

Saroj Regmi, PhD
Program Director

Therapeutics, Diagnostics, Imaging, Digital Health, Investor Initiatives, Small Business Transition Grant, I-Corps

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

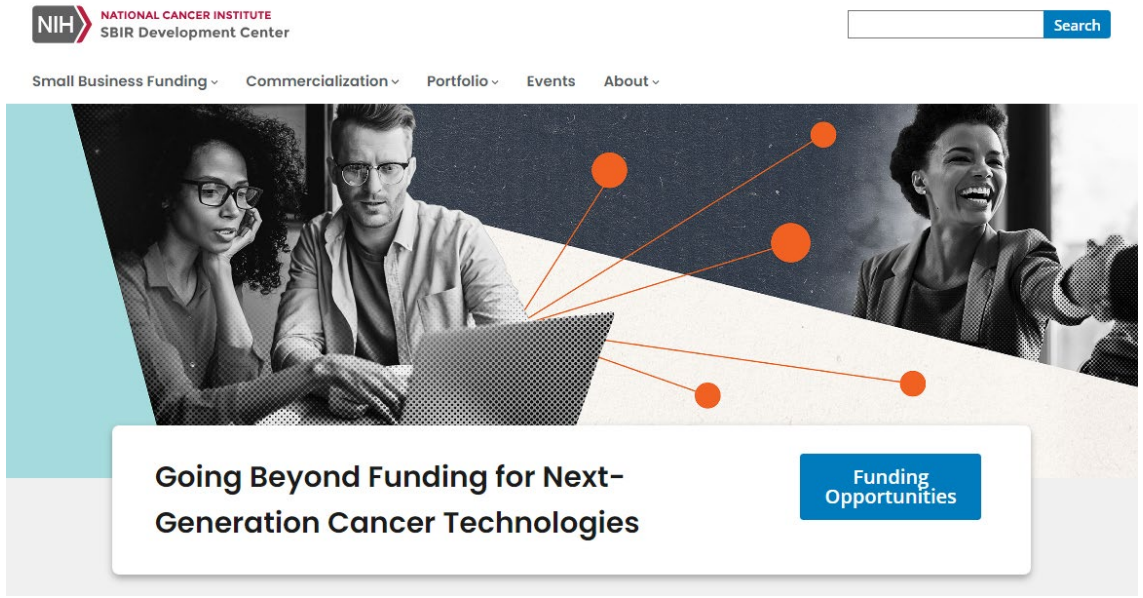
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

Linda Zane, PhD
Program Director

Therapeutics, Diagnostics, Research Tools

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

STAY IN TOUCH!



https://sbir.cancer.gov

https://www.linkedin.com/company/nci-sbir-development-center/

https://twitter.com/ncisbir

NCI SBIR Innovation Lab Podcast

https://sbir.cancer.gov/about/innovation-lab-podcast

MICHAEL WEINGARTEN weingartenm@mail.nih.gov

THANK YOU

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SBIR
DEVELOPMENT CENTER

NIMHD SBIR/STTR Health Disparities Program

CDR Michael Banyas, USPHS, MPA, MA NIMHD
SBIR/STTR Program Manager
Community and Scientific Programs

NIH National Institute on Minority Health and Health Disparities

NIMHD PROGRAM GOALS

We are disease-agnostic
Focus not drugs, but devices, services, digital health, and other means to close health equity gaps (market opportunities)

1) Promote research to understand and to improve the health of racial/ethnic minority populations

2) Advance scientific understanding of the causes of health disparities

3) Develop and test interventions to reduce health disparities

4) Create and improve scientific methods, metrics, measures, and tools that support health disparities research

NIH HEALTH DISPARITY TERMS & RECOGNIZED POPULATIONS

Health Disparity Definition

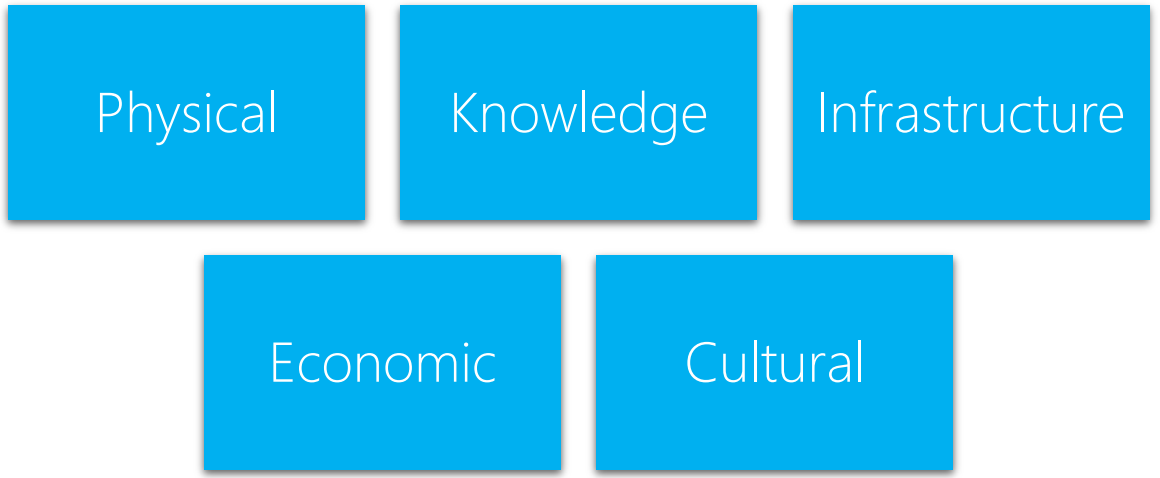
A health disparity is a health difference that adversely affects disadvantaged populations in comparison to a reference population, based on one or more health outcomes. All populations with health disparities are socially disadvantaged due in part to being subject to racist or discriminatory acts and are underserved in health care.

Health Disparities Recognized Populations
Hispanics/ Latinos
Rural areas
American Indians/ Alaska Natives
Sexual/gender minorities
Socio economically disadvantaged individuals
African Americans/ Blacks
Native Hawaiians and Other Pacific Islanders
Asian
People Experiencing Disabilities NEW Sept 2023
North African and Middle Eastern New 2024

NIH National Institute on Minority Health and Health Disparities

NIMHD SBIR/STTR RESEARCH CONSIDERATIONS

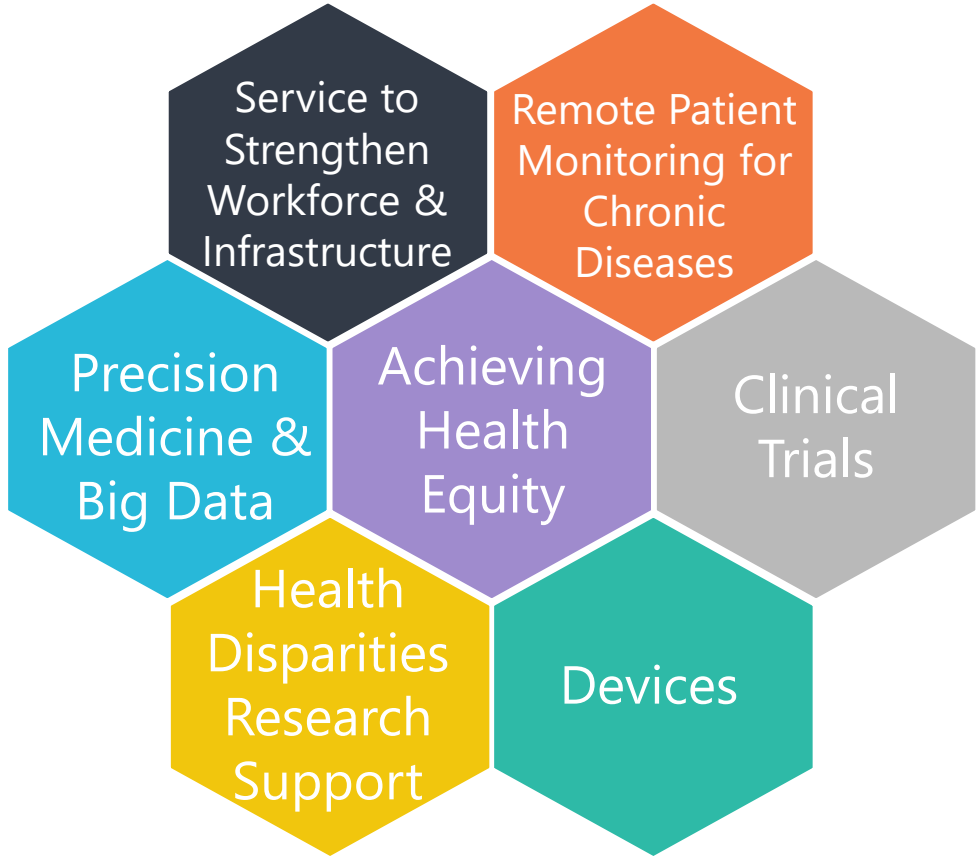
Buckets Identified as Barriers for Health Equity (i.e, access) at the individual, family, community, and population level



If a process takes steps A+B+C+D= health delivery, how to eliminate or amend a step (reduce friction) to delivery your ends

EXAMPLES OF SAFETY NET PROVIDERS & DIGITAL HEALTH MARKET OPPORTUNITIES

Types of Safety Net Providers
Federally Qualified Health Centers
Medicaid and Medicare Providers
Social Services
Homeless Shelters
Community Care Clinics
Public Hospitals
HRSA & SAMHSA funded Programs



QUESTIONS & CONTACT INFO

NIH SBIR/STTR Omnibus Jan, April and Sept Application Dates

NIMHD Innovations for Health Living June and December Application Dates

Womens Health and Research for Health Disparities Populations
COMING SOON

National Institute on Minority Health and Health Disparities	**CDR Michael Banyas** **Phone: 301-402-1366** **Email: banyasmj@nih.gov**

NIH National Institute on Minority Health and Health Disparities