

November 30, 2023

Small Business Transition Grant (SBTG)

RFA Concept Review

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SBIR and STTR: *congressionally mandated programs*

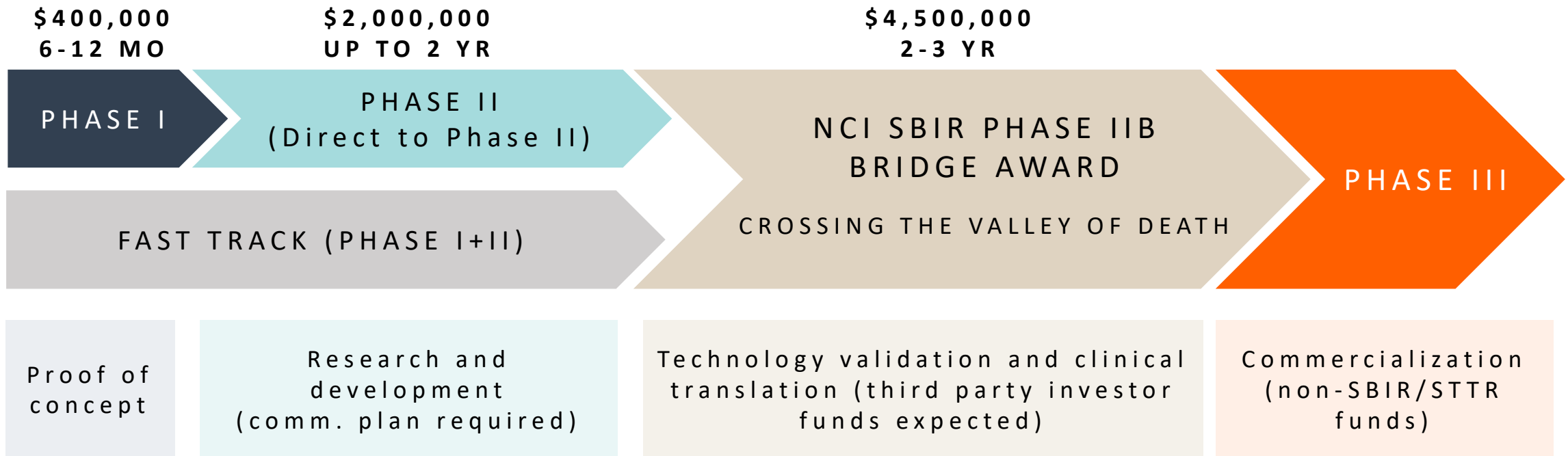
Set Aside for FY23

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
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
	Total	\$203M for NCI \$1.3B for NIH

STTR requires a university (non-profit) partner; SBIR allows it.

No impact on RPG!

SBIR/STTR is a Three-Phase Program



The award is ALWAYS made to the small business concern

Postdocs are vital for tech translation

Based on 62/70 NCI Cancer Center-serving Institutions:

1. Postdocs are key for spin out of university technology. They move with the technology to a small business
2. However, they are mostly early career scientists and need business experience and/or training



Experienced NIH investigators* have highest SBIR/STTR success

*Have received an R01 or equivalent award

- Includes SBIR/STTR Phase II. Does not include SBIR/STTR Phase I.

How can SBIR awards help spin out of NCI-funded technologies?

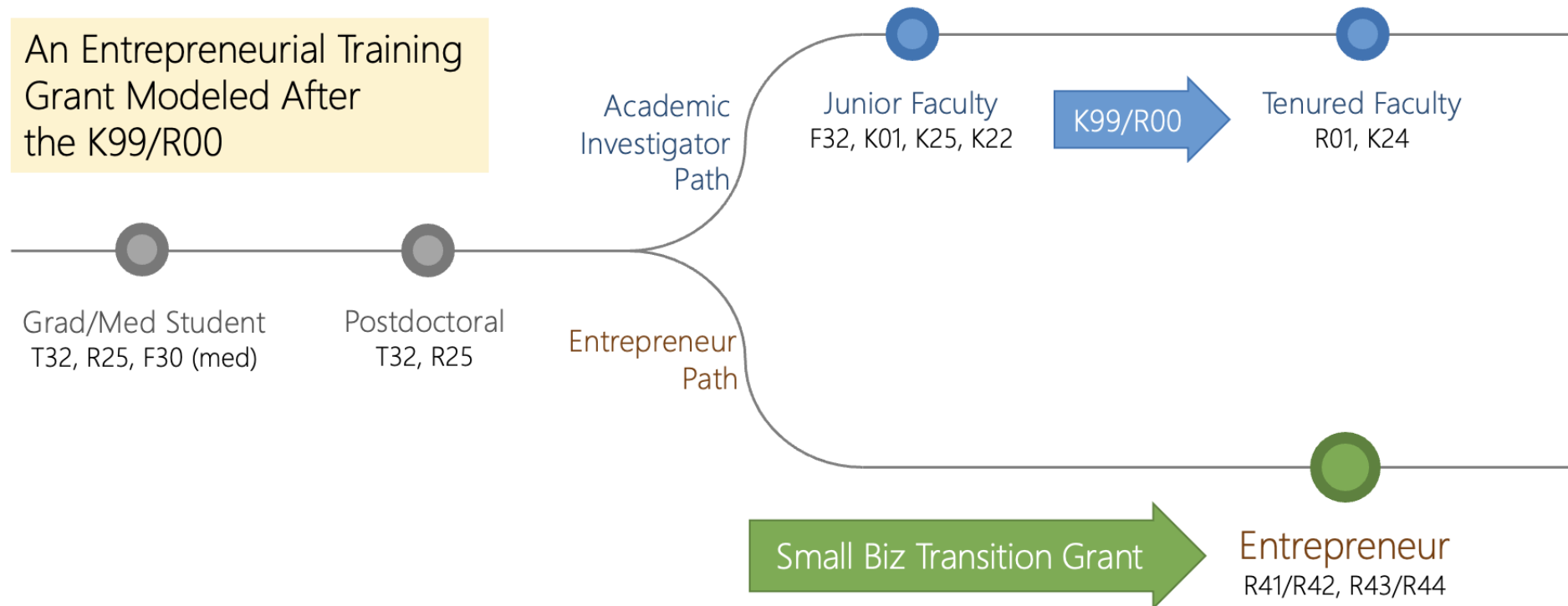
- Create SBIR grant focused on early-stage investigators
- Require mentoring (both research and entrepreneurial)
- Provide entrepreneurial training
- Provide funds to spin out technology
- Provide flexibility by allowing them to remain at a university initially



Small Business Transition Grant (SBTG)

Goal: Facilitate technology transfer from university to startups by providing funds and a mentored opportunity to ESIs

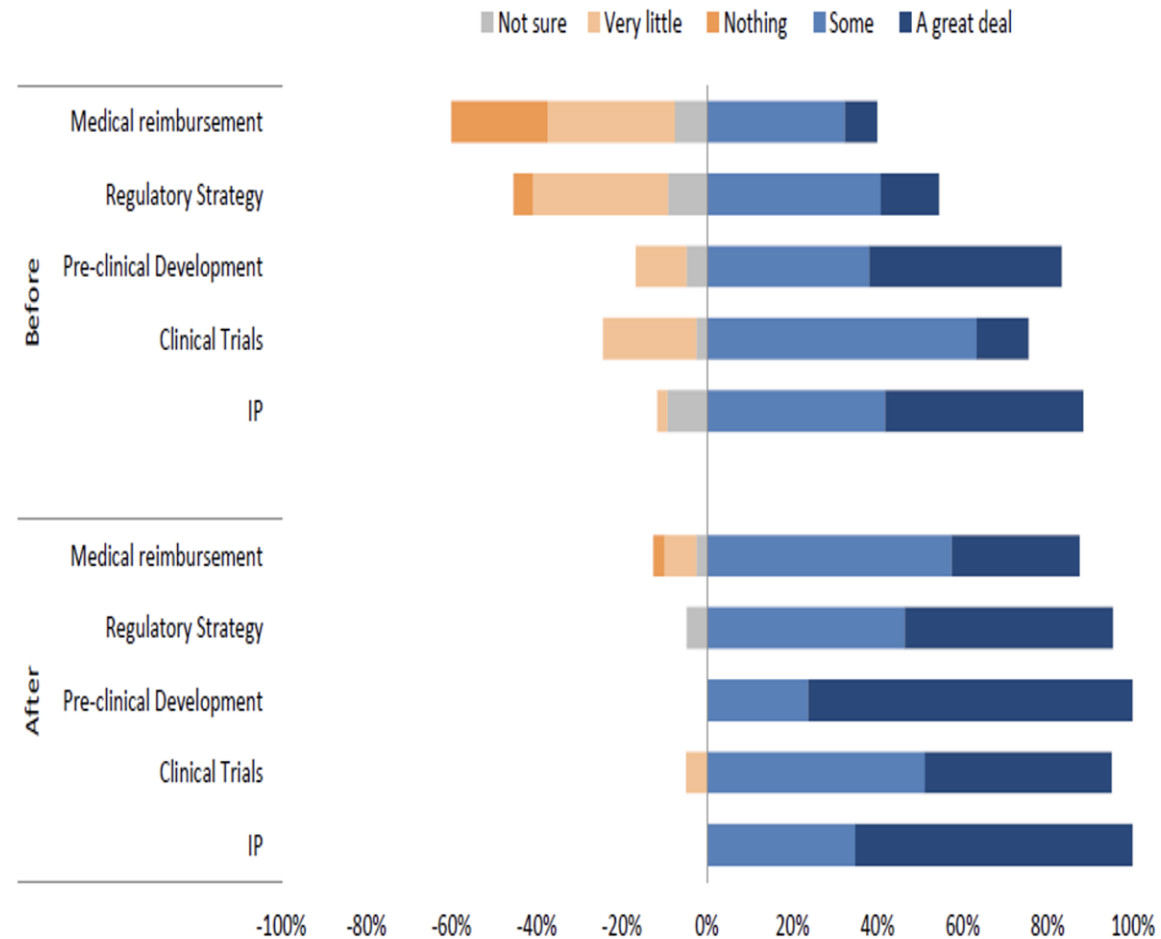
- Modeled on K99/R00: *phase I at University, phase II at Small Business*



Small Business Transition Grant

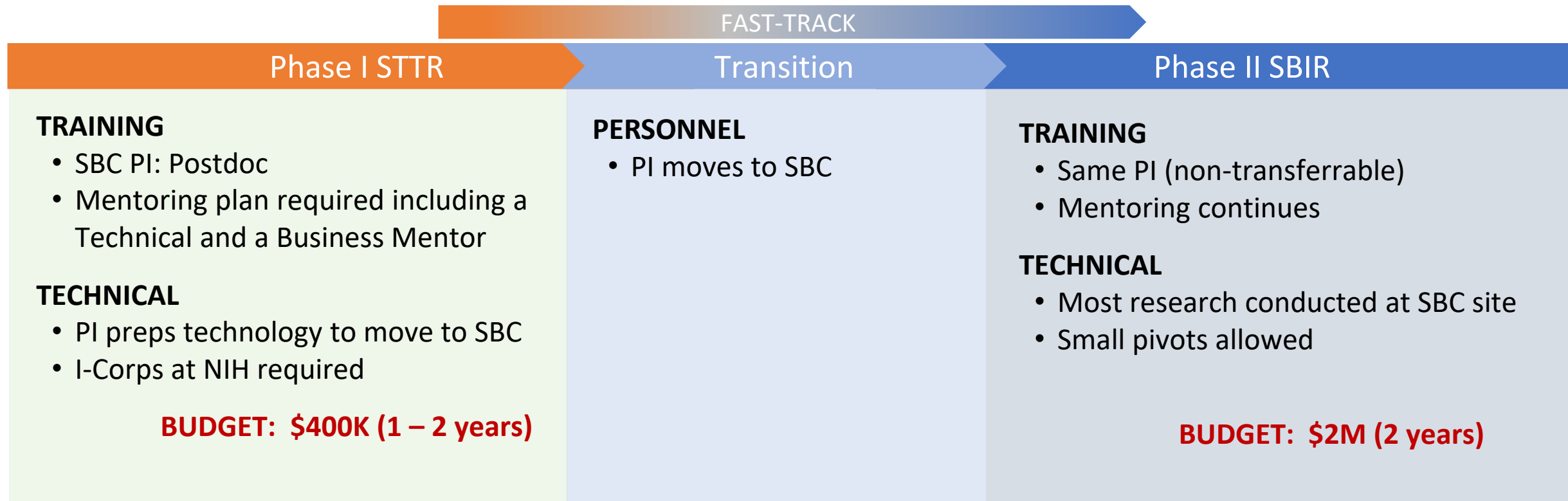
Entrepreneurial training required through I-Corps entrepreneurial training program

Commercialization of life science technologies requires consideration of the following key topic areas. For each component, indicate your level of knowledge.



Small Business Transition Grant

- Fast-track mechanism: *requires 1 application for Phase 1 and Phase 2 both!*
- PI within 10 years of PhD; 2 mentors: *Technical & Business Mentor*
- Permanent residency and/or US Citizenship required



Program has a strong interest

- Strong interest from potential applicants:
 - One-on-One
 - Conferences
 - Academics
- Positive feedback from community, applicants and awardees:
 - Cancer Center
 - Small Businesses
- NIH wide program in development given the interest and feedback

	2018	2019	2020	2021	2022	2023
SBTG Applications	n/a	n/a	n/a	15	11	15
SBTG Awards	n/a	n/a	n/a	4	1	TBD
All Phase II STTR (excluding SBTG)	42	31	40	39	44	34
All Phase II STTR Awards (excluding SBTG)	12	6	6	3	10	9

First cohort of awards: Kovina Therapeutics



KOVINA
THERAPEUTICS, INC.



PI:

- Dr. Anne Reitz worked in Dr. Elliott Androphy's lab, who has developed Spinraza (a therapeutic to treat spinal muscular atrophy).

Technology:

- Small molecular inhibitor of HPV-16 E6 oncoprotein to treat HPV-related cancers including cervical cancers
- The therapeutic has the potential to stop HPV infections before cancer develops and to treat HPV-related cancers after detection

Project status:

- Identified lead compound and tested *in vivo* in Phase I and successfully transitioned to Phase II in summer 2023 where they will complete IND-enabling studies
- Closed \$2M seed round and began Series A raise recently

First cohort of awards: Leukogene Therapeutics



PI:

- Dr. Robinson Reeder worked in Dr. Nathan Dollof's lab at the Medical University of South Carolina

Technology:

- Developing cancer vaccine to treat PDAC
- The vaccine uses a mutated form of Streptococcal Mitogenic Exotoxin Z-2 along with the protein Anterior Gradient-2 (AGR-2).
- AGR-2 normally ER-associated; cell surface expression observed in cancer cells

Project status:

- Completed *in vivo* efficacy studies of AGR2-SMZ2 in KPC mouse models
- Successfully transitioned in Phase II in summer 2023
- Phase II will assess efficacy in orthotopic KPC mouse models in combination with check-point inhibitors and complete IND-enabling work

Evaluation Committee and Methodology

- Individuals from academia, industry and tech-transfer
- Our Office (NCI SBIR Executive Secretary) presented Concept Award overview and update, including program metrics and non-confidential project information
- Evaluation Committee interviewed awardees regarding the overall program, as well as I-Corps instructors to understand the need and value of the program
- Based on this, the committee generated a written Evaluation Report detailing findings and recommendations
- Evaluation Report included in renewal documentation

Strong enthusiasm for the program but recommended some changes, particularly to increase the application numbers and eligibility

Major findings and recommendations

CHALLENGES

Most (up to 2/3rd postdoc foreign)

RECOMMENDATIONS

Expand eligibility for foreign trainees

Major findings and recommendations

CHALLENGES

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Not enough data for a fast-track

RECOMMENDATIONS

Expand eligibility for foreign trainees

Allow a Phase I STTR option

Major findings and recommendations

CHALLENGES

Most (up to 2/3rd postdoc foreign)

Not enough data for a fast-track

More outreach

RECOMMENDATIONS

Expand eligibility for foreign trainees

Allow a Phase I STTR option

Outreach involving multiple stake-holders

PI

*AACR,
Cancer Ctr.,
University*

Trainees

*Meetings,,
University,
Nucleate*

Mentors

*Tech transfer,
I-Corp Instr.,
Investors*

State BIO

*BIO
Webinars*

Fostering an ecosystem is a major challenge!

Most trainees require additional mentorship and training for a career in entrepreneurship

Building pipeline:

NOSI in development with the collaboration of CCT; entrepreneurship education for early-stage trainees

Market research & customer discovery:

NIH SEED Office currently developing an I-Corps program for entrepreneurs that do not have an SBIR grant

Application assistance:

Contracting in process for development of program that guides first-time applicants with customer discovery, grant writing, and post-award process

Company creation, IP, evaluation:

SBIR development center currently developing a new program to help university-based researchers with company creation, IP and technology assessment

Request: reissue the program

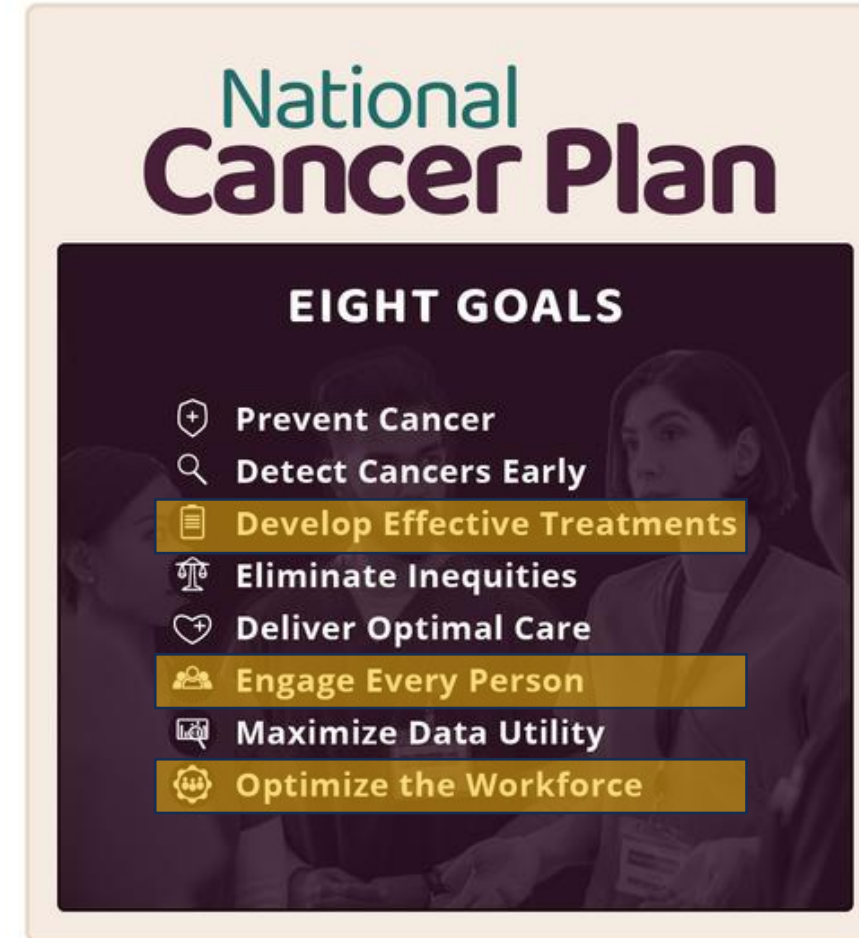
Phase I only STTR; allow foreign trainees

Why reissue the program?

- Facilitates spinout from NCI-Cancer Centers (4/5 funded)
- Aligns with National Cancer Plan goals (3,6 & 8)
- Provides training and mentorship for ESIs
- Uses SBIR/STTR funds => no RPG impact

Why use RFA mechanism?

- NCI DEA peer review important (*reviewers consisting of academics, industry and tech transfer professionals and I-corps instructors*)
- Set-aside reflects our commitment



A blurred background image of a laboratory setting, showing various pieces of glassware like beakers and flasks on a lab bench, with a person's hands visible in the upper part of the frame.

Questions?

Thank you!