SEPTEMBER 3, 2025

NCI STEP INFORMATIONAL WEBINAR

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PROGRAM DIRECTOR

SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE

SBIR
DEVELOPMENT CENTER

HOUSEKEEPING

- If you have questions, **please type them in the Q&A box**. Speakers will answer the questions at the end of the presentation.
- For additional questions about NCI STEP, contact ncistep@evagarland.com
- For additional questions about NCI SBIR, contact ncisbir@mail.nih.gov
- Next webinar: NCI STEP Q&A Webinar September 17, 2025

WEBINAR OVERVIEW

- **April 6, 2026 deadline cohort**

- About NCI SBIR/STTR
- About NCI STEP
- NCI STEP Application
- Q&A

NCI STEP

NCI SBIR/STTR Training and Entrepreneurship Program

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

ABOUT NCI SBIR/STTR

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.

SBIR 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)

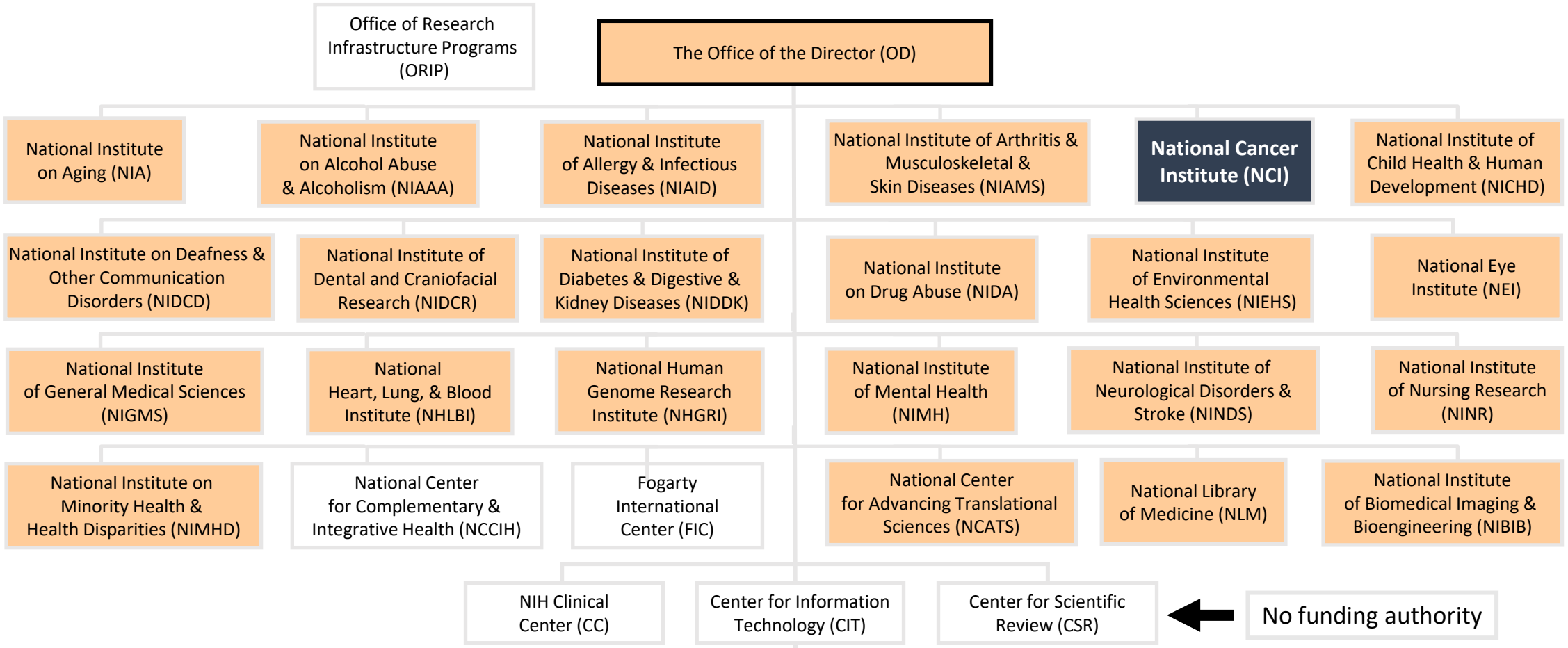
The award is ALWAYS made to the small business concern

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



CONGRESSIONALLY MANDATED PROGRAM

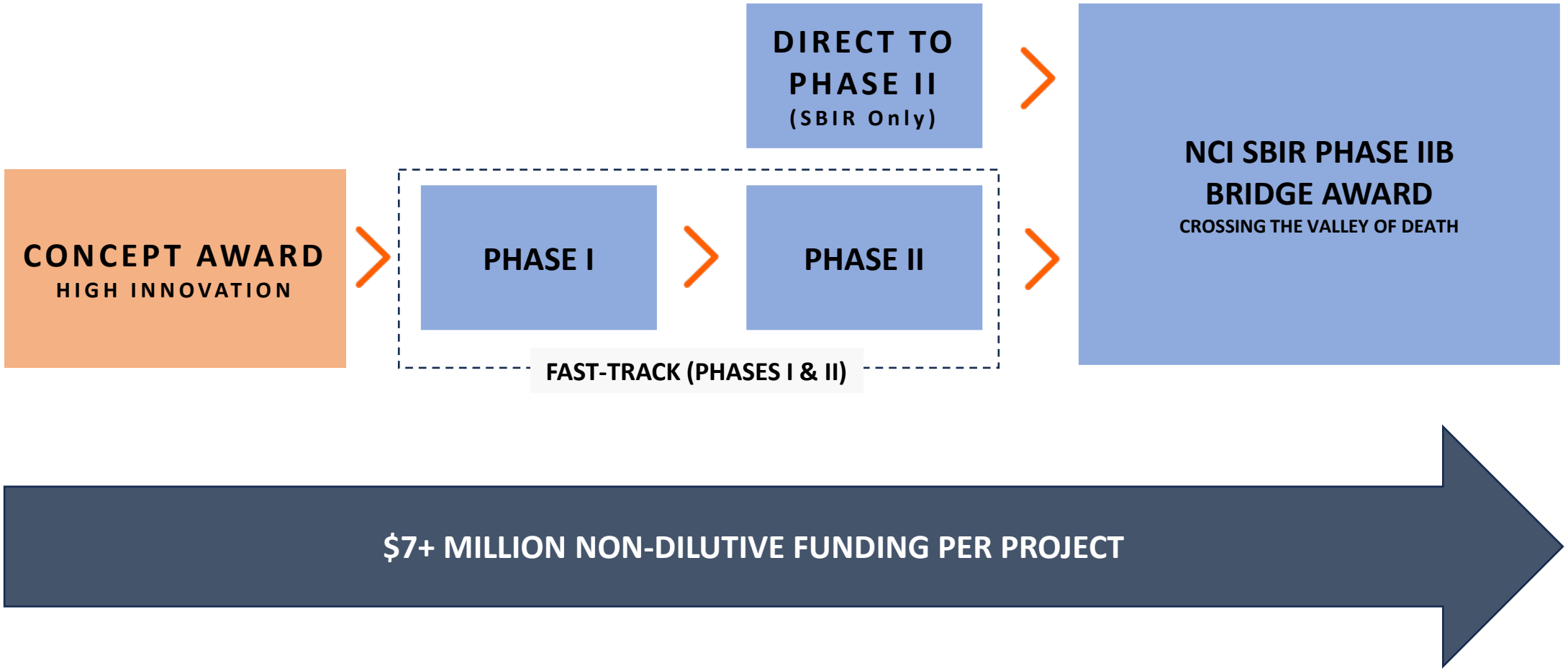
		Set Aside for FY24
SBIR SMALL BUSINESS INNOVATION RESEARCH	Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization *Federal agencies with an extramural R&D budget > $100M*	**$172M (3.2%)**
STTR SMALL BUSINESS TECHNOLOGY TRANSFER	Set-aside program 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*	**$24M (0.45%)**
	Total	**$196M for NCI** **$1.3B for NIH**

SBIR VS. STTR

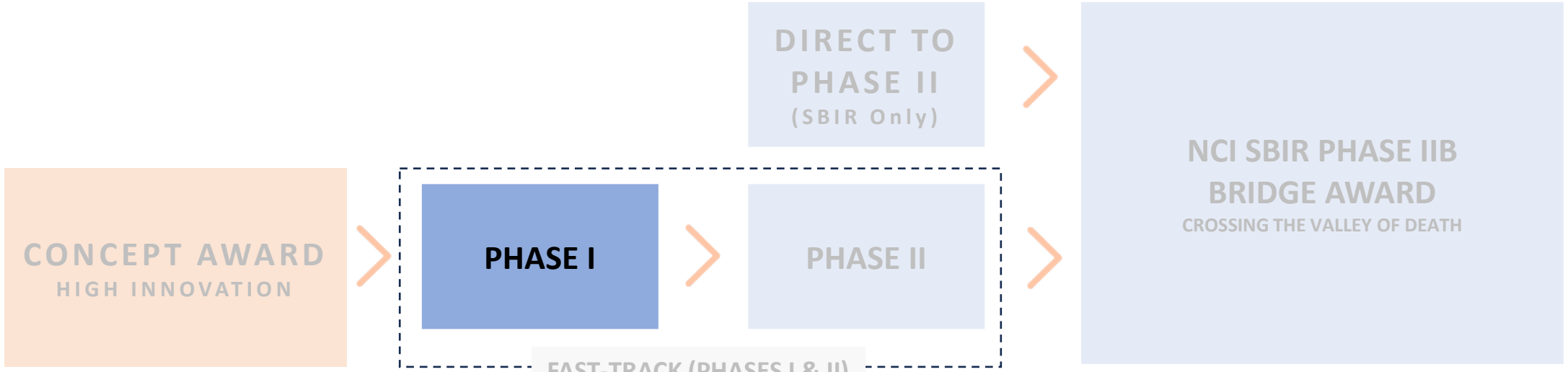
SBIR		STTR
Permits research institution partners (e.g., universities)	PARTNERSHIP	**Requires** research institution partners (e.g., universities)
Small businesses may outsource ~33% of Phase I activities and 50% of Phase II activities	DIVISION OF LABOR	Minimum 40% of the work should be conducted by the 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 INVOLVEMENT	PI primary employment not stipulated (min.10% effort to project)

The award is ALWAYS made to the small business concern

NCI SBIR/STTR FUNDING PHASES



NCI SBIR/STTR FUNDING PHASES



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

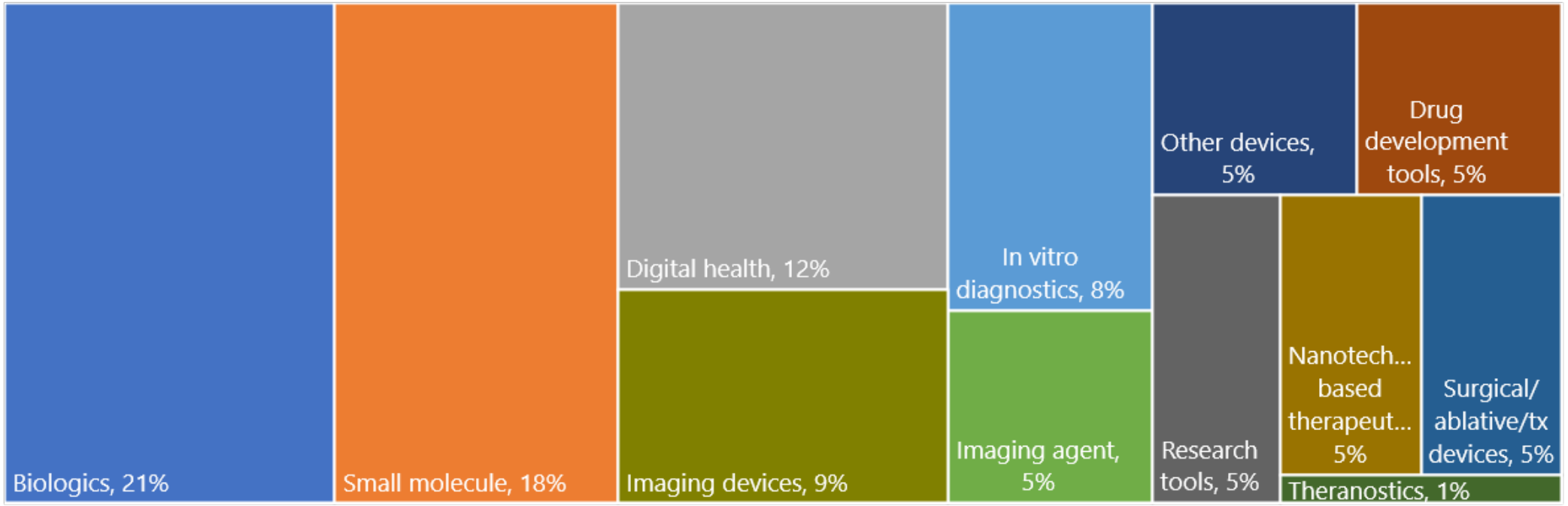
- **Proof of concept**
- **$400K over 1 year**

- Research & Development
- Commercialization plan required
- $2.25M 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

PORTFOLIO

- **475+ active projects**
- **$196M SBIR/STTR funds in FY 2024 (86% grants, 14% contracts)**



ABOUT NCI STEP

NCI STEP | NCI SBIR/STTR Training and Entrepreneurship Program

NCI STEP is a FREE entrepreneurial training and application preparation assistance program

Goal	Increase NCI SBIR/STTR program participation of small businesses who have a great cancer technology, but have little to no access to NIH experience in their network
How	Provide instructors on customer discovery and mentors on Phase I SBIR/STTR grant application preparation and submission
Who	Small businesses eligible for SBIR/STTR that have never applied or won an NIH SBIR/STTR award in the last 10 years
When	Cohorts submit NCI Phase I SBIR/STTR for April 5 and September 5 deadlines

NCI STEP ELIGIBILITY

You have a **US-based small business** eligible for the SBIR/STTR program

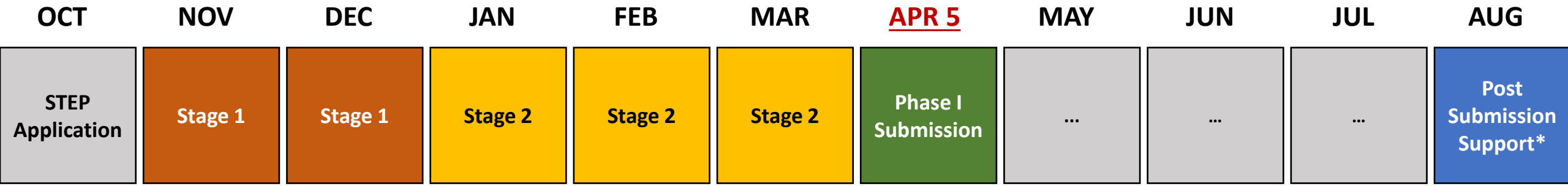
You are seeking support to submit an **NCI Phase I SBIR/STTR**

You do **not** have a NCI SBIR/STTR application under review for the same scope of work

You have **not received** an NIH SBIR/STTR award (in the last 10 years)

https://www.evagarland.com/nci-sbir-sttr-training-program/

NCI STEP TIMELINE



Program Length: ~16 weeks (10-25 hours effort per week)

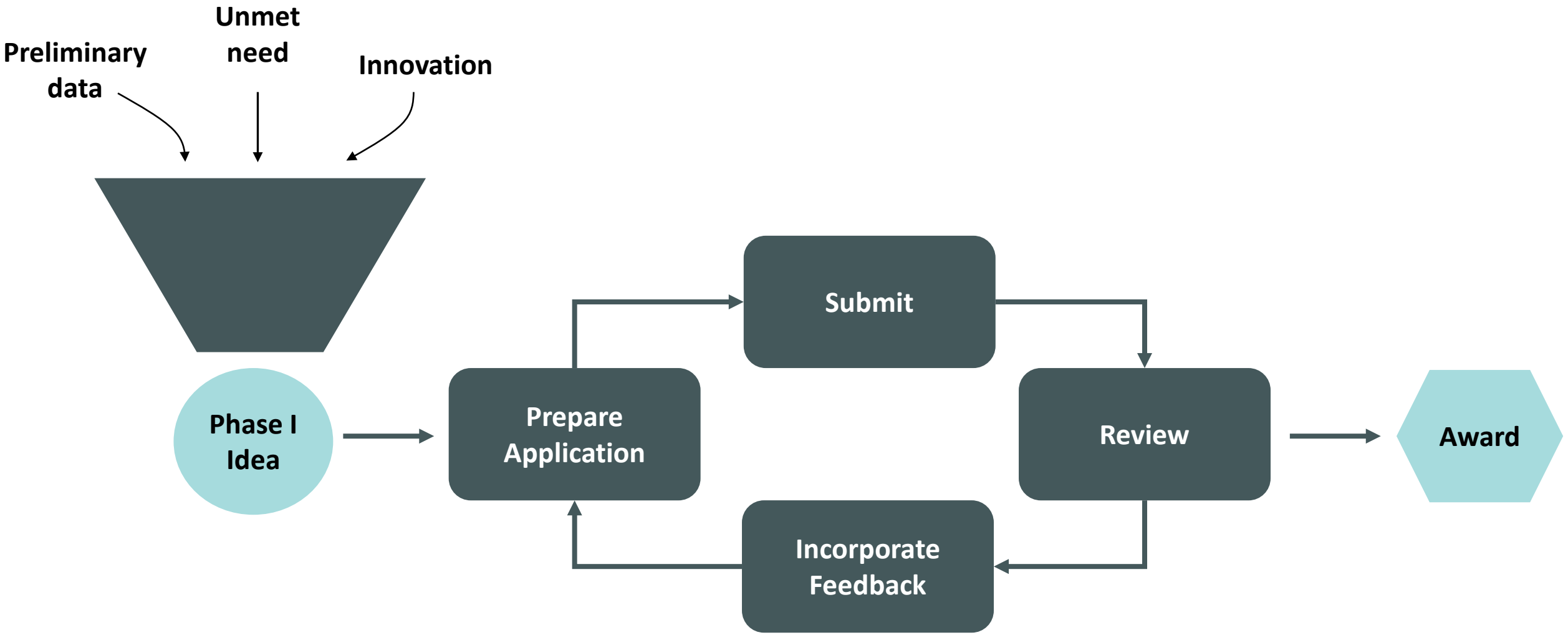
Support Length: ~8 months*

Phase I SBIR/STTR Deadlines: April 5, 2026**

Participants per cohort: 8-10 small businesses

*Post submission support until 4 weeks after summary statement released
**Next cohort for September 5, 2026. STEP application open ~February 2026

PATH TO PHASE I SBIR/STTR AWARD



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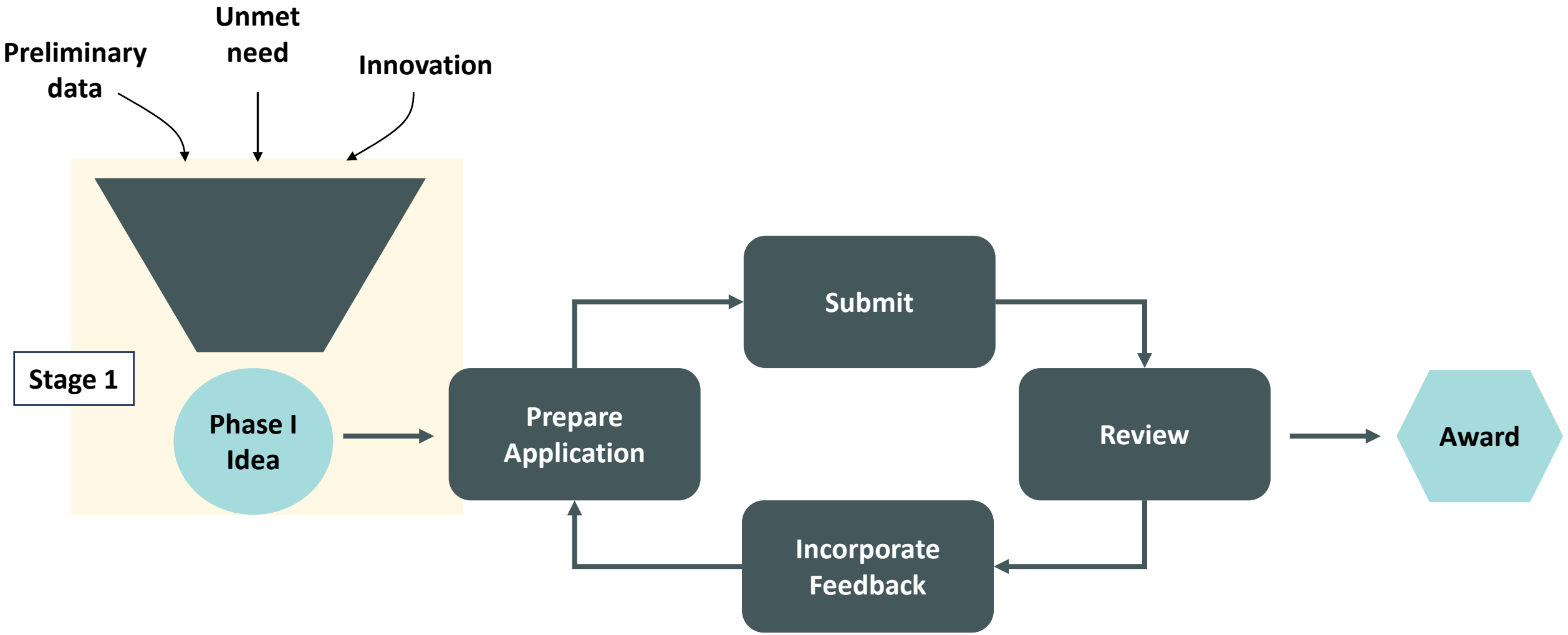

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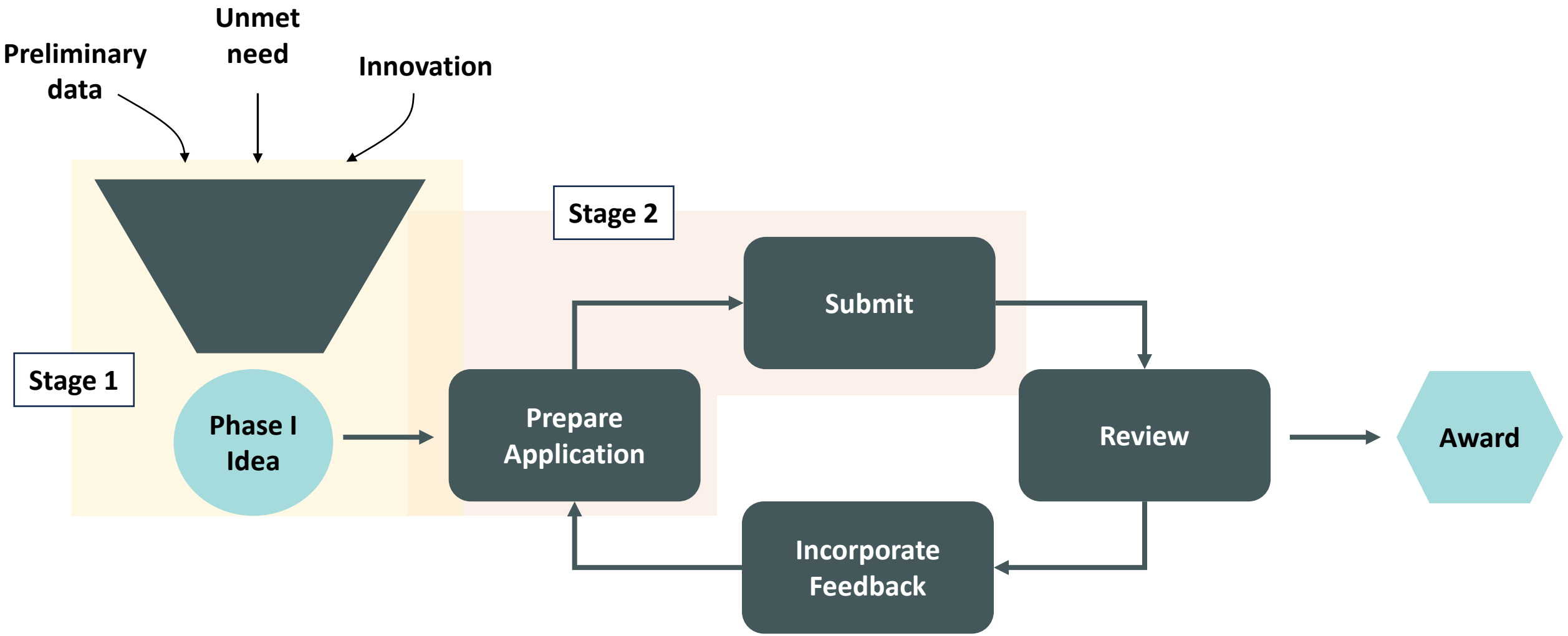

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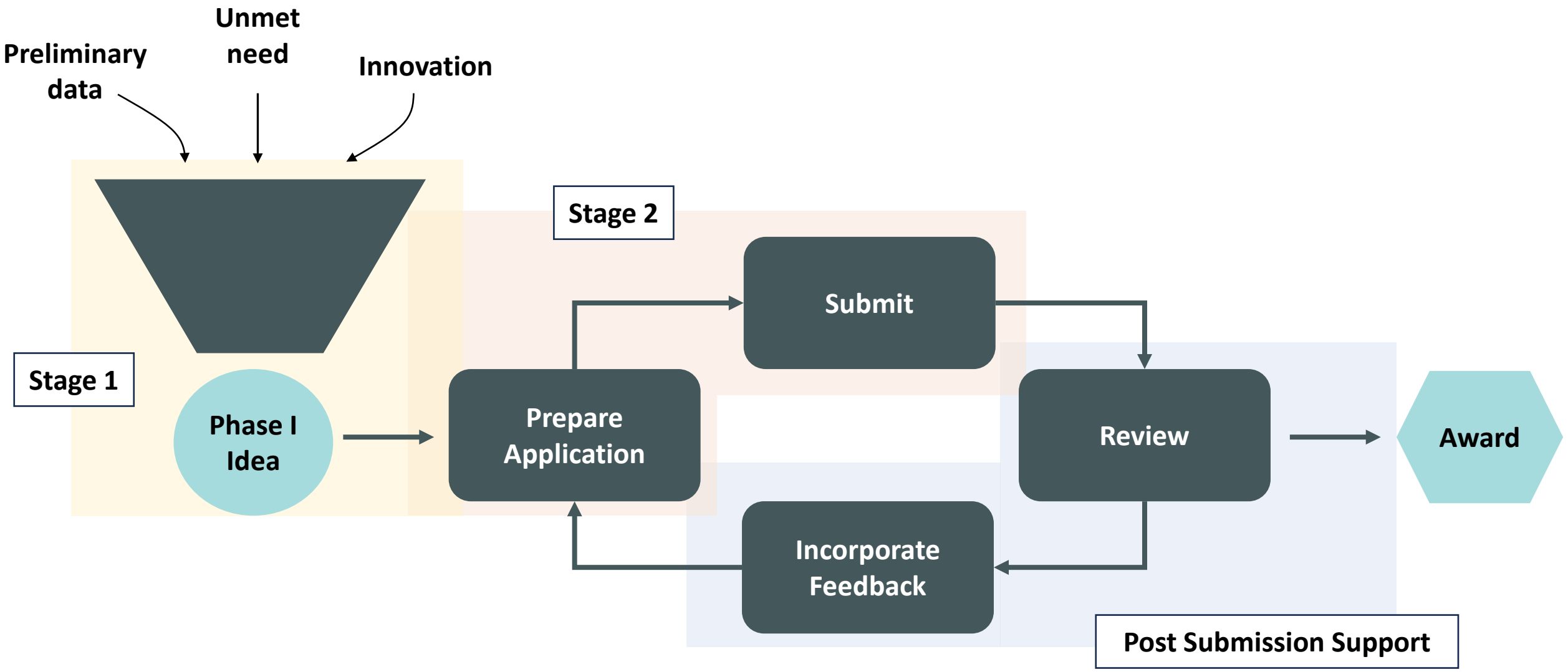


NCI STEP STAGES

Stage 1
Customer Discovery

- 6 weeks, 2-person teams
- Weekly webinars and office hours
- Conduct ≥20 customer discovery interviews
- Refine what you want to propose for Phase I SBIR/STTR

Stage 2
Application Preparation

- 10 weeks
- Weekly webinars and one-on-one trainer meetings
- Prepare and submit a complete and compliant Phase I SBIR/STTR to NCI

Post-Submission Support

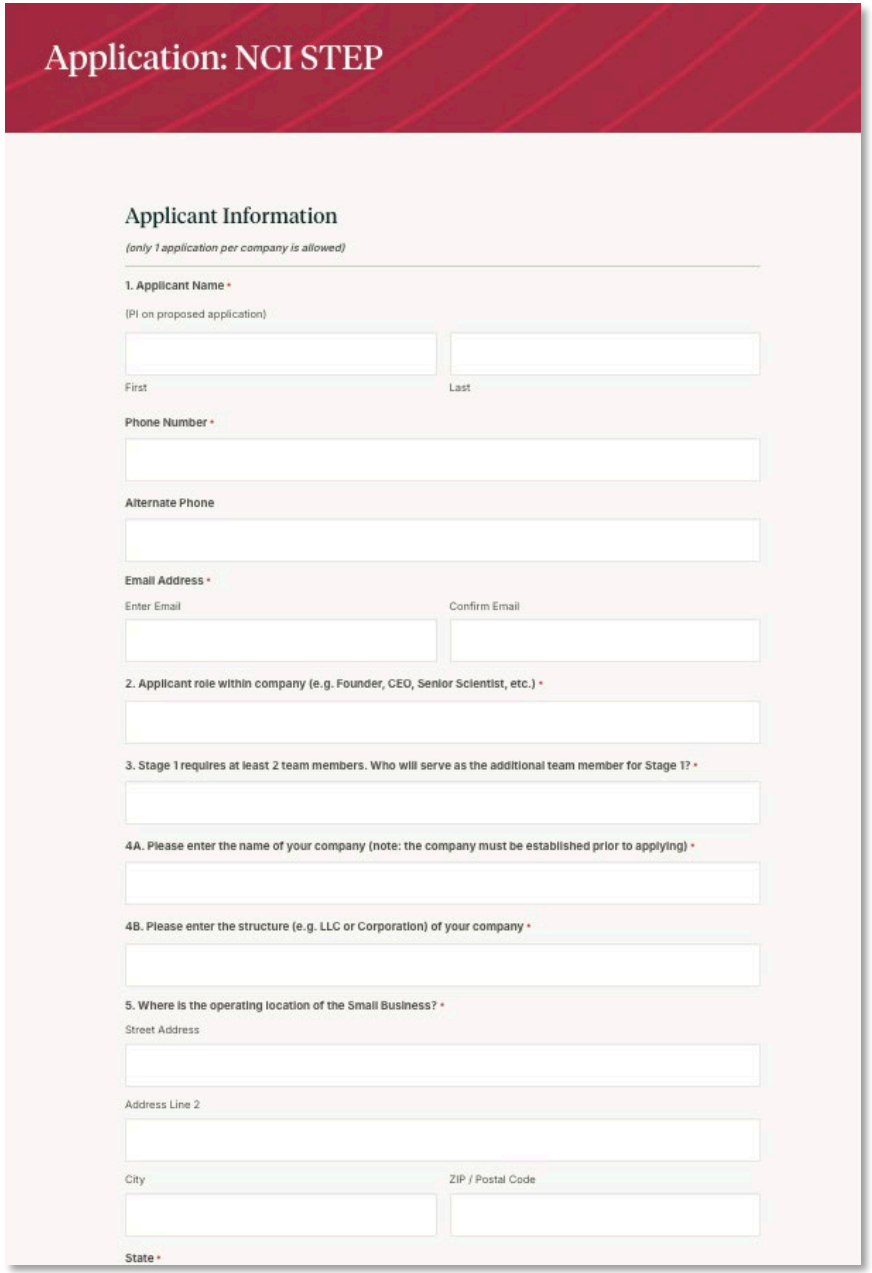
- 5 hours, until 1 month after summary statement is released
- Advice on post-submission activities like reviewing a summary statement, resubmission

WHAT NCI STEP PROVIDES

	STEP PROVIDES ✓	STEP DOES NOT PROVIDE ✗
Stage 1	Instruction on conducting customer discovery and business model development	Conducting customer interviews
		Direct introductions
Stage 2	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 assistance	Small business registration or NIH application submission services
Postsub	Support on post-submission activities including summary statement review, resubmission process, and just-in-time procedures	NIH application/JIT submission services

NCI STEP APPLICATION

- Portal to application: https://www.evagarland.com/nci-sbir-sttr-training-program/
- **DOUBLE CHECK STEP APPLICATION DEADLINE**
- Review criteria to assess fit for STEP:
  - **Significance:** Does your technology address a clinical unmet need? Does it align with NCI mission?
  - **Innovation:** Is your technology sufficiently innovative? Does the application articulate differentiation from existing technology?
  - **Appropriateness:** Are there preliminary data to be competitive? Does the proposed Phase I project fit within the scope of a Phase I?
  - **Resources Access:** What resources does the applicant already have access to?



PROJECT TITLE

15. Project Title (limit 200 characters) *

- Descriptive and specific to inform the reviewer the essence of your project: what is the problem you are solving and what is your solution?

T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
Preventing chemotherapy-related toxicities and infections with a novel phosphorylated triblock copolymer									
1 R41CA287593-01			ALVERDY, JOHN C	COVIRA SURGICAL	2024	NCI	NCI	$400,000	View
Targeting pancreatic cancer metastases with Targefrin									
1 R43CA277917-01A1			BAGGIO, CARLO	ARMIDA LABS, INC.	2023	NCI	NCI	$400,000	View
Monitoring Immunotherapy Response via Gene Silencing Landscapes in Cell-Free DNA									
1 R43CA285041-01			BARRETT, MICHAEL T PATEL, ABHIJIT	BINARY GENOMICS, INC.	2023	NCI	NCI	$398,040	View
Two-Color Near-Infrared Fluorescence Guided Surgery Tools Enabling Simultaneous Cancer Margin and Nerve Visualization during Head and Neck Squamous Cell Carcinoma Resection									
1 R43CA272030-01A1			BARTH, CONNOR WILLIAM	TRACE BIOSCIENCES INC	2023	NCI	NCI	$386,211	View

THE UNMET NEED

16. What is the NCI-related public health problem or indication that you are addressing? (Up to 1,500 characters) *

Note: NCI's mission is to lead, conduct, and support cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

- Does your project align with the NCI mission? NCI SBIR funds technology across the cancer continuum from prevention, diagnosis, treatment, survivorship, and end-of-life
- Describe the **significance** of the problem you are trying to solve and how your technology will benefit patients with cancer
  - Be concise, specific, and quantitative
  - What population is affected by the problem
  - What is the desired outcome customers would expect if the problem was addressed

THE TECHNOLOGY INNOVATION

17. The Technology Innovation. (Up to 1,500 characters) *

What is the envisioned end product or service? Does the proposed product or service represent an innovative approach to addressing an important problem, barrier to progress, or unmet need in research or clinical practice? What are the significant advantages over existing approaches or methodologies, instrumentation, or interventions or those in development?

- What is the product that your Phase I SBIR/STTR will be funding the development of?
- What is the technology **innovation** that is enabling the products advantages?
- What competitive advantages does your product have over current standards?
- Is your product a significant improvement upon current standards?

CURRENT STATE OF TECHNOLOGY

18. Describe the current state of your technology (i.e., concept, prototype phase, in vitro testing, etc.). (Up to 200 characters) *

- Is your technology at a stage that is **competitive** for an NCI Phase I SBIR/STTR application?
- What research and development have you already completed for your product?
  - Do you have *in vitro* and/or *in vivo* data?
  - Do you have a prototype?
  - Have you tested your technology with potential users?

SCIENTIFIC PREMISE

19. Describe the premise that supports the scientific rationale for your proposal (upload 1-page pdf only) *

- What is the **underlying scientific premise** to your technology innovation and product?
- What is the evidence that your idea for your product or service is valid (include references)?
- Include key preliminary data that you and/or collaborator have generated (you can include figures and tables in the 1-page PDF)

PHASE I GOALS & MILESTONES

20. NIH SBIR/STTR Phase I Goals and Milestones. This should reflect a scope of work that can be accomplished in a Phase I SBIR/STTR project that is up to 1 year within a budget of up to $400,000. (Up to 3,000 characters) *

- Is your proposed project **within scope** of an NCI Phase I SBIR/STTR?
- Does your project directly support product development? By the end of Phase I, does your project build upon your preliminary data and demonstrate proof of concept efficacy of your product?
- Generally 2-3 goals (“specific aims”) that will be accomplished with $400,000 over 1 year
- Provide milestones (quantitative, metrics of success) that should be achieved by the end of each goal

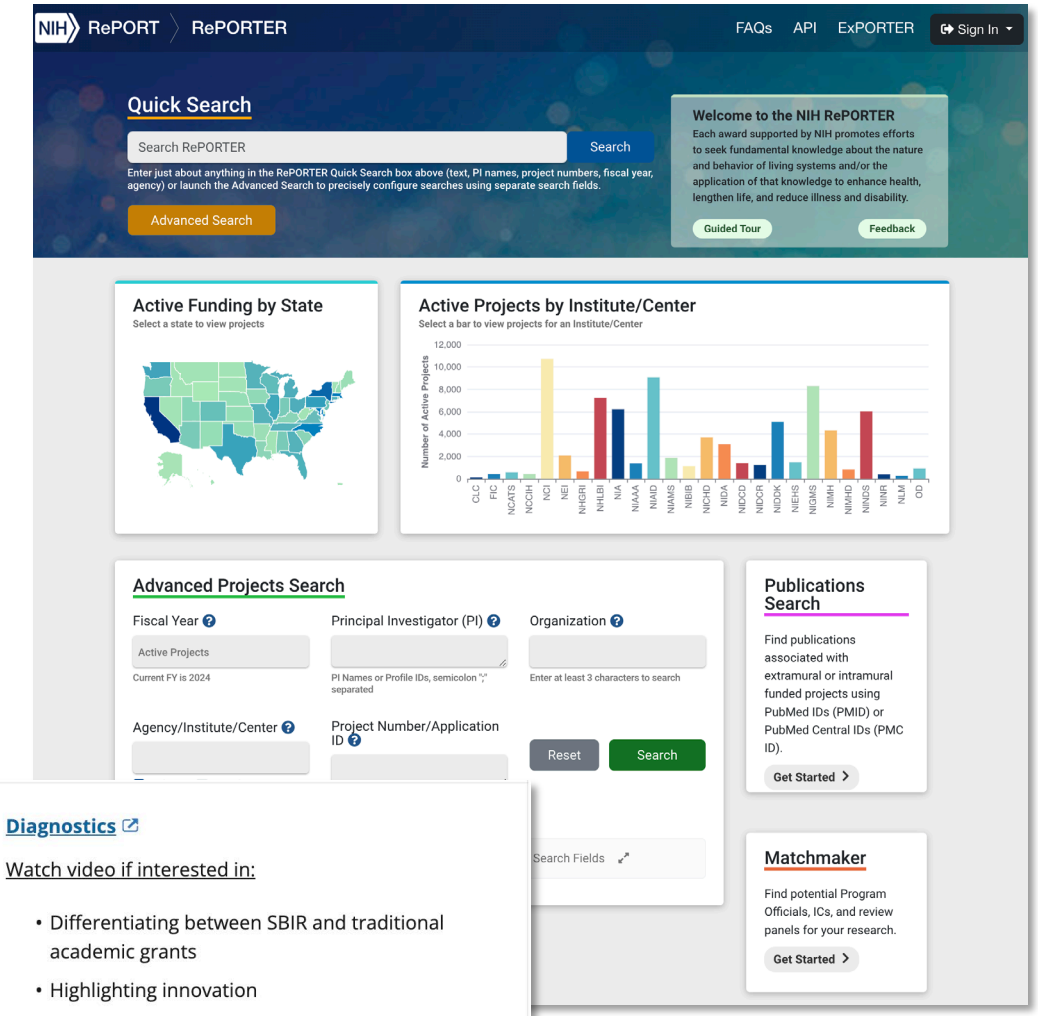
PROTECTION STRATEGY

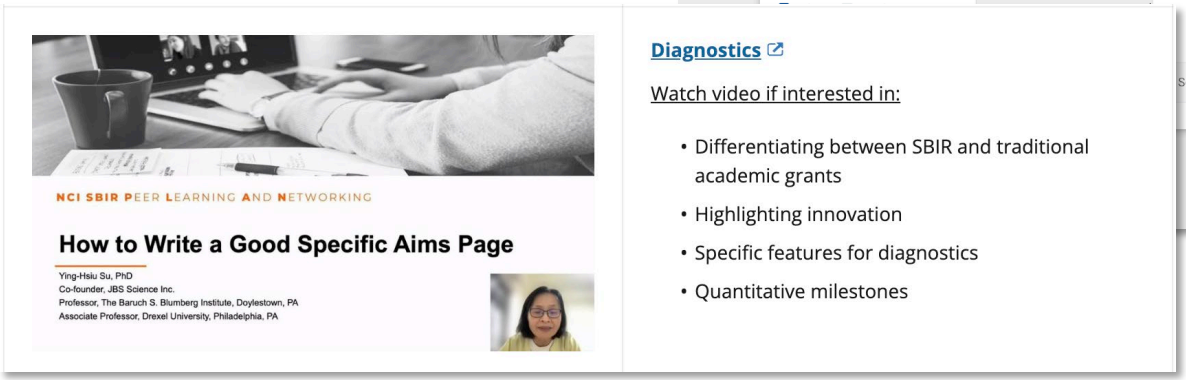
21. Describe your strategy to protect your technology from competitors (i.e., patents, copyright, etc.). (Up to 500 characters) *

- Do you have **protection** to successfully commercialize your product?
- Describe your intellectual property (IP) strategy)
  - Submitted, granted patents
  - Copyrights
  - Trademarks
  - Trade secret

HELPFUL RESOURCES

- Use NIH Project RePORTER to look at abstracts of previously awarded projects
- Take a look at sample SBIR/STTR applications:
  - NCI SBIR sample applications
  - NIAID SBIR sample applications
  - NIA SBIR sample applications
- Listen to advice from previous awardees on the NCI SBIR PLAN webinar series focused on how to write a good specific aims page





JOIN US!
NCI STEP Q&A WEBINAR

Wednesday, September 17, 2025, at 2:00 p.m. ET
[Register Here]

THANK YOU

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