

NCI SBIR Phase IIB Strategic Breakthrough Award

Transforming Scientific Promise into Patient Impact

Accelerating Pediatric and Rare Cancer Breakthroughs

Promising cancer technologies can transform patient care. However, even after early clinical development, they often face significant barriers to commercial readiness—especially the need for capital to generate Phase II efficacy and pivotal evidence.

These potential life-saving technologies are at key inflection points. Yet many of these innovations are stalled because they encounter a steep and often unachievable funding gap. This challenge is particularly pronounced in pediatric and rare cancers. The patient populations are small, thus limiting traditional investment. Without targeted funding, many programs simply cannot cross the finish line. This results in fewer therapies reaching the rare and pediatric cancer populations where the standard of care has seen limited progress and innovation is urgently needed.



How the Strategic Breakthrough Award Can Help at NCI SBIR

The **Strategic Breakthrough Award** provides up to \$15 million in **National Cancer Institute (NCI) Small Business Innovation Research (SBIR)** funding, paired with a required 1:1 third-party match, mobilizing up to \$30 million in total project capital to advance clinical-stage therapeutics and medical devices for pediatric and rare cancers. This structure is designed to help companies leverage NCI SBIR support to attract the additional capital needed to execute late-stage clinical development and reach critical commercial inflection points. Matching funds may come from venture capital investors, strategic partners, foundations, government sources, or a combination of these funding streams.

This level of investment expands what NCI SBIR can do for the first time:

- Funding Phase II efficacy, registrational, and pivotal clinical trials
- Supporting technologies at the exact moment that clinical and commercial inflection points occur
- Helping companies generate the critical efficacy data that open doors to regulatory approval, partnerships, acquisition, and follow-on investment
- Stimulating private investment in historically underfunded pediatric and rare cancer technology development

A strong Phase II clinical trial readout can change a company's future and the future for patients.

How the Strategic Breakthrough Award Is Unique

The **Strategic Breakthrough Award** is a first-of-its-kind NCI SBIR opportunity:



Unprecedented capital: The largest NCI SBIR funding level ever deployed for late-stage clinical development



Mandatory external matching: Built to catalyze new private, strategic, or philanthropic investment and demonstrate strong commercial readiness



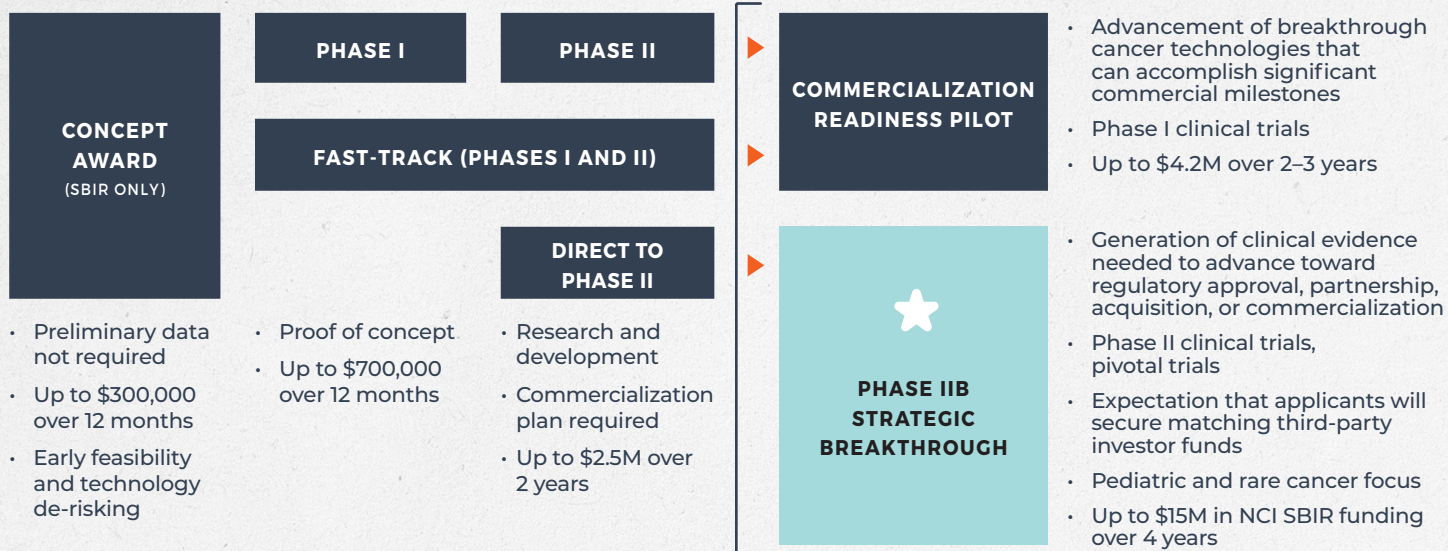
Designed specifically for clinical-stage technologies that address pediatric and rare cancers



Aligned with U.S. Food and Drug Administration (FDA) flexibility: Orphan and fast-track pathways, surrogate endpoints, and adaptive designs make this stage of development especially high-impact and efficient

This structure does more than fund a trial. It accelerates technologies precisely where traditional markets fall short.

Strategic Breakthrough Award Bridges the NCI SBIR Funding Pipeline to Late-Stage Development



Strategic Breakthrough Award Eligibility Requirements

- ✓ Prior qualifying National Institutes of Health SBIR/STTR Phase II award as described in the solicitation
- ✓ Clinical-stage therapeutic or medical device intended to directly treat pediatric and/or rare cancers
- ✓ Ready to advance into Phase II or pivotal trials over a 4-year project period
- ✓ Ability to secure the required 1:1 third-party matching funds

Characteristics of Strong Candidates



Significant unmet medical need and the potential to improve outcomes where the standard of care has seen limited progress



Clear regulatory pathway and evidence of FDA engagement



Feasible clinical trial plan, including enrollment and site/network strategy



Credible commercialization and matching-capital strategy



Ability to reach meaningful clinical and commercial inflection points

Resources

Apply:

[PA-27-101](#)

Deadlines:

September 5, January 5, and April 5

Web Page:

[Phase IIB Strategic Breakthrough Award – NCI](#)

Applicants are encouraged to discuss their technology and development plans with the NCI SBIR Program Director associated with their Phase II award. For additional questions about the Strategic Breakthrough Award, please contact the NCI SBIR Development Center at ncisbir@mail.nih.gov.

Contact

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

