TABA Consulting Services

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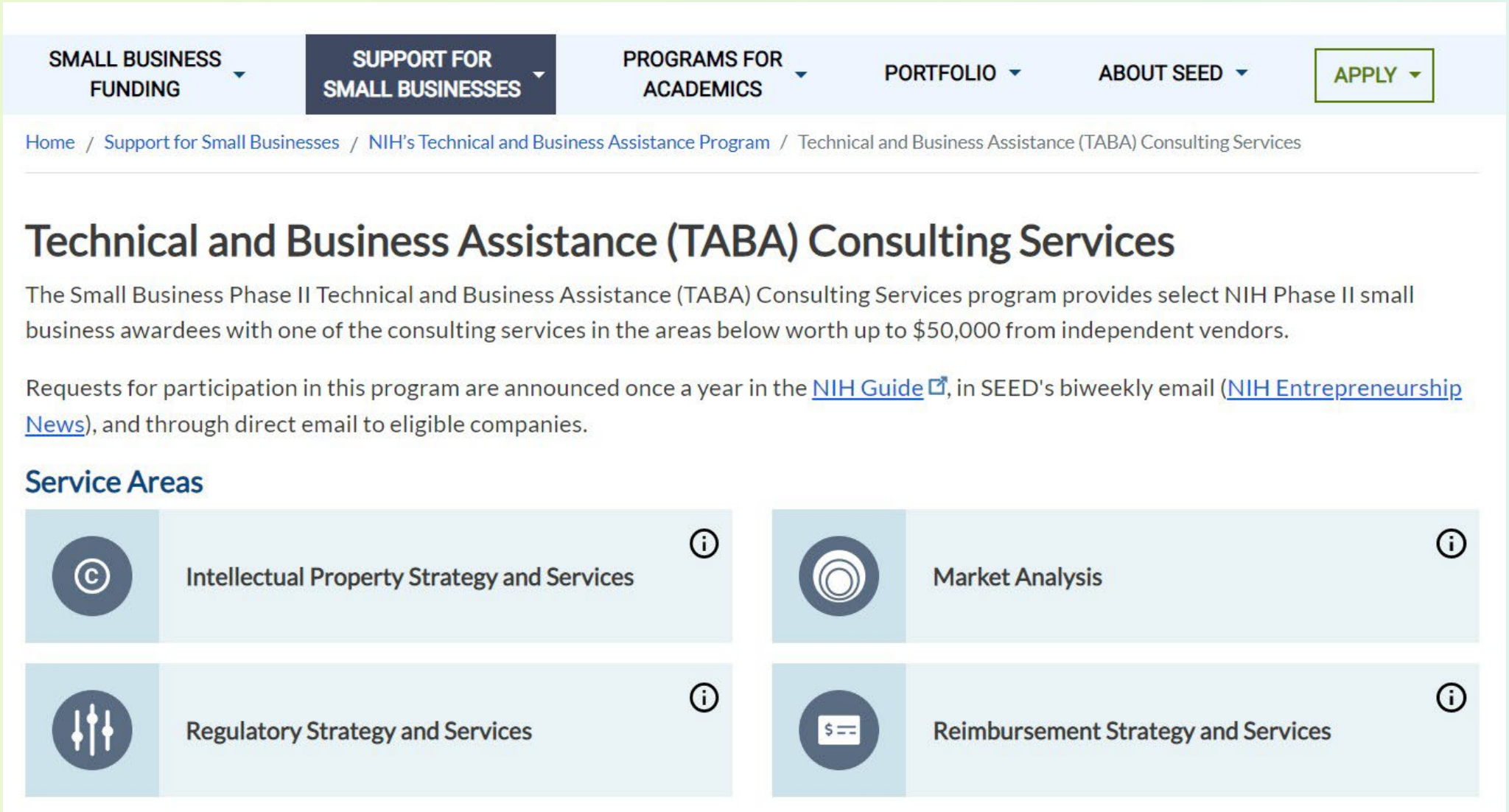
Webinar Housekeeping

- **Note: This webinar is being recorded**. The recording and materials will be made available to participants 7-10 business days after the session.
- Please submit all questions in the Q&A box located in your control panel.

Service Areas



Examples of Services Requested

Intellectual Property

IP landscape analysis (FTO)

Patentability search

IP portfolio strategy

License negotiation

Draft and submit patent application

Market Analysis

Commercial launch strategy

Competitive landscape analysis

Customer / market discovery

Marketing plan and materials development

Influencer identification

Regulatory

Gap analysis

Regulatory strategy/ roadmap development

INTERACT; pre-IND; pre-submission meeting support

Action plan for 510(K) data development

Reimbursement

Reimbursement landscape analysis

Pricing model and reimbursement strategy

Reimbursement plan / playbook

Payer market access strategy document

Small Business Eligibility

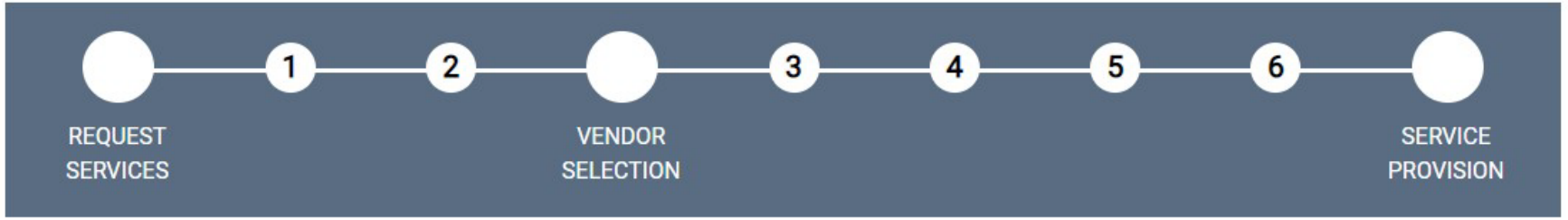
Eligibility

A project is eligible for the Consulting Services Program if:

- It was an active Phase II/IIB award within two years of the date of the TABA Consulting Service request
- TABA Funding was NOT awarded in either the original Phase II/Phase IIB award or as an Administrative Supplement to the original Phase II/Phase IIB award
- The company is currently participate in the Small Business Program

Each company may only request one service for one Phase II/IIB project each year. If a request is not selected, the company may resubmit in a future cycle if ir remains eligible.

TABA Consulting Services – Requesting Participation



Request Services

Step 1 – Eligible companies request participation

During the open request period (announced in the Guide and by email), companies submit information through an online portal describing their need, desired deliverable(s), and vendor criteria.

The next request cycle opens at 8am EDT on June 7, 2023

The next request cycle closes at 5pm EDT on July 7, 2023

Step 2 – NIH selects projects, notifies companies of their status

NIH staff considers requests and emails company leadership with questions (if any). Prompt responses are required; a lack of responsiveness may decrease your prioritization for the program. This program has a limited number of available spaces per fiscal year. As a trans-NIH program, equitable access to the program across all sectors of NIH is an important selection criterion.

NIH sends companies one of the following messages:

- Your project has been selected to participate in the program.
- Your project has been waitlisted for the program.
- Your project has not been selected for the program.

*Companies receive the status message **within 2 months** of the end of the request period. Waitlisted companies receive their final status within an additional 2 months (maximum of 4 months from submitting a request).*

Example Application: “Fake Hats”

Company Overview

Company Name	Fake Hat Co
Support Requested	Regulatory
CEO	Bob Sacamano
CTO (PI)	Elaine Benes
Company website	FakeHats.Net
Sponsoring NIH Component	NIDCD
Technology Description	Small molecule therapeutic targeting Purple Ear Syndrome
Major market(s)	Adults with Purple Ear Syndrome
Technology stage	Pre-clinical testing
Primary regulatory path	Orphan Indication, NDA (New Drug Application)

What to tell us in your application

Describe the public health impact of the product/project for which you are requesting consulting services. Response limited to 50 words.

Purple Ear Syndrome - excessive blood flow to the eardrum - is a debilitating condition that affects up to 60,000 Americans. Excessive blood flow can obstruct auditory processing of external sounds, resulting in accidents, disrupt

What one specific outcome are you seeking through the TABA Consulting Services program? Response limited to 100 words.

Fake Hats is requesting support from NIH TABA Consulting Services in the area of Regulatory Affairs to help us file our IND for effective small molecule who will explain the reg our IND to FDA.

Why are you requ development of t

We are asking for patients. We war been talking with and these families often their family of ability to hear accumulated a lot placebo in our clir

What interim and final program? Response lim

The expected outcome Fake Hats to begin regu outcomes with the regu prepare for our FDA filir of FDA approval of the f

What qualifications and experience should a vendor possess and highlight to demonstrate their capability to create your desired deliverables? Response limited to 100 words.

- Experience submitting INDs for auditory therapeutics

Please include any work your company has done towards the goal of this request (include examples)

Fake Hats has optimize 456. We have identifie cats (there is no mouse formulated PES-456 to multiple scientific mee and the people we spo Forum members to inc

If you have a preferred vendor you would like to include for consideration in the vendor selection process, please include contact information below. *There is no guarantee of preferred vendors participating in this program.*

Vendor Name: Vandelay Industries

Vendor Point of Contact: Art Vandelay

Point of Contact Email: Art@Vandelay.com

Point of Contact Phone Number: 212-555-1212

Service Request Development

Develop Request and Select Vendor

Step 3 – Selected companies work with the SEED Innovator Support Team to finalize a Statement of Work (SOW)

Information provided by companies is used to draft an initial SOW for vendor response. Each company refines their SOW during a one-hour teleconference with business and subject matter experts from the SEED Innovator Support Team and the company's Program Officer.

*Companies are expected to finalize the SOW and return it to NIH **within 3 weeks** of the teleconference.*

SOW Revision

- Companies meet with SEED Subject Matter Experts (SMEs) to refine their request and create a formal Scope of Work (SOW) document
- Applications are used to generate the initial draft SOW
- Draft SOW is circulated to company representatives, NIH Program Officer, SMEs, and additional SEED program support staff, no less than 2 business days before meeting
- 1 hour meeting during which SMEs share their experience working in the area of the request, companies clarify their need/request.
  - *The SOW is actively revised during the call.*
- Companies receive an updated SOW within 5 business days of the call
- Companies finalize the SOW within 10 business days of receipt from NIH

Fake Hats final SOW: Option 1 – IND filing

Context of Service Request:

Fake Hats Co. needs assistance with the development of an initial FDA interaction and submission of a new IND file to support the development of its first therapeutic molecule PES-456. PES-456 is being developed to resolve the symptomology of Purple Ear Syndrome – a condition where excessive blood flow to the tympanic membrane results in a characteristic purple color and which impacts the lives of effected people in one or more of the following ways: difficulty hearing; tinnitus; inability to "clear" ears during changes in altitude (leading to increased potential for ruptured ear drums); and challenges in balance (due to unequal pressure in eustachian tubes). Purple Ear Syndrome is an intermittent condition that can affect one or both ears, individually or simultaneously.

Fake Hat Co. has not had any documented interactions with the US FDA, though we have spoken with FDA representatives at scientific meetings and were guided to several relevant and informative guidance documents. We also met with the regulatory team at NIH to discuss possible pathways and used information from the following documents to guide our manufacturing and early animal studies:

- Current GMP for Phase 1 Investigational Drugs
- ICH Q6A Specifications: Test procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
- ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH Q7 QandAs Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH S1B-R1 Testing for Carcinogenicity of Pharmaceuticals
- FDA Guidance Rare Diseases Natural History Studies

We are in the final stages of engaging a CRO to conduct our IND enabling P/T studies and anticipate submitting our IND by Q2 next calendar year. We are seeking regulatory support through the TABA Consulting Services program to assist in the development and submission of our IND, including drafting SAD/MAD clinical protocols.

Deliverables and Reporting Requirements:

The expected deliverable for this program is submission of our IND to the appropriate FDA Office and allowance of our clinical trial. Interim milestones to achieve this deliverable might include:

- An analysis of documentation developed by Fake Hats to support the IND submission
- Review of data provided by the CRO performing the IND enabling P/T studies to ensure the data they will provide is sufficient to support the review of the IND file
- Collaborative development of an IND application for PES-456
- Development of an Investigators Brochure to support the Phase 1 trials for PES-456
- Successful submission of the IND for PES-456
- Collaborative development of response to reviewer comments during the IND review cycle

Vendor Qualifications:

- Recent experience (within the past 3 years) working with the relevant FDA review division
- Extensive expertise successfully submitting documents to FDA for small molecules
- Experience submitting INDs for auditory therapeutics

Preparing and submitting an IND is unlikely to fit within the allowable program budget

Fake Hats final SOW: Option 2 – pre-IND

Context of Service Request:

Fake Hats Co. needs assistance with the development of an initial FDA interaction to support the development of its first therapeutic molecule PES-456. PES-456 is being developed to resolve the symptomology of Purple Ear Syndrome – a condition where excessive blood flow to the tympanic membrane results in a characteristic purple color and which impacts the lives of effected people in one or more of the following ways: difficulty hearing; tinnitus; inability to "clear" ears during changes in altitude (leading to increased potential for ruptured ear drums); and challenges in balance (due to unequal pressure in eustachian tubes). Purple Ear Syndrome is an intermittent condition that can affect one or both ears, individually or simultaneously.

Fake Hats Co. has not had any documented interactions with the US FDA, though we have spoken with FDA representatives at scientific meetings they were excited about our early data.

We have identified an optimized synthetic scheme for and are able to produce up to 500 mg of material in our company labs. We have explored both topical and systemic dosing approaches and believe our drug will be delivered as ear drops. There are no animal models for PES, therefore, we modeled PES using organ-on-a-chip technology. We need to understand what, if any, animal data FDA will require before we can begin human trials. We are seeking regulatory support through the TABA Consulting Services program to assist in the development and submission of a pre-IND meeting with FDA.

Preparing a gap analysis, developing and supporting a pre-IND meeting request is likely to fit within the allowable program budget

Deliverables and Reporting Requirements:

The expected deliverable for this program is a documented plan, validated in a pre-IND meeting with FDA, describing the data required to successfully submit an allowable IND and begin clinical evaluation of PES-456. Interim milestones to achieve this deliverable might include:

- A review of documentation developed by Fake Hats to support the pre-IND meeting
- Collaborative development of pre-IND questions and briefing packet for PES-456
- Submission of the pre-IND request and briefing packet for PES-456
- Support reviewing FDA's pre-IND response comments, revising the meeting agenda to address questions, and debriefing the company after the meeting to clarify required activities to support successful IND filing.

Vendor Qualifications:

- Recent experience (within the past 3 years) working with the relevant office in FDA
- Extensive expertise working with small companies to guide early FDA interactions
- Experience supporting pre-IND meetings for auditory therapeutics

Guidehouse Vendor Solicitation

Step 4 – Guidehouse identifies potential vendors* and collects proposals

NIH forwards the final SOW to Guidehouse, to engage up to five potential vendors. Vendors are encouraged to meet with company teams to clarify nuances of the SOW before submitting proposals. Companies should anticipate evaluating 2-4 proposals as not all vendors will submit one.

A company may suggest a vendor for consideration, but this program is not a "pass-through" of funds to a company's current service provider or provider with whom the company has a long-standing relationship.

*The maximum time from vendor outreach to receipt of proposals is **4 weeks**.*

Step 5 – Company reviews proposals and selects a vendor

Guidehouse presents all proposals to the company that meet the requirements in the SOW and are within the program budget. The company evaluates the proposals and selects a vendor. Company leadership may request to speak with a vendor(s) to aid in the decision.

*Vendor selection is expected **within 2 weeks** of receipt of the final proposal.*

Step 6 – Guidehouse negotiates the contract with the selected vendor

Finalizing the terms takes approximately 4-6 weeks.

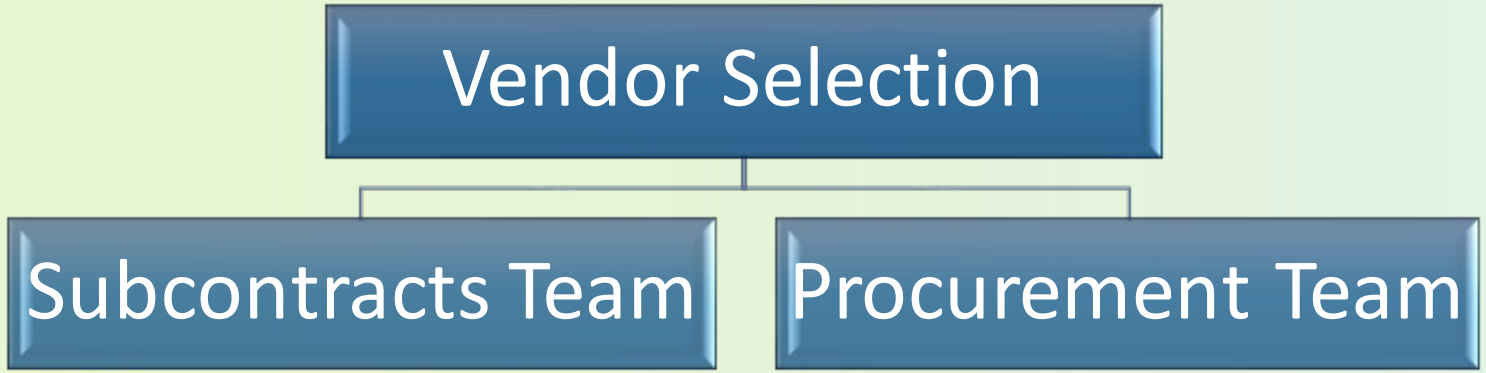
Vendor Selection

Guidehouse maintains active agreements with a diversified portfolio of hundreds of trusted, results-driven, subcontractors and specialized consultants with expertise across many areas of life science.

Customized vendor selection process is based on:

- Subject matter expertise
- Past performance
- Value proposition
- Competency
- Cost effectiveness

Adequate competition is considered to the maximum extent practical when selecting potential subcontractors and vendors



Proposal Submission & Contract Execution

Vendor solicitation and Proposal Development (28-days)

- **Proposal Submission Outline / Content from Vendors**
- Vendor qualifications
- Methodology/ Approach
- Period of performance
- Milestone based budget
- Qualifications of consultants

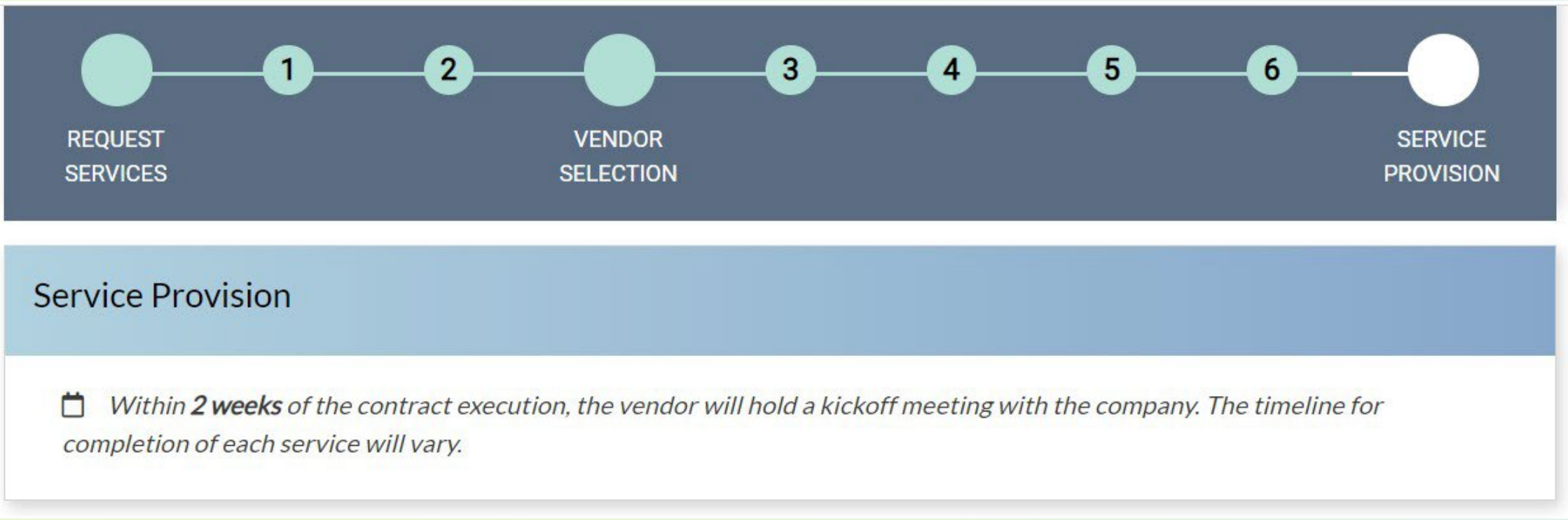
Vendor selection (14-days)

- **Vendor selection is finalized with the small business**
- Project execution overview
- Subcontract process updates
- Kick-off Meeting preparation

Subcontract negotiation and execution: 4 to 6 weeks

28–Day Vendor Solicitation Process	
SOW Acceptance	Days 1 – 7
Pre-Proposal Meeting	Days 8 – 21
Proposal Submission	Days 15 – 28

Service Provision



Project Execution

Project Kick Off Meeting

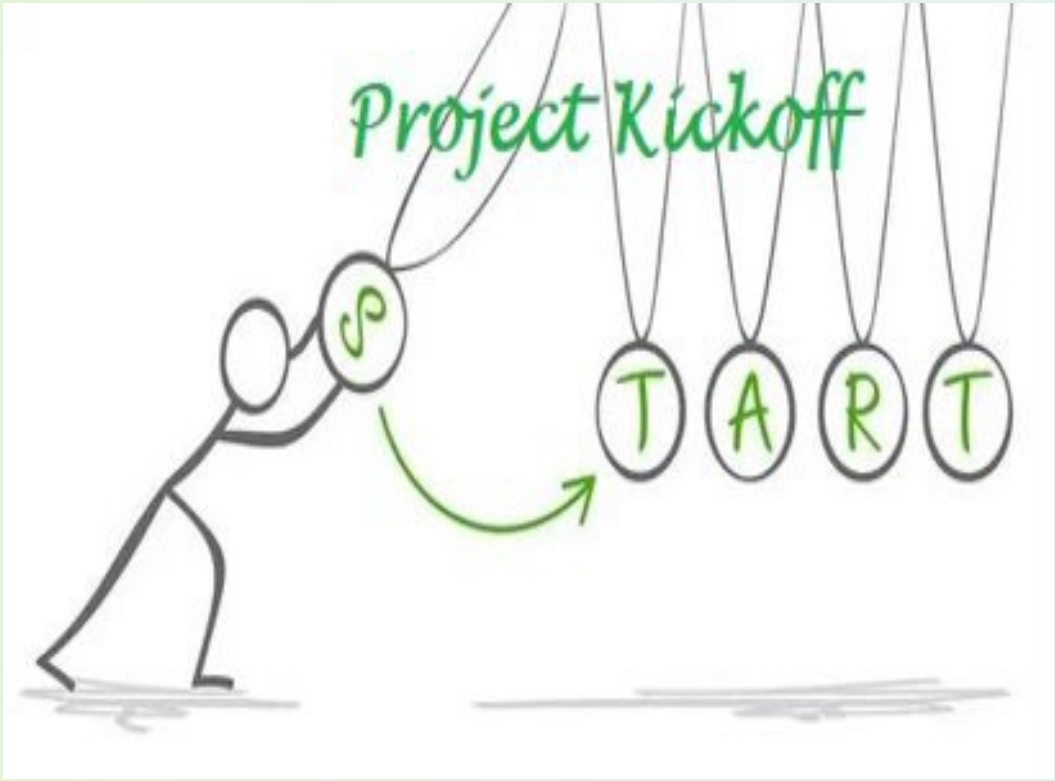
- **Official handoff to the vendor**

Confirm

- Milestone deliverables
- Period of performance
- Expected contributions for small business and vendor

Guidehouse Project Management Activities

- Milestone timeline compliance
- Monthly status reports
- Scope changes / Timeline extensions
- Company feedback
- Close-out meeting



Generalized Timeline

TODAY!

Requests Open, Info Webinar

July 9

Requests Due

August 9

Status Notification, SOW Call Scheduled

August – September

SOW Development

September – November

Vendor Selection

October – December

Vendor Contract Execution

October 2023 – January 2024

Projects Kick-off

March – October 2024

Projects Completed

March – October 2024

Close Out Calls with SBC, Vendor, and NIH

Questions