Technical and Business Assistance (TABA): Needs Assessment Program

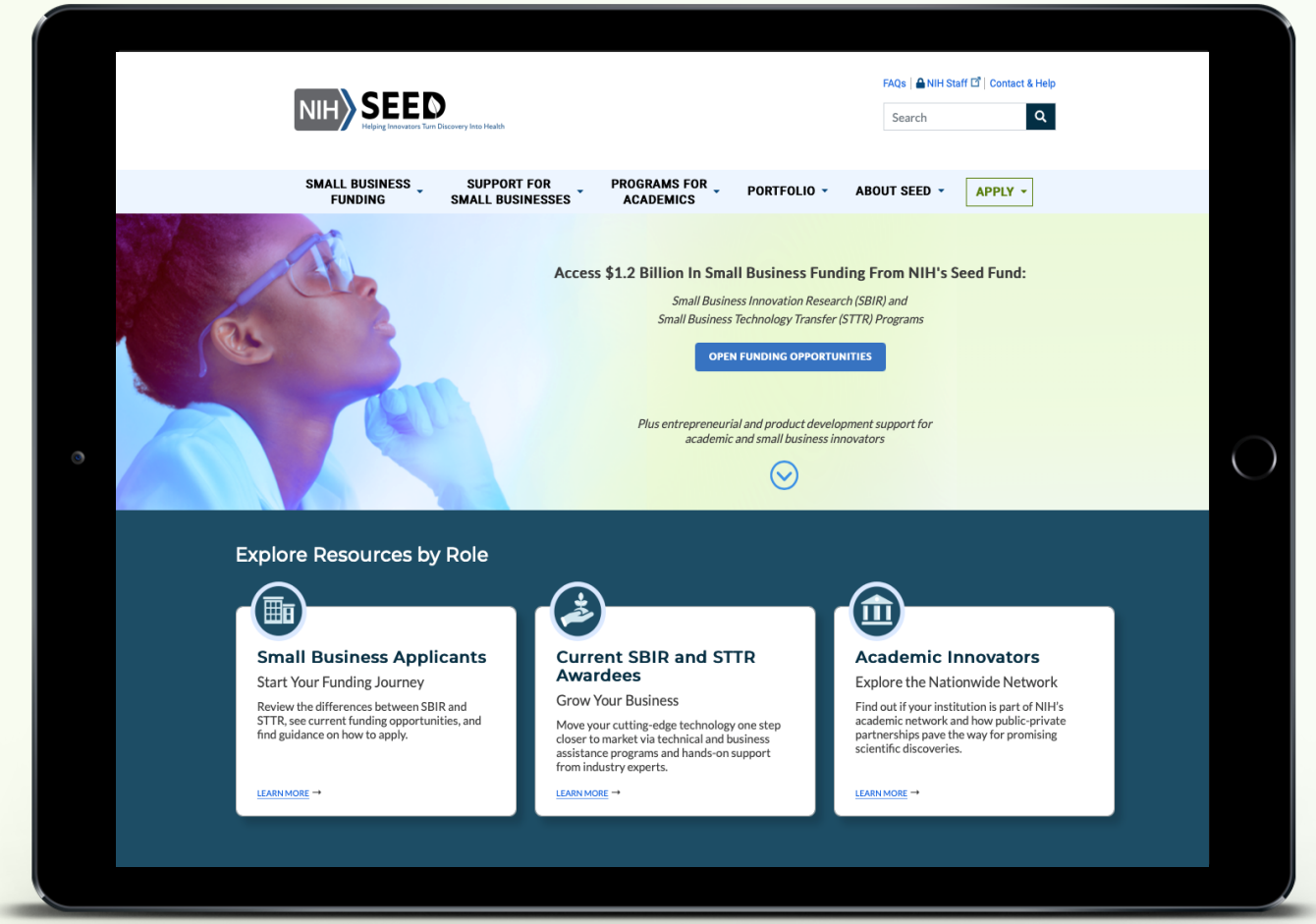
STEPHANIE FERTIG, MBA

HHS Small Business Program Lead
SEED (Small business Education & Entrepreneurial Development)

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

NIH SEED

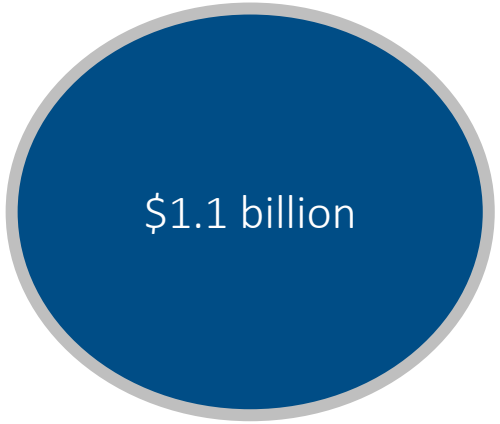
Small Business Program Website



http://seed.nih.gov

Congressionally Mandated Programs

$1.2 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

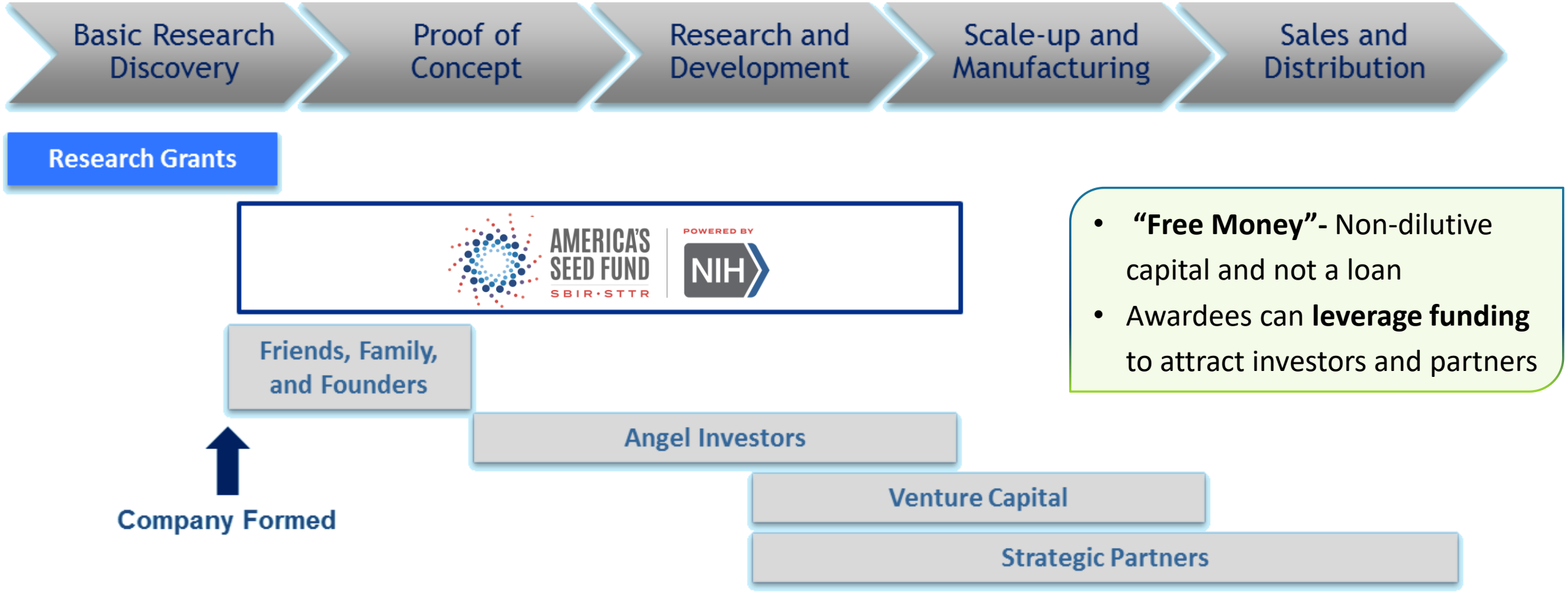
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Benefits of NIH Funding

The largest sources of early-stage capital for life sciences in the US



- **"Free Money"-** Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Phased Programs

Feasibility
Phase I

Full R&D
Phase II

Competing Renewal Award
Phase IIB

Commercial Market
Partner or Investor

Commercialization
Readiness Pilot (CRP)

Phase I → Phase II
Fast-Track

Direct to Phase II
(SBIR only)

Only Some NIH Institutes/Centers Participate

Phase I: $275,766/1-2 years*
Phase II: $1,838,436/1-3 years*

***NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected topics**

Other Innovator Support

Regulatory & Business Development Consultants

Business Development

Regulatory/Reimbursement

Intellectual Property

Entrepreneurial Support

I-CORPS at NIH

Partnering & Investment Opportunities

BIO International Convention

THE MEDTECH CONFERENCE
Powered by AdvaMed

ACA
ANGEL CAPITAL ASSOCIATION

LIFESCIENCES™ SUMMIT

RESI REDEFINING EARLY STAGE INVESTMENTS

Purpose of Technical and Business Assistance (TABA)

The TABA Program helps small businesses identify and address their most pressing product development needs.

Enables companies to:

- Make better technical decisions
- Solve technical problems that are beyond the scope of the funded R&D
- Minimize technical risks
- Commercialize the product

TABA Programs

Phase I

TABA Needs Assessment*

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

Phase II

TABA Consulting Services*

Available to limited number of awardees in the areas of Intellectual Property, Market Analysis, Regulatory Affairs, or Reimbursement Planning.

***NIH ONLY**

Phase I

Phase II

TABA Funding

Provides funding in grant to use your own vendors for Technical and Business Assistance

https://seed.nih.gov/support-for-small-businesses/

NIH SEED

TABA Funding

New Instructions in Forms G

- Request TABA Funding as part of the application
- **Some** Institutes/Centers allow for supplements after award (NOT-OD-21-062)
- TABA costs **may not** exceed:
  - $6,500 in additional funding **per year** for a Phase I
  - $50,000 in additional funding **per project period** for a Phase II

Talk to program staff before submission: Institutes/Centers can set individual budget guidelines for their SBIR and STTR programs

Projects that are awarded TABA Funding **cannot** use NIH TABA Programs (TABA Needs Assessment or TABA Consulting Services) during that SBIR/STTR Project Phase

TABA Funding Guidelines

Funding CAN Support

Subcontracts or consultants to:

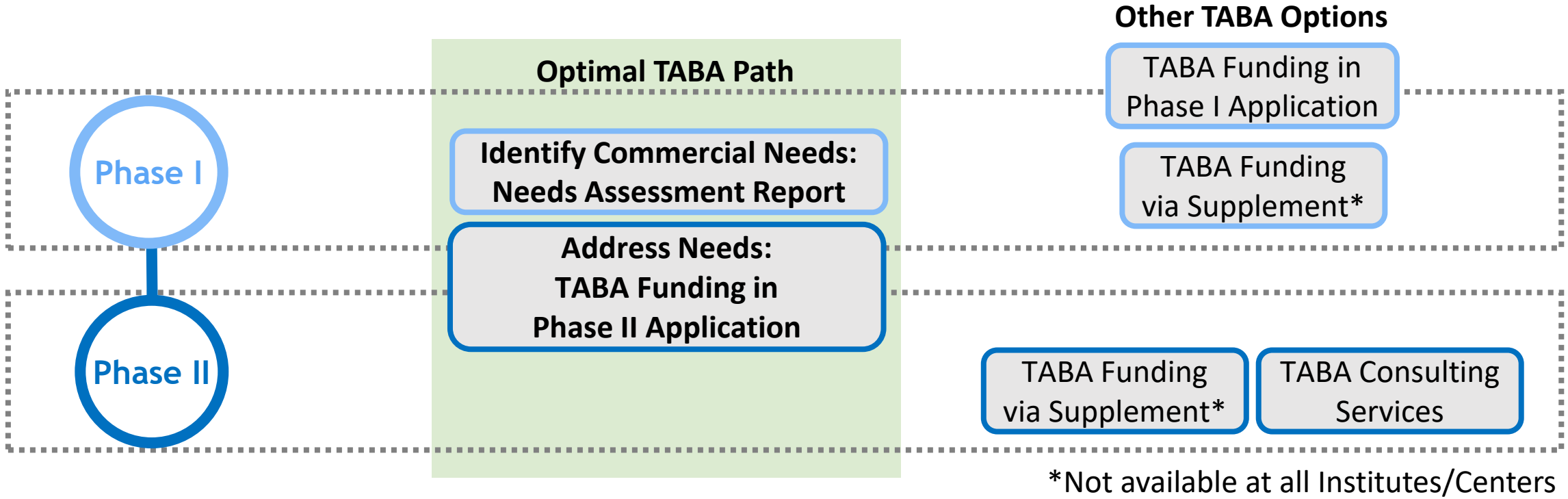
- Assistance with product sales
- Intellectual property protections
- Market research and/or validation
- Development of regulatory plans
- Development of manufacturing plans
- Access to technical and business literature available through on-line databases

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/sbir-sttr-forms-g.pdf

Funding CANNOT Support

- Activities that the recipient can provide internally
- General maintenance of or investment in:
  - an applicant/division within the small business
  - an affiliate/investor of the small business
  - a subcontractor/consultant required as part of the awarded Phase I or Phase II
- Contributions to the SBIR/STTR fee
- Audit services
- Bookkeeping services, including payroll management or general accounting services
- Patent costs above and beyond those outlined for the NIH funded program
- Contingency costs or costs associated with the research and development activities of the award

Technical and Business Assistance (TABA)

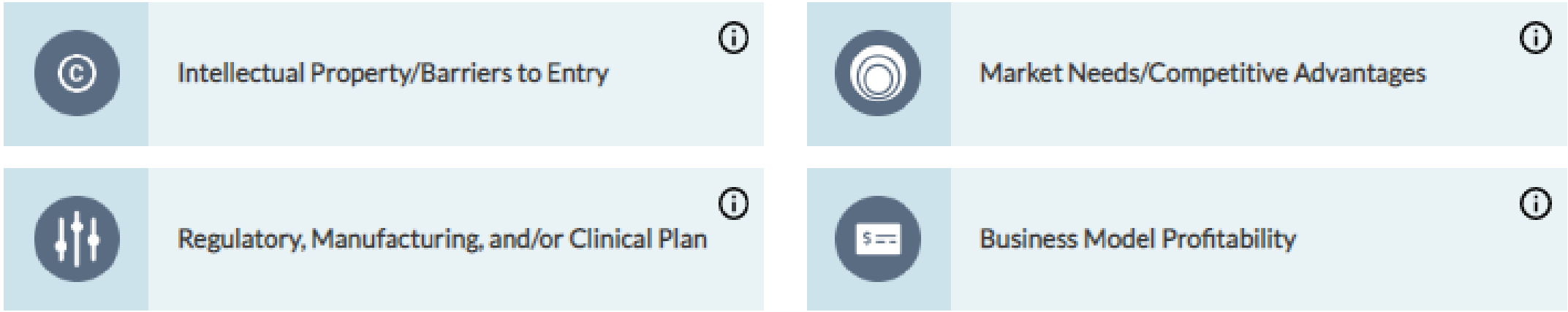


*Not available at all Institutes/Centers

https://seed.nih.gov/support-for-small-businesses/technical-business-assistance-program

TABA Needs Assessment

- Provides a third party, unbiased assessment (provided by RTI Innovation Advisors) to help small businesses identify their most pressing product development needs



- Suggests highest priority steps to improve the commercial potential
- Supports companies developing all types of technologies
- **Structure and scope are fixed**

NOT-OD-21-023

TABA Needs Assessment: Eligibility

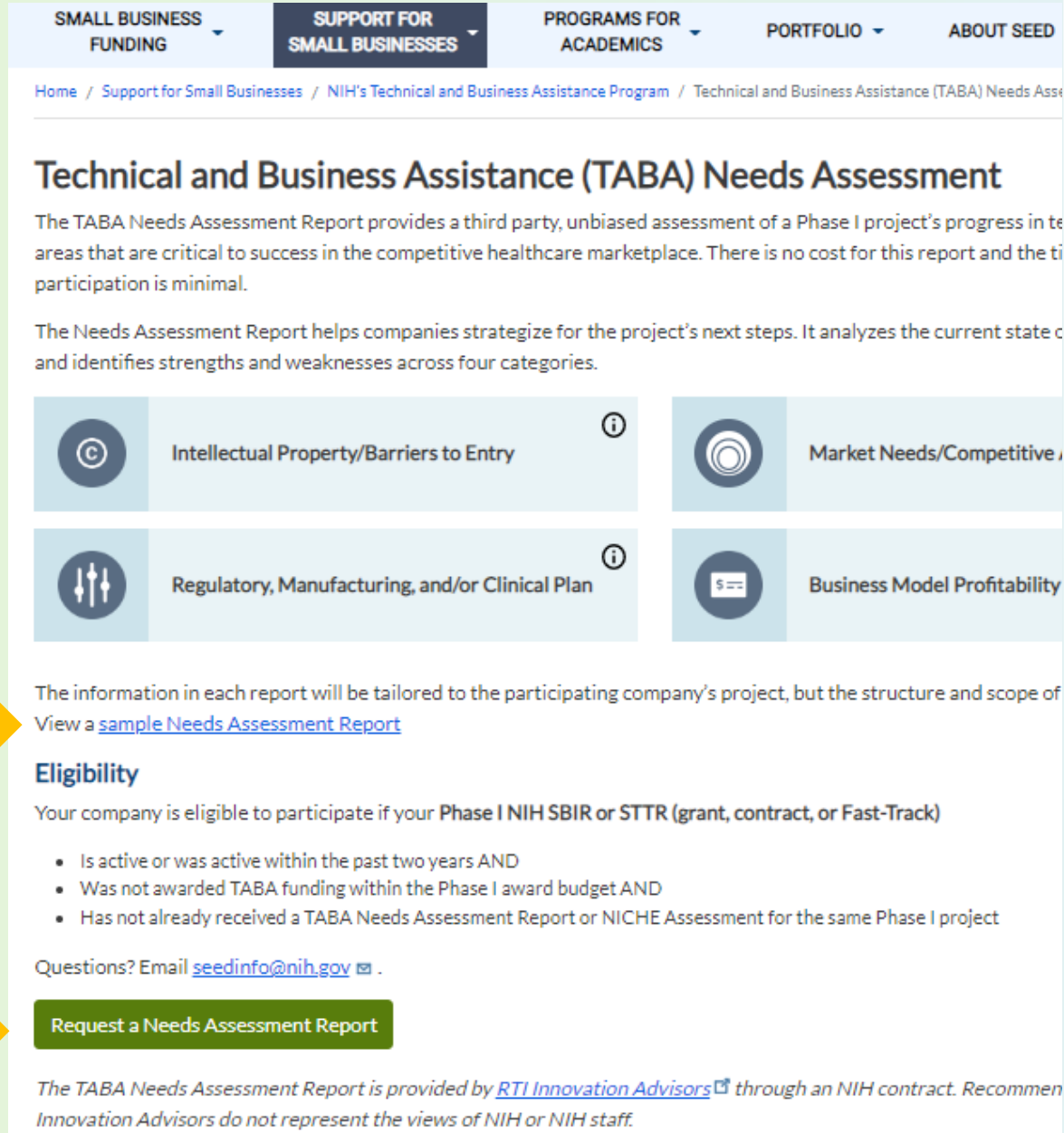
SBIR and STTR Phase I and Phase I Fast-Track recipients that have had an active Phase I grant, cooperative agreement, or contract within two years of request

Projects that received TABA Funding (or a Niche Assessment) in the Phase I are **ineligible**

Projects can participate in other Support Programs (e.g., I-Corps or C3i) **and remain eligible**

Request Process

- Open all year
- Review the sample report **BEFORE** requesting
- **MUST** request an assessment at https://sbir.nih.gov/support-for-awardees/taba-needs-assessment
- Requests must be complete
- NIH will confirm eligibility
- Notification of status within 60 days of submission



NIH SEED

Needs Assessment Process

Company Notification

- Must Confirm:
  - Reviewed and acknowledged the deliverable (sample report)
  - Ready to proceed
  - Appropriate contact

RTI Performs Analysis

- Initial Phone interview within two months
- RTI works with company to verify information

RTI Delivers Draft

- Delivered within 3-4 months
- Company has 10 business days to review for accuracy and ask questions
- RTI will have 10 business days to incorporate questions/feedback

RTI Delivers Final Needs Assessment Report

NIH SEED

RTI Innovation Advisors

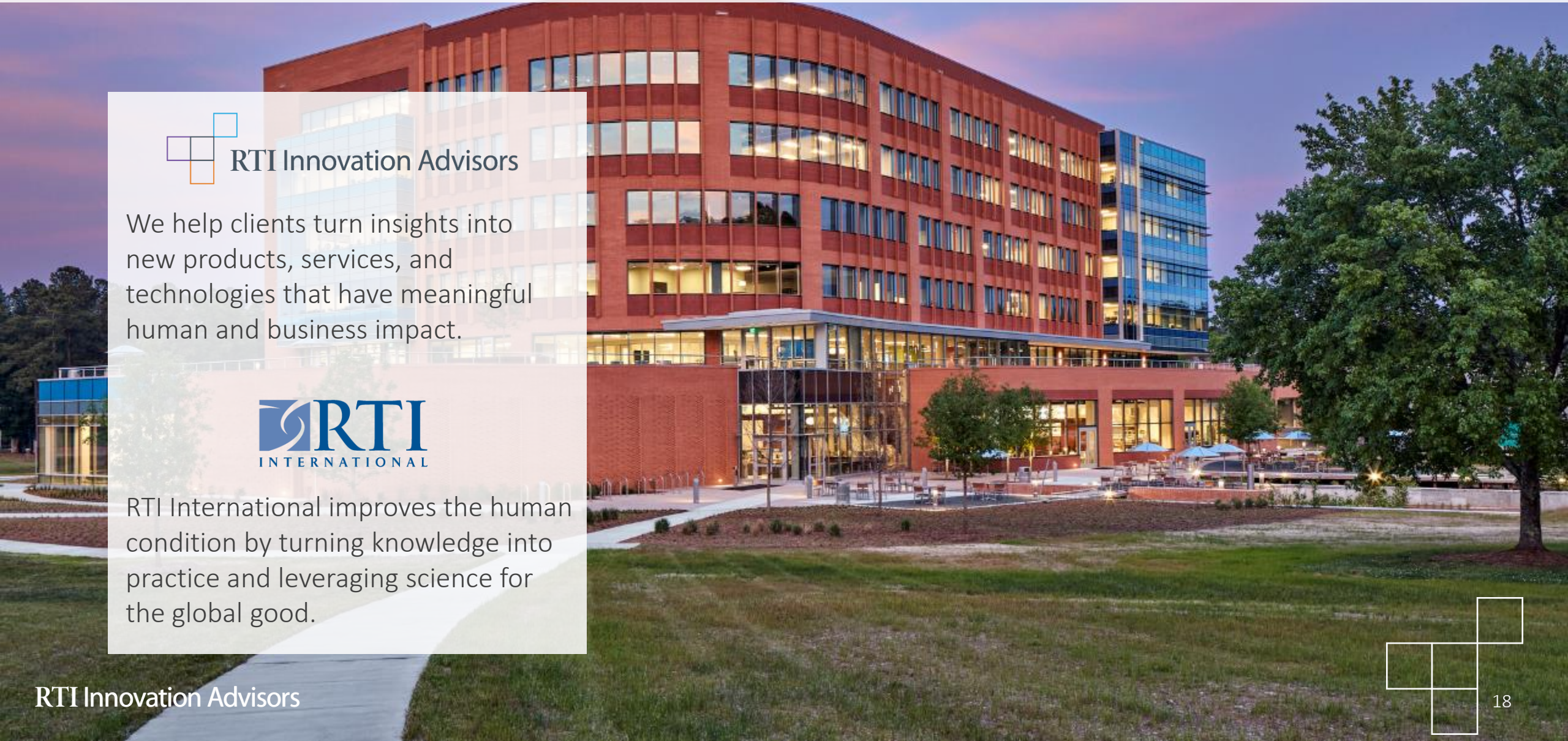
Introduction to RTI Innovation Advisors

Supporting the Technical and Business Assistance (TABA) Needs Assessment Program

October 2022

RTI Innovation Advisors

RTI Innovation Advisors is a business unit of RTI International, an independent, global research institute.



RTI Innovation Advisors

We help clients turn insights into new products, services, and technologies that have meaningful human and business impact.

RTI INTERNATIONAL

RTI International improves the human condition by turning knowledge into practice and leveraging science for the global good.

With over 5,000 private and public sector projects, we have served and produced results for innovation-driven organizations.

Industry

Government

Academia & NGOs

Client list above is illustrative, not exhaustive.

Our core services center on building innovation capacity, delivering insights, and accelerating technologies and innovation to market and impact.

Innovation Strategy

We work with you to build and improve a team's internal innovation capabilities and processes, building confidence to transform the right things the right way.

Insights

We perform market and user research, technology and partner scouting, expert consultations, forecasting, and trend analysis to uncover actionable insights and develop strategies that help you solve your toughest challenges.

Commercialization

We help organizations gain efficiencies and streamline their path from strategy to impact through our commercialization, technology transfer, and in-field testing and prototyping services.

When you work with us, you also tap into RTI International's vast network and resources.

RTI encompasses over 250 disciplines and hundreds of experts and researchers.

$1.078B
FY2021 Revenue

1,217
FY2021 Clients

3,977
FY2021 Projects

5,893
Staff Worldwide

Services and Capabilities

Rigorous methods, innovative technology R&D, and science-based solutions our clients can trust

- Innovation advising and commercialization support
- Evaluation, assessment, and analysis
- Drug discovery and development
- Engineering and technology R&D
- Research technologies
- Analytical laboratory science
- Surveys and data collection
- Statistics and data science
- Program design and implementation

Practice Areas

Multidisciplinary expertise needed to inform policy, practice, and programs

- Health
- Innovation ecosystems
- Food security and agriculture
- Environmental sciences
- Social and justice policy
- Energy research
- Education and workforce development
- International development

Each participating SBIR/STTR Recipient will be assigned an Assessment Lead who will conduct the needs assessment, with support from a diverse set of commercialization experts.

Moline Pandiyan - *RTI TABA Support Program Manager*

Wout Salenbien - *RTI TABA Support Deputy Program Manager*

Participating SBIR/STTR Recipient

Assessment Lead

Key Advising Personnel

- *Medical Product Regulation SME*
- *Medical Product Manufacturing SME*
- *Life Science Market Research SME*
- *Life Science Industry Business Development SME*
- *Life Science Intellectual Property SME*

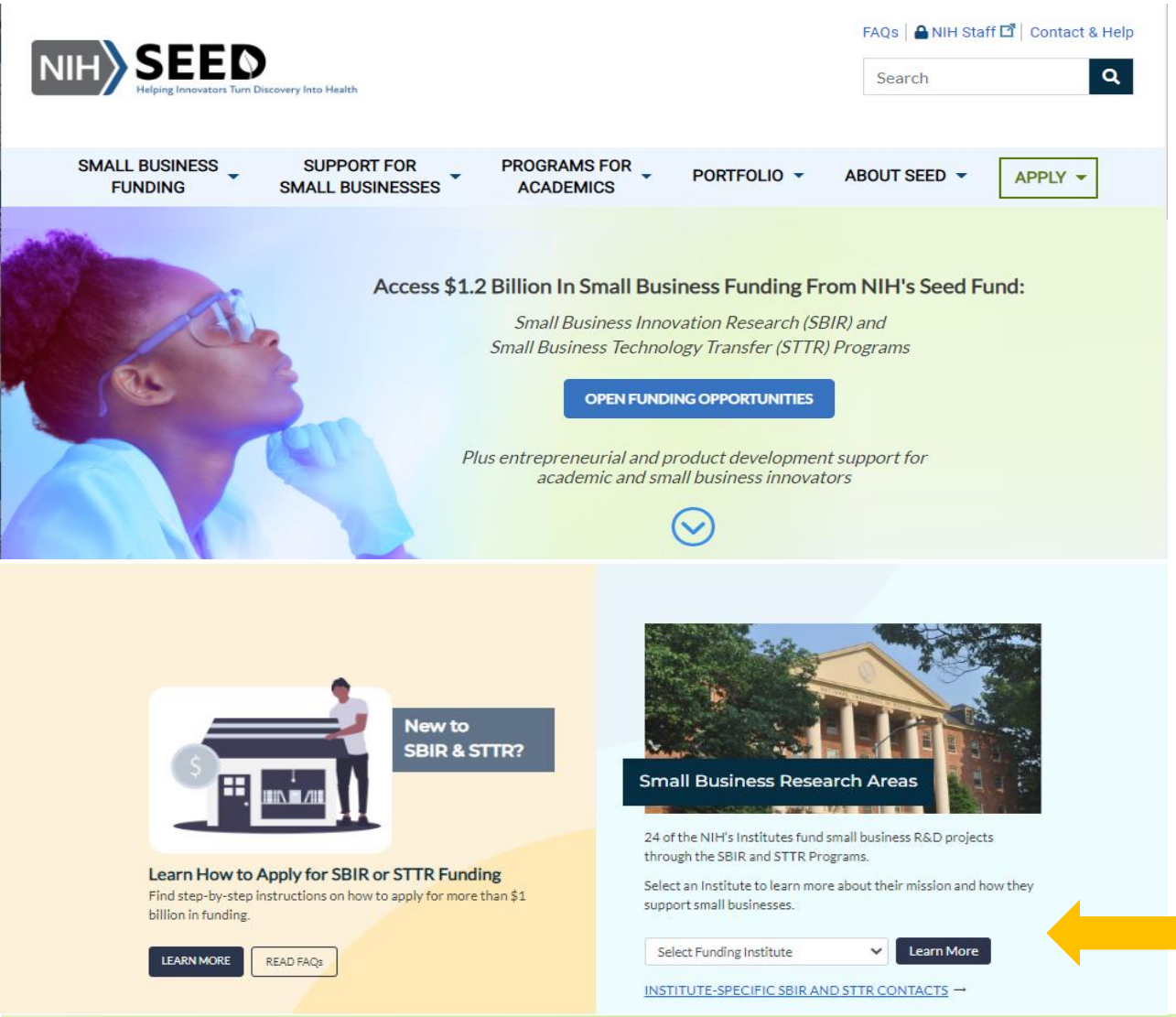
The estimated time commitment for each participating SBIR/STTR Recipient is minimal (approximately 3-5 hours).

We welcome the opportunity to support you!

Moline Pandiyan
moline@rti.org
919-541-6785

Wout Salenbien
wsalenbien@rti.org
919-485-1167

Most Important Piece of Advice



Talk to a Program Officer

List of SBIR Program Managers: https://seed.nih.gov

Not sure who to contact?

Research Portfolio Online Reporting Tools (RePORT): https://report.nih.gov/

Email: SEEDinfo@nih.gov

Connect with SEED

Online
http://seed.nih.gov/

Email us
SEEDinfo@nih.gov

@nihseed
https://twitter.com/nihseed

NIH SEED
https://www.linkedin.com/company/nihseed

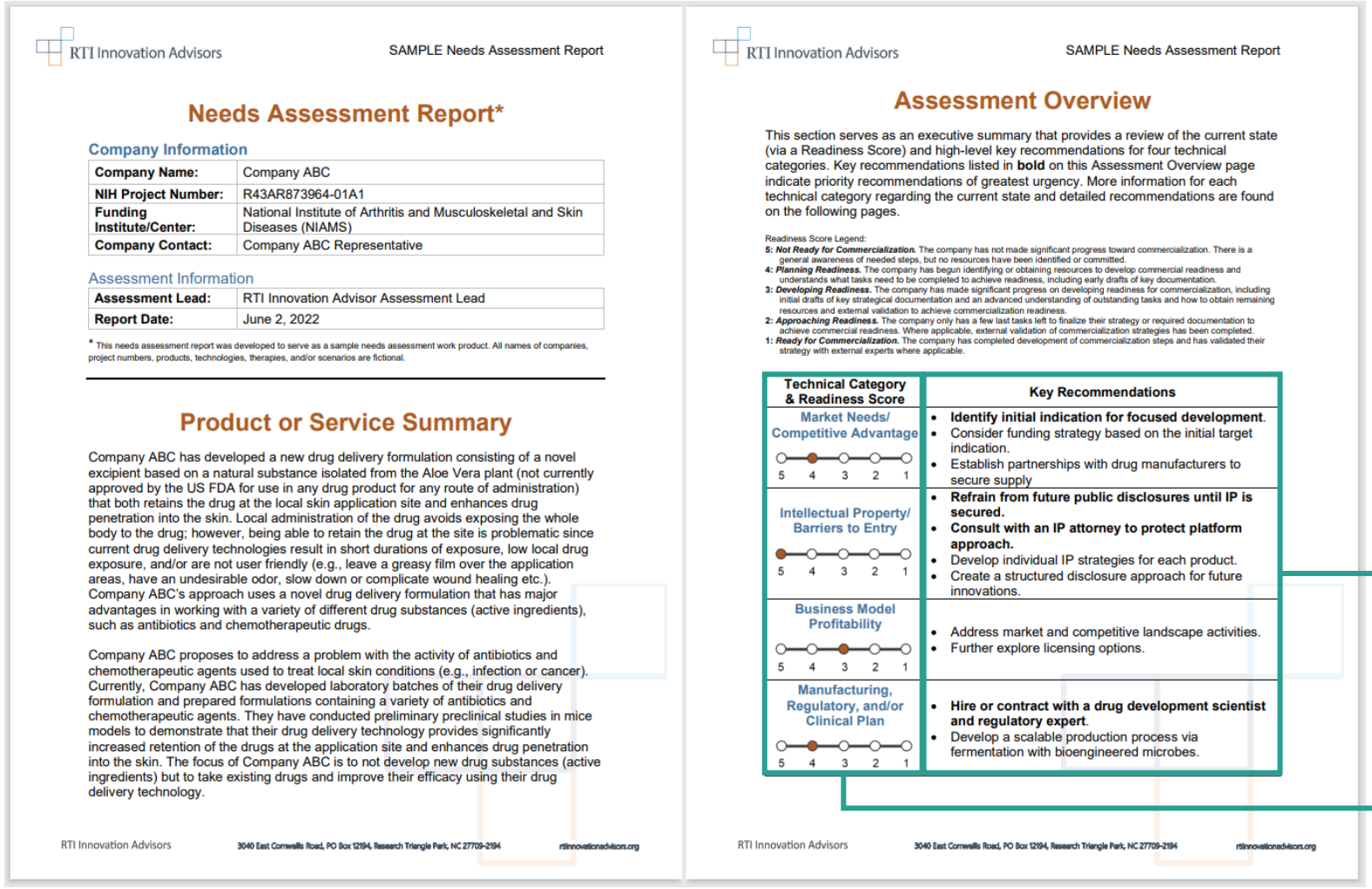
Sign up for NIH and SEED updates:
https://seed.nih.gov/subscribe

The NIH Guide for Grants and Contracts:
http://grants.nih.gov/grants/guide/listserv.htm

NIH SEED Events
https://seed.nih.gov/aboutseed/events

Backup Slides

Under the NIH SEED TABA Needs Assessment Program, our needs assessment reports evaluate the Recipient's product or service offering based on four technical categories.



RTI Innovation Advisors SAMPLE Needs Assessment Report

Needs Assessment Report*

Company Information

Company Name:	Company ABC
NIH Project Number:	R43AR873964-01A1
Funding Institute/Center:	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Company Contact:	Company ABC Representative

Assessment Information

Assessment Lead:	RTI Innovation Advisor Assessment Lead
Report Date:	June 2, 2022

* This needs assessment report was developed to serve as a sample needs assessment work product. All names of companies, project numbers, products, technologies, therapies, and/or scenarios are fictional.

Product or Service Summary

Company ABC has developed a new drug delivery formulation consisting of a novel excipient based on a natural substance isolated from the Aloe Vera plant (not currently approved by the US FDA for use in any drug product for any route of administration) that both retains the drug at the local skin application site and enhances drug penetration into the skin. Local administration of the drug avoids exposing the whole body to the drug; however, being able to retain the drug at the site is problematic since current drug delivery technologies result in short durations of exposure, low local drug exposure, and/or are not user friendly (e.g., leave a greasy film over the application areas, have an undesirable odor, slow down or complicate wound healing etc.). Company ABC's approach uses a novel drug delivery formulation that has major advantages in working with a variety of different drug substances (active ingredients), such as antibiotics and chemotherapeutic drugs.

Company ABC proposes to address a problem with the activity of antibiotics and chemotherapeutic agents used to treat local skin conditions (e.g., infection or cancer). Currently, Company ABC has developed laboratory batches of their drug delivery formulation and prepared formulations containing a variety of antibiotics and chemotherapeutic agents. They have conducted preliminary preclinical studies in mice models to demonstrate that their drug delivery technology provides significantly increased retention of the drugs at the application site and enhances drug penetration into the skin. The focus of Company ABC is to not develop new drug substances (active ingredients) but to take existing drugs and improve their efficacy using their drug delivery technology.

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RTI Innovation Advisors SAMPLE Needs Assessment Report

Assessment Overview

This section serves as an executive summary that provides a review of the current state (via a Readiness Score) and high-level key recommendations for four technical categories. Key recommendations listed in **bold** on this Assessment Overview page indicate priority recommendations of greatest urgency. More information for each technical category regarding the current state and detailed recommendations are found on the following pages.

Readiness Score Legend:
5: ***Not Ready for Commercialization.*** The company has not made significant progress toward commercialization. There is a general awareness of needed steps, but no resources have been identified or committed.
4: ***Planning Readiness.*** The company has begun identifying or obtaining resources to develop commercial readiness and understands what tasks need to be completed to achieve readiness, including early drafts of key documentation.
3: ***Developing Readiness.*** The company has made significant progress on developing readiness for commercialization, including initial drafts of key strategical documentation and an advanced understanding of outstanding tasks and how to obtain remaining resources and external validation to achieve commercialization readiness.
2: ***Approaching Readiness.*** The company only has a few last tasks left to finalize their strategy or required documentation to achieve commercial readiness. Where applicable, external validation of commercialization strategies has been completed.
1: ***Ready for Commercialization.*** The company has completed development of commercialization steps and has validated their strategy with external experts where applicable.

Technical Category & Readiness Score	Key Recommendations
Market Needs/ Competitive Advantage 5 4 3 2 1	• **Identify initial indication for focused development.** • Consider funding strategy based on the initial target indication. • Establish partnerships with drug manufacturers to secure supply
Intellectual Property/ Barriers to Entry 5 4 3 2 1	• **Refrain from future public disclosures until IP is secured.** • **Consult with an IP attorney to protect platform approach.** • Develop individual IP strategies for each product. • Create a structured disclosure approach for future innovations.
Business Model Profitability 5 4 3 2 1	• Address market and competitive landscape activities. • Further explore licensing options.
Manufacturing, Regulatory, and/or Clinical Plan 5 4 3 2 1	• **Hire or contract with a drug development scientist and regulatory expert.** • Develop a scalable production process via fermentation with bioengineered microbes.

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Key Recommendations

The Overview page lists Key Recommendations for each of the four technical categories:

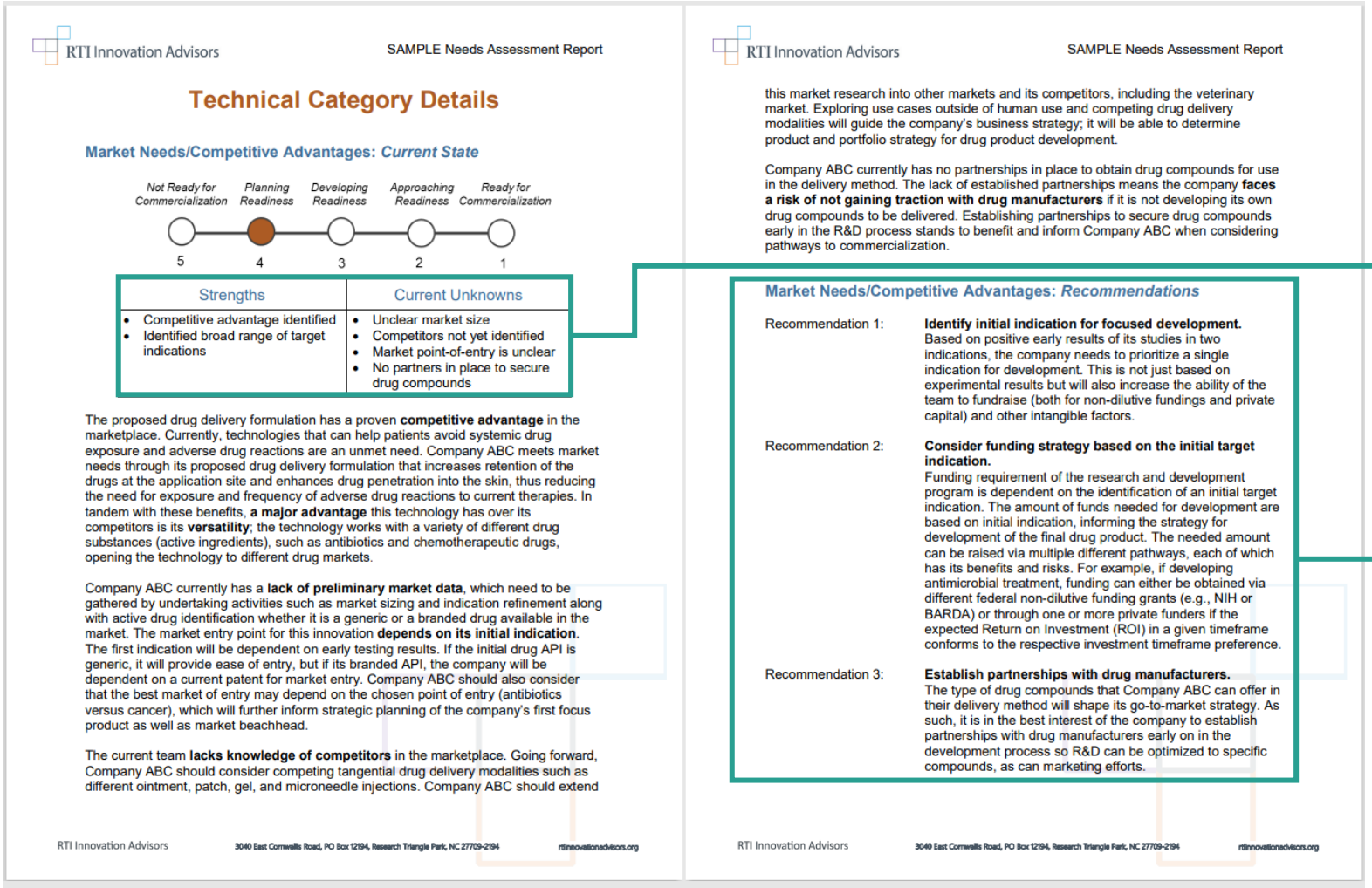
1. Market Needs/Competitive Advantage
2. Intellectual Property/Barriers to Entry
3. Business Model Profitability
4. Manufacturing, Regulatory, and/or Clinical Planning

Urgent recommendations are bolded to help innovators prioritize resources.

Readiness Score

Each of the four technical categories receives a readiness score ranging from 5 (*Not Ready*) to 1 (*Ready for Commercialization*).

For each technical category, the needs assessment captures the current state and provide specific, individualized recommendations to guide the Recipient's next steps.



RTI Innovation Advisors SAMPLE Needs Assessment Report

Technical Category Details

Market Needs/Competitive Advantages: *Current State*

Not Ready for Commercialization	Planning Readiness	Developing Readiness	Approaching Readiness	Ready for Commercialization
5	4	3	2	1

Strengths	Current Unknowns
• Competitive advantage identified • Identified broad range of target indications	• Unclear market size • Competitors not yet identified • Market point-of-entry is unclear • No partners in place to secure drug compounds

The proposed drug delivery formulation has a proven **competitive advantage** in the marketplace. Currently, technologies that can help patients avoid systemic drug exposure and adverse drug reactions are an unmet need. Company ABC meets market needs through its proposed drug delivery formulation that increases retention of the drugs at the application site and enhances drug penetration into the skin, thus reducing the need for exposure and frequency of adverse drug reactions to current therapies. In tandem with these benefits, **a major advantage** this technology has over its competitors is its **versatility**; the technology works with a variety of different drug substances (active ingredients), such as antibiotics and chemotherapeutic drugs, opening the technology to different drug markets.

Company ABC currently has a **lack of preliminary market data**, which need to be gathered by undertaking activities such as market sizing and indication refinement along with active drug identification whether it is a generic or a branded drug available in the market. The market entry point for this innovation **depends on its initial indication**. The first indication will be dependent on early testing results. If the initial drug API is generic, it will provide ease of entry, but if its branded API, the company will be dependent on a current patent for market entry. Company ABC should also consider that the best market of entry may depend on the chosen point of entry (antibiotics versus cancer), which will further inform strategic planning of the company's first focus product as well as market beachhead.

The current team **lacks knowledge of competitors** in the marketplace. Going forward, Company ABC should consider competing tangential drug delivery modalities such as different ointment, patch, gel, and microneedle injections. Company ABC should extend

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RTI Innovation Advisors SAMPLE Needs Assessment Report

this market research into other markets and its competitors, including the veterinary market. Exploring use cases outside of human use and competing drug delivery modalities will guide the company's business strategy; it will be able to determine product and portfolio strategy for drug product development.

Company ABC currently has no partnerships in place to obtain drug compounds for use in the delivery method. The lack of established partnerships means the company **faces a risk of not gaining traction with drug manufacturers** if it is not developing its own drug compounds to be delivered. Establishing partnerships to secure drug compounds early in the R&D process stands to benefit and inform Company ABC when considering pathways to commercialization.

Market Needs/Competitive Advantages: *Recommendations*

Recommendation 1: **Identify initial indication for focused development.**
Based on positive early results of its studies in two indications, the company needs to prioritize a single indication for development. This is not just based on experimental results but will also increase the ability of the team to fundraise (both for non-dilutive fundings and private capital) and other intangible factors.

Recommendation 2: **Consider funding strategy based on the initial target indication.**
Funding requirement of the research and development program is dependent on the identification of an initial target indication. The amount of funds needed for development are based on initial indication, informing the strategy for development of the final drug product. The needed amount can be raised via multiple different pathways, each of which has its benefits and risks. For example, if developing antimicrobial treatment, funding can either be obtained via different federal non-dilutive funding grants (e.g., NIH or BARDA) or through one or more private funders if the expected Return on Investment (ROI) in a given timeframe conforms to the respective investment timeframe preference.

Recommendation 3: **Establish partnerships with drug manufacturers.**
The type of drug compounds that Company ABC can offer in their delivery method will shape its go-to-market strategy. As such, it is in the best interest of the company to establish partnerships with drug manufacturers early on in the development process so R&D can be optimized to specific compounds, as can marketing efforts.

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Current Strengths vs. Unknowns

For each of the four technical categories, a summary of the current state is provided based on key strengths and current unknowns.

Detailed Recommendations

Detailed recommendations for each technical category are provided for additional guidance and context. These details further help each Recipient better understand their individual commercialization needs and next steps.