INSPIRALIA USA

MHUB

INTRO TO FEDERAL FUNDING:
THE SBIR/STTR SEED FUND PROGRAM

SBIR·STTR
America's Seed Fund

inspiralia
Group

Welcome to the INSPIRALIA Group

Our companies

Inspiralia EUROPE
HQ: Madrid, Spain

Inspiralia USA
HQ: Miami, US

TORO VENTURES

Toro Ventures
HQ: Madrid, Spain

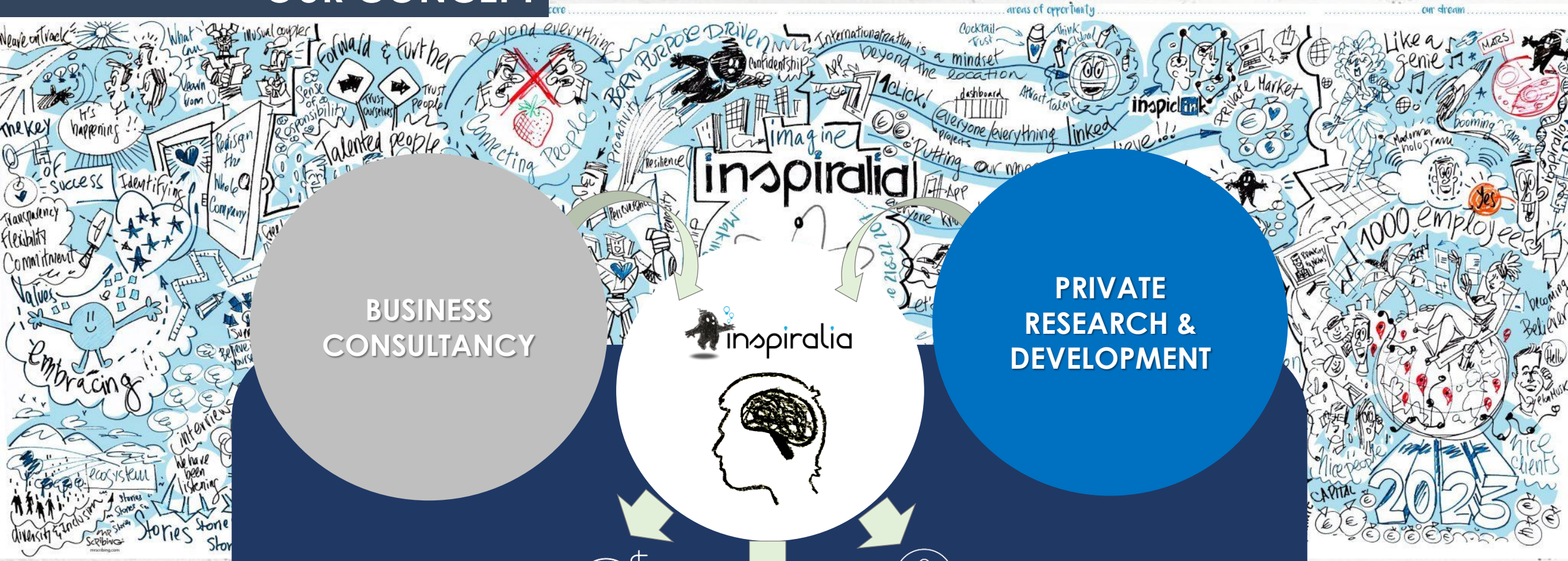
Fen
an Inspiralia Group company

Fen Technology
HQ: Cambridge, UK

m27

M27 Finance
HQ: Vienna, Austria

OUR CONCEPT



BUSINESS CONSULTANCY

inspiralia

PRIVATE RESEARCH & DEVELOPMENT

US/EU R&D FUNDING

TECHNICAL DEVELOPMENT

GROWTH OPPORTUNITIES

The Inspiralia Group

Combining business expertise and R&D experience

21	155	20%	500+	60%
Nationalities	Full-Time Employees	PhDs	Small Businesses Funded Worldwide	**Success Rate for R&D Grant Applications**

Inspiralia USA

A b o u t U s

Inspiralia USA, the American entity of Inspiralia, is a ***New Product Development Company*** headquartered in Miami with offices in Boston and Houston.

Our mission since 2005 has been to organize funding and develop new products for our clients, improve their sustainability, heighten their profitability, and thereby contribute to a better society.

To accomplish this, we offer a complete *360-degree* service. Our combination of federal funding acquisition and in-house R&D provides our clients with necessary seed funding, access to technical development resources, and a pathway to global product launch.

MIAMI (HQ)

BOSTON

HOUSTON

SBIR & STTR: OUR SERVICES

SOLICITATION TOPICS & AGENCIES

- ✓ Inspiralia evaluates funding potential & open topics. We maintain personal contact to Project Officers

PROPOSAL CREATION & SUBMISSION

- ✓ We create your proposal, register your company and submit your project to the different available calls for proposals

PHASE 1 OR PHASE 2 AWARD

- ✓ We accompany you during all stages of the project supporting you in all administrative efforts

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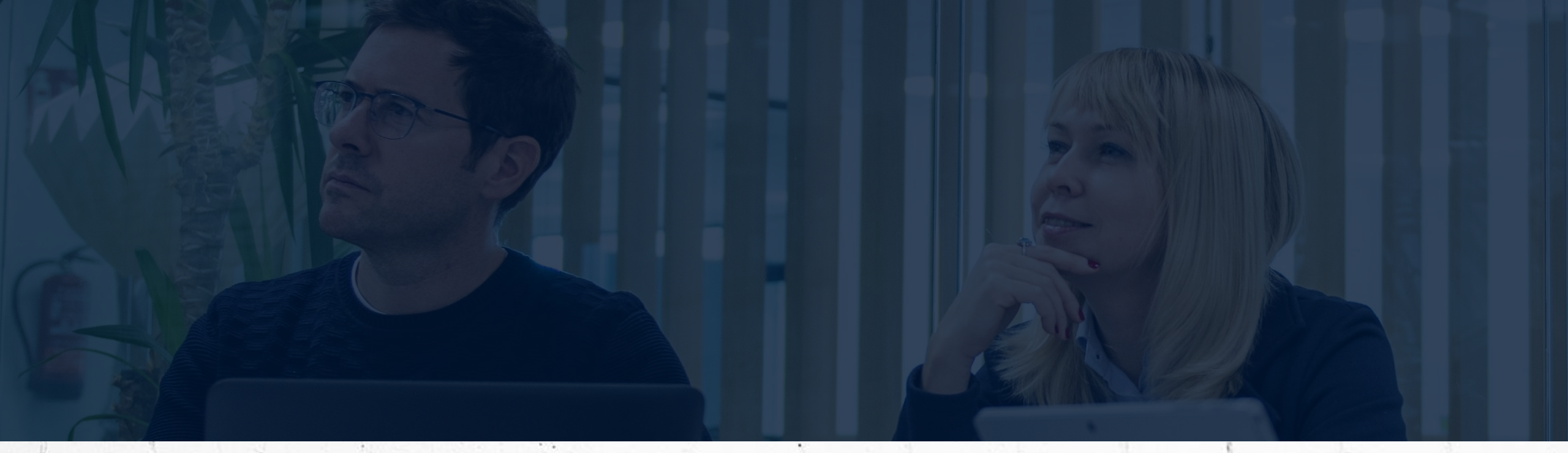

WHAT IS THE SBIR?

THE SBIR/STTR PROGRAM

- **THE** largest and most important source of federally-funded early stage R&D funding.

- Backed by the Small Business Administration, the SBIR has an **annual budget of $2.5 billion.**

  - Takes ZERO equity
  - A grant – does *not* have to be paid back
  - Funds all project costs – direct *and* indirect costs

$41 billion. 70,000 patents. 700 public companies. 450k+ scientists. That's the SBIR program in a nutshell

SBIR · STTR
America's Seed Fund

SBIR - WHO PARTICIPATES?

11 **Federal Agencies :**

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of Transportation
Environmental Protection Agency
NASA
National Science Foundation

The Department of Defense

The National Institutes of Health

The National Science Foundation

The Department of Energy

ARE YOU ELIGIBLE?

WHO CAN APPLY TO THE SBIR?

- Small business (<500 employees)
- U.S. based and >51% American citizen or American resident owned.
- Will do R&D on American soil (with some exceptions)

CHECK YOUR ELIGIBILITY HERE

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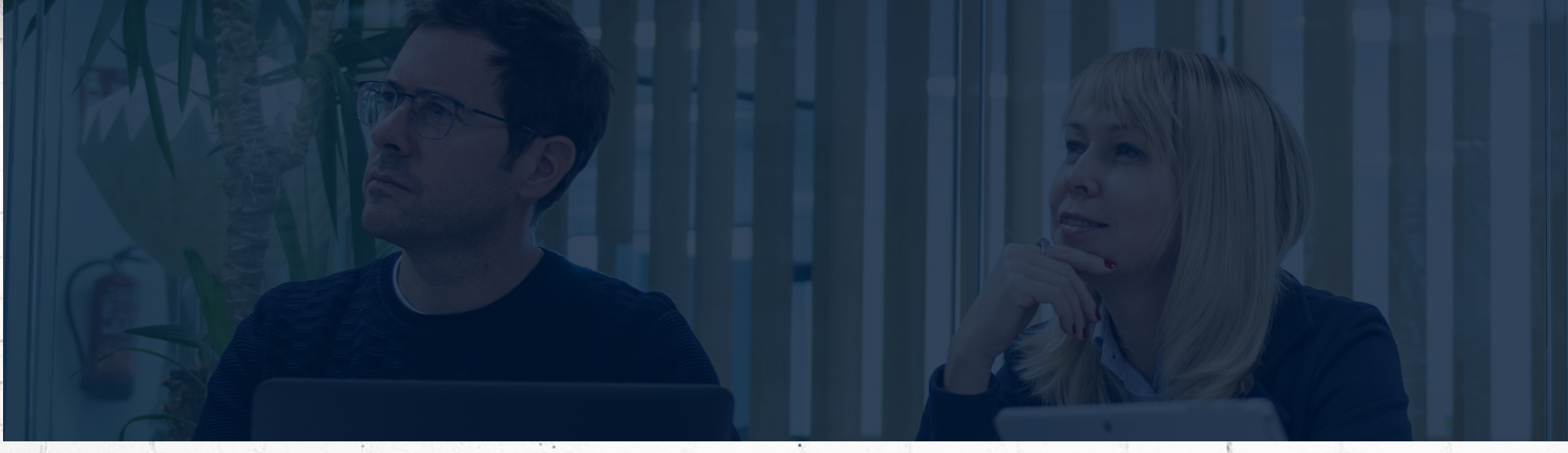
HARD FACTS

- Principal Investigator (PI) must be > 51% employed by the business.
- ALL R&D must happen within the U.S.
- Up to 1/3 of the activities can be subcontracted to other parties.
- Company must have at least a *plan* for IP protection

HOW DO I FIND THESE?

FINDING OPPORTUNITIES



IS THE SBIR A FIT FOR ME?

WHAT IS AN SBIR-READY COMPANY?

ELIGIBLE COMPANY

- Have the staff
- Have the facilities
- Have the *time*

FOCUSED TEAM

- Have a cohesive, well-rounded team
- Have the ability to write academic quality papers
- Can problem-solve in a tight time frame

YOUR TURN!

Company A is proposing a patch that monitors fetal heart rate non-invasively.

- They have a 2000 sq ft laboratory with machinery to make and test this patch
- They have access to 50-100 participants on which to test the patch.
- Team consists of a PhD in mechanical engineering (CTO), a former director of a prenatal clinic (Director), and an MBA in health technologies (CEO).

Are they ready for an SBIR?

WHAT IS AN SBIR PROJECT?

INNOVATIVE

REVOLUTIONARY

FOCUSED

INNOVATIVE

High degree of technical risk

- Has never been done *successfully* before
- Has clear technical hurdles to overcome (and solutions are presented in the proposal)

A new take or an existing idea that takes the modus operandi to the next level

REVOLUTIONARY

Is a step above the competition

Holds the potential to shift the common practice

Examples

- Google search algorithm
- Virtual reality for workforce training
- Silent airplane for reconnaissance

FOCUSED

Has clearly defined milestones

- Measurable
- Achievable

Has a logical path to commercialization

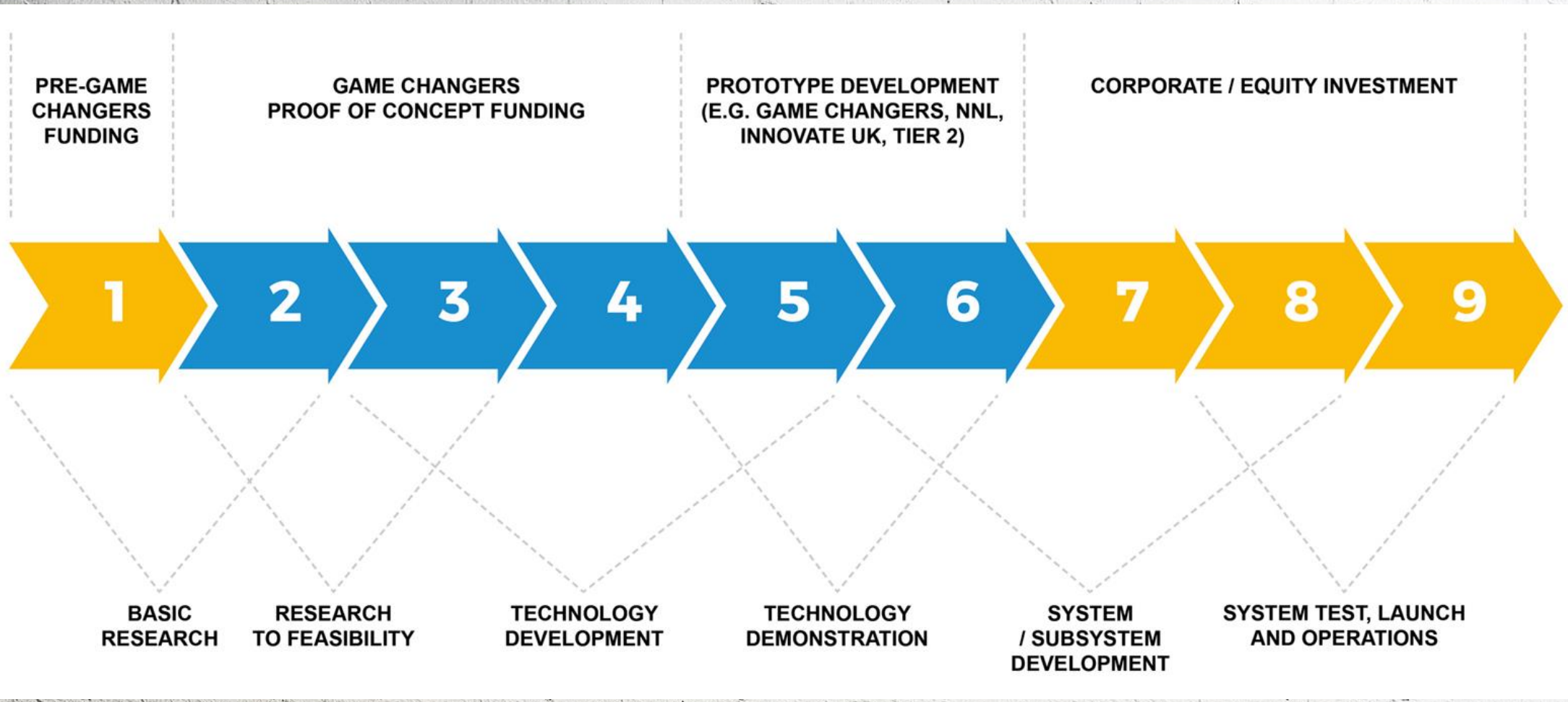
- E.g.; We will have a minimally viable prototype and will commercialize to X local market by year 5, expand to X regional market by year 8,…..
- ***Not:*** Global market for product is $Y MM, we expect to have 2% of market share by year 5 for a total revenue of $Z MM

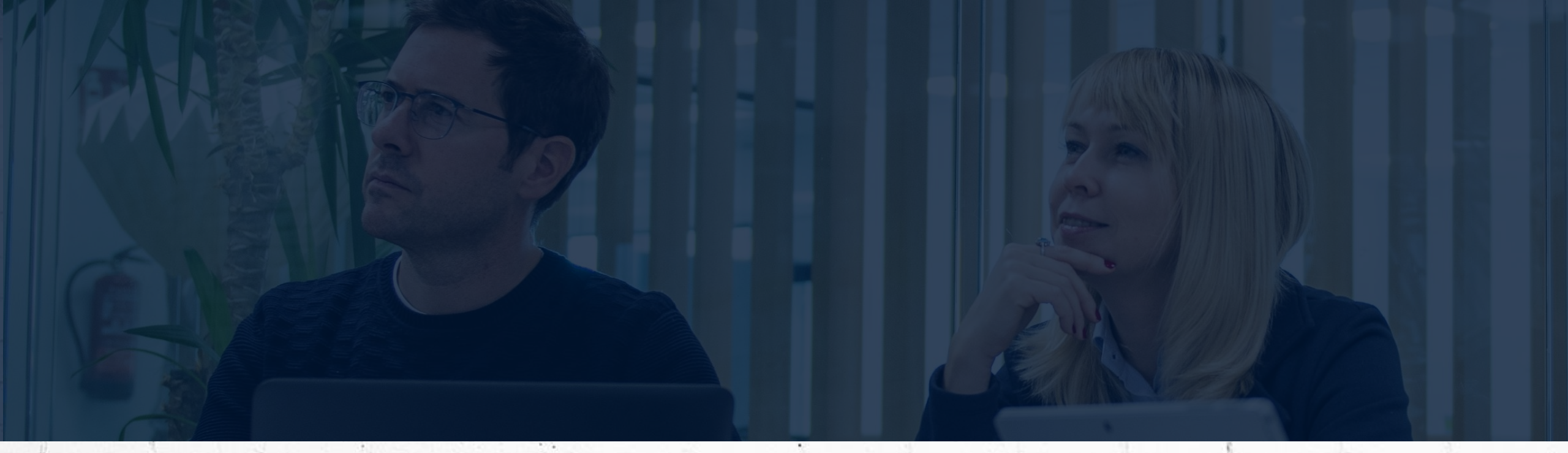
COMMERCIALIZATION

- The SBIR program is ***not*** for basic research.
- Phase I proposals must have *at least*:
  - A basic business plan (plan of attack)
  - Ideas of revenue streams
  - A plan to protect IP
  - A review of the market
- Phase II proposals must have a fully fleshed out commercialization plan.

No matter how great the technology, if it cannot be commercialized **it is not a fit for the SBIR**.

TECHNOLOGY READINESS





GENERAL PROPOSAL STRATEGY TIPS

ELECTRONIC REGISTRATIONS

EIN

Employer Identification number

DUNS

Duns and Bradstreet Universal Numbering System

SAM

System for Award Management

Grants.gov

Federal-wide portal to apply for federal funding

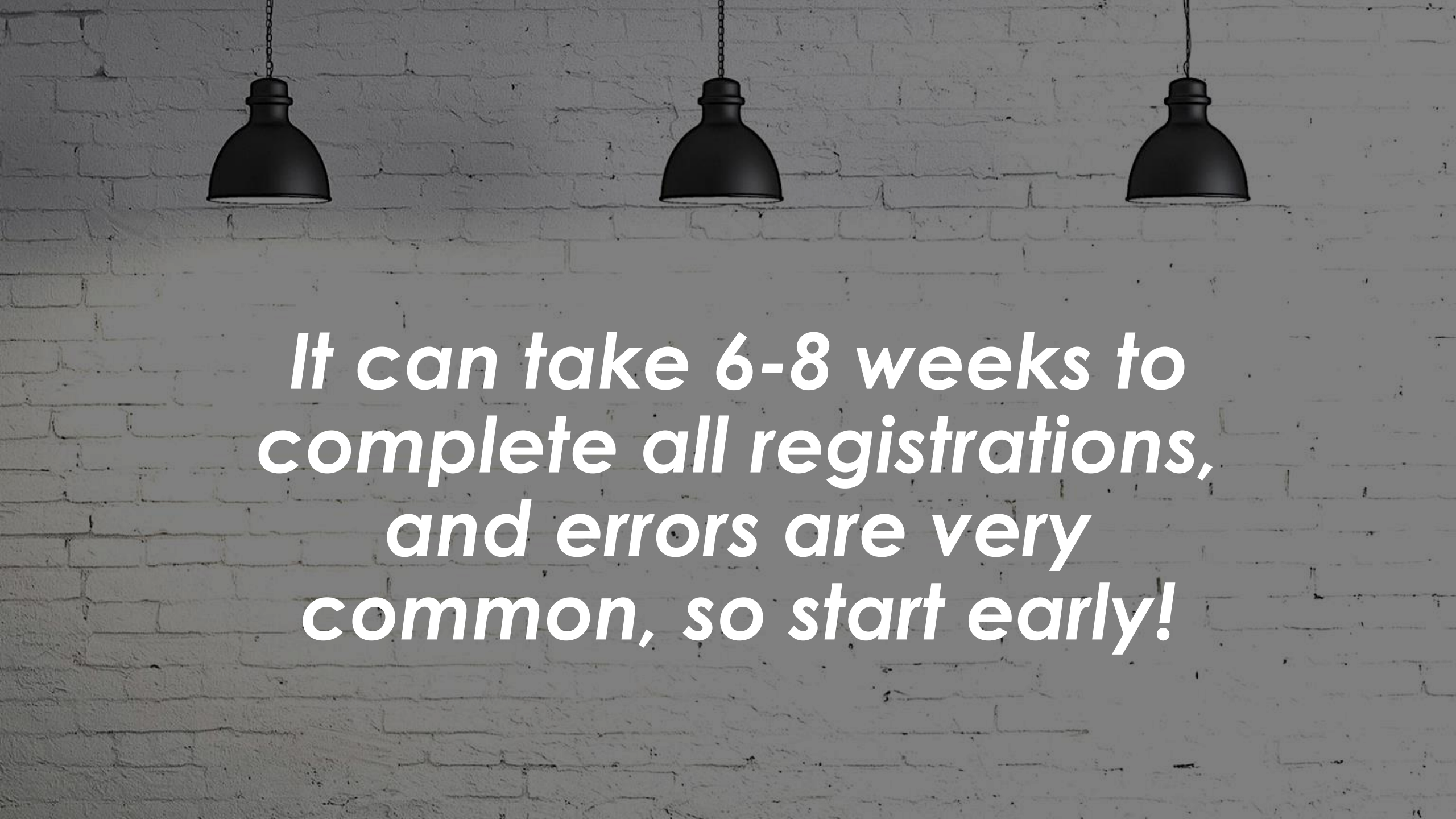
Agency Portals

eRA Commons

Research.gov

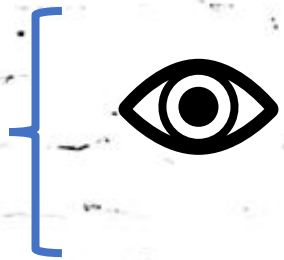
SBA company registry

All applicants must attach proof of registration


It can take 6-8 weeks to complete all registrations, and errors are very common, so start early!

PROPOSAL LIFE CYCLE

- Find the perfect topic match
- Multi-pronged funding approach



Idea conception

Validation

Kickoff meeting

Draft the proposal

Submit!

- Determine objectives
- Build your team
- Obtain letters of support

Adapt to another agency or funding mechanism

Expand to encompass another aspect of the project

Project Validation

- Company X is creating a home-based intervention and teletherapy model where caregivers will carry out tasks previously performed by a therapist. This shifts the burden of execution from therapists to caregivers. Furthermore, Company X is creating a machine-learning based tool for speech therapy patient and clinician support to both tailor therapy plans, and identify developmental delays earlier.
- What agencies would Company X fit?
- How many can we apply to?

APPLICATION ESSENTIALS

Innovative product with significant societal impact

Strong evidence that the technology works as intended

Understanding of the market potential, customers and commercialization strategy

Support letters from potential partners, customers or investors

Strong management team/advisory board

Communication with PD's strongly encouraged

Letters of Support

- Why?
  - Adds credibility to your proposal
  - From the right contact, a reviewer will see commercialization potential
  - Shows focus on commercialization as the goal of the project

One of the objectives!

DO

Find potential customers, funding sources, or potential clients.

State value and importance of innovation within a certain market

Get commitment from writer if possible

Writer should offer their time for further questions

DON'T

Write more than one page

Find experts to attest the niftiness of your innovation. No universities or consultants!

Have an old date. Must be recent!

Have the same format and verbatim on different letters

WRITING THE PROPOSAL

1

Language

- Avoid jargon
- Sales vs. academese
- Use words and phrase in the FOA
- Proofread!

2

Formatting

- Simple color scheme
- Anchor statements
- Use formatted text wisely

3

Content

- Spell it out
- Quantify wherever possible
- Use figures and tables instead of number-heavy text

FORMATTING

1. EXCELLENCE

1.1 OBJECTIVES

Can current pesticides win the war against insect pests?

- **Greenhouse farmers can lose up to 30% of the annual crop yield due to pests and diseases**, accounting for €25-45 billion year worldwide, €1 billion in Europe alone. This loss occurs despite the application of about 3 million tons of pesticide/year plus the use of non-chemical methods, like crop rotations and biopesticides.
- **Insect resistance to conventional chemical pesticides makes them less effective.** Even within a single growing season a pest can develop a resistance to a given chemical. For this reason, the agro-chemical industry is constantly developing new pesticides, in a pest-chemical war that is very lucrative for large chemical manufacturers of pesticides. A large number of these pesticides are no longer commercially available due to their toxicity as impo Regulation (EC) No 1107/2009. The ones that can be still commercialized, cannot be used during the critica pre-harvest period (number of days it takes for the chemicals to break down), since no traces of chemicals are allowed in products for human consur markets. Thus, crops are not well protected during this interval, which is responsible for approx. 15% of the economic losses.
- **Natural solutions, like biopesticides also suffer from certain drawbacks in this war again insect pests.** The main are narrow target pest range (only one to very few pathogens), suppressing the growth of pest rather than completely eliminating them, and causing even faster resistance development at high doses. Besides, the efficacy of biopesticides is sometimes unpredictable as a consequence of many environmental factors, like high sunlight (which normally photodegrades biopesticides) or low temperature (reduces the effectiveness). Also, biopesticides are less efficient when pest populations increase rapidly (days) due to their slower action.
- **Pesticides are a key pollutant in Europe not only affecting agricultural lands and targeted pests:** it's a well-known fact that pesticides are washed away from crops and accumulate everywhere. The best proof are the results of the first large-scale risk assessment of organic chemicals in European rivers and lakes (monitoring data for 223 chemicals at 4001 testing sites across the continent in 2014). Levels of organic chemicals were high enough to likely cause chronic problems, such as fewer offspring, at 42% of the sites. And at 14% of sites, the levels were high enough to kill a significant number of individuals of one or more of the three test species.

How Gatekeeper avoids crop damages without killing insects

Herbivorous insects are said to be responsible for destroying 20% of the world's total crop production annually. In a closed chamber like a greenhouse, where crops are clustered in a confined area to avoid the entrance of pests, if this security perimeter is trespassed pests bloom inside without control. The mild environmental conditions (temperature and humidity) and the lack of competing species (both the plants and for the insects) make it easy for pest freely develop. **We realized that it is simpler and more respectful with the environment to avoid the first fight with insects by keeping them out of the gate of the greenhouse**, than to use chemicals and biochemical to win the whole war against th ice they are inside. At **EdenShield Ltd**, an Israel-based agritech company established in 2012, we have been producing plant extracts for the last 5 years with outstanding results (see 1.3)

If insects do not get inside the greenhouse, there will be no need to fight them: Gatekeeper is based on a natural extract from medicinal desert plants able to camouflage the insect-attractive plant scents, achieving a proven decrease of 90% insect damages on crops at 10% of the cost of alternatives (1,560€/ha/year instead of current 15,000€/ha/year). GateKeeper is sprayed during 8 min/day at the greenhouse entrances by a simple system of sprinklers, so the active extract do not contact plants. By means of this simple but effective mechanism never used before in agriculture, we have overcome the big challenge of successfully blocking the extremely fine-tuned mechanism of insect attraction by plants. Since insects do not detect plants inside the greenhouse (i.e. plant's smell turns "invisible" to the insect), they feed on other plants outside.

Gatekeeper does WORK

In October 2015, we tested GateKeeper in 6 locations in Israel to keep whitefly away from greenhouses. We obtained a consistent 79% reduction in the penetration of insects inside a tomato field and 88% reduction of the penetration in a basil crop. Also in October 2015 we tested GateKeeper in Spain and Italy, obtaining an 88% reduction in the

VS.

3. RESEARCH PLAN

3.1. Significance and Impact

We propose to develop a broadly protective virus-like particle (VLP) based influenza vaccine that can neutralize a spectrum of influenza A virus subtypes by eliminating the major epitopes on HA to expose the more highly conserved universal and less available epitopes in the molecule.

Seasonal influenza infections continue to pose a significant burden in the US and around the world. Influenza A viruses cause respiratory infections that afflict more than 60 million Americans of all ages every year causing some 200,000 hospitalizations and about 36,000 deaths per year [1,2]. In addition to seasonal circulating viruses, pandemic strains periodically emerge with dire consequences [3,4]. For example, the H5N1 avian virus, continues to circulate in birds and causes occasional human infection with high mortality [5,6]. If this virus acquires the capacity to effectively transmit amongst humans, the consequences are likely to be severe [7,8]. In recent studies, airborne transmission of the H5N1 occurred in ferrets after four mutations in the HA and one mutation of the PB2 protein[9,10]. In addition, outbreak of flu in chickens, as happened recently in Mexico, could disrupt conventional production of vaccines.

The rapid antigenic evolution of influenza virus driven by the continuous accumulation of mutations (antigenic drift) or by gene swapping through reassortment (antigenic shift) overcomes the immune responses elicited by natural infection or vaccination. This necessitates periodic reformulation of vaccines with the predominant circulating strains and annual re-immunization to upgrade vaccine composition and to improve efficacy. Furthermore, the large number of avian and mammalian species susceptible to influenza virus provides additional sources of emerging virus that have the potential to give rise to a pandemic. Creation of a vaccine able to protect against both drifting viruses and those emerging from gene-shifting has been a major objective in the influenza vaccine field. Significant efforts have been applied to develop a universal vaccine, but achieving it has been elusive. However, the recent identification of broadly neutralizing antibodies from infected individuals [11,12] provides new possibilities for the design of vaccines able to elicit broad neutralizing protection. These broadly neutralizing antibodies predominantly bind to highly conserved sites on the stem regions of the hemagglutinin (HA), blocking virus infection by the steric inhibition of membrane fusion rather than receptor binding. Proper presentation of these highly conserved but subdominant (cryptic) antigenic sites in a vaccine composition could elicit broadly neutralizing antibodies. To achieve this goal, we propose to utilize VLPs displaying remodeled HAs that mainly exhibit these conserved epitopes. Development of a broadly protective (universal) vaccine able to withstand antigenic variation and sustain efficacy for an extended time should have a major impact on influenza prevention. Used not only as a stand-alone vaccine, but also as a component of seasonal vaccines, it could reduce both the incidence and severity of infection.

3.2. Innovation

We have shown that we can produce Virus-Like Particles (VLPs) with high immunogenicity and efficacy by expressing 4 flu proteins M1, M2, HA and NA simultaneously [31, 20, 21]. Also, we have produced VLPs with 2 different HAs in the same particle as well as chimeric molecules indicating the versatility of the system. The dominant immunogenic epitopes in HA are located in the globular domain necessary for binding to cellular receptors. If these are removed the virus would no longer be infectious and able to multiply. Current concepts suggest that these domains block immunogenic recognition of other regions of the HA molecule by steric hindrance and by immunodominance. The discovery of broadly neutralizing antibodies in formerly infected individuals indicates that these other epitopes are immunogenic and elicit a broad and effective immune response [11, 13]. We have designed a series of modified HA molecules to express in our VLP expression system. Preliminary studies with two of these reengineered HAs indicate that they are incorporated into VLPs produced in CHO cells, and elicit a immune response after immunization as tested in micro-neutralization assays of flu virus.

While these VLPs are produced by transient transfection in CHO cells expressing the M1 and M2 proteins, we have also created another VLP production system using continuous cell lines suitable for laboratory 5 liters scale up. Here we describe our preliminary findings and our proposal to produce several differently modified HAs to assess assembly, immunogenicity and efficacy that they would elicit against diverse flu strains. This cannot be done with egg based or cell based virus production methods.

POST-APPLICATION

Your reviewers…

APPLICATION REVIEW PROCESS - NSF

- **Month 1: Compliance Review**
  - Sufficient technical and commercial potential to justify a review?
  - Falls within the scope of the solicitation topic?
  - Proposes research in science, engineering or education?
- **Months 2-3: Merit Review (panel of reviewers)**
  - "All proposals are carefully reviewed by a minimum of three experts in the particular fields represented by the proposal"
  - Reviewers might not be experts in your subfield – so write accordingly
  - Panels will often include an expert in commercial product development to assess commercial viability
- **Month 3-4: Programmatic Review (NSF Internal Program staff)**
- **Month 5+: Funding recommendation/ Decision**
- **Month 5+: Funding Commitment**

AFWERX

Established in 2017 to create transformative opportunities and foster a culture of innovation in the Air Force

The ultimate goal is to solve problems and enhance the effectiveness of the AF by:

Uncovering ideas and opportunities

Connecting your ideas with real options

Assisting access to capital through different efforts, e.g. SBIR/STTR, network partners.

AFWERX and SBIR

- Created an Open Topic section for companies to submit their technologies
- Experiments to increase efficiency, effectiveness, and transition rate of the SBIR program
- For companies with existing commercial products or services that the AF might use
- A shorter application process and accelerated contract award has opened the doors for companies to work with the AF!

Success Stories

- Vita Inclinata: Awarded PHI in hours at a sprint day in October 2018 for their Load Stability System. That same month, they completed their first test flight. Went public in the NASDAQ in July 2019.
- IncludeHealth: standardizes next-generation fitness protocols for fighters. They are now working on adding multiple installations across the AF network for their PHII and PHIII.
- Analytical Space: have been awarded a PHII to deploy their data relay technology onboard a network of shoebox sized satellites across the globe. Generating more data in space and getting it to the earth faster.

How does it work?

- ✓ Feasibility study
- ✓ Maximum award of $50K to be done over 3 months
- ✓ Validate product market fit
- ✓ Define clear objectives and milestones

- ✓ Trial your solution with AF
- ✓ Maximum award of $1.5M to be done over 27 months
- ✓ Describe how it can be scaled
- ✓ Define a clear transition path
- ✓ Identify DoD or gov't customers who will use your proposed tech

- ✓ Sole-source government purchase
- ✓ No limit on $ amount
- ✓ Engage with potential government users
- ✓ This is the main goal of the topic

Deadline to submit PHI

June 17th

Thank you!

Feel free to contact us for any questions

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Our Model & Timeline

Writing Fee

The one and only fee that allows us to:

- ✓ file all your government registrations
- ✓ Write a new proposal from scratch
- ✓ Adapt your new proposal to different agencies
- ✓ Include one free edit per proposal

Performance-based

Phase 1 Success Fee

Our Phase 1 Success Fee includes the Administrational Management of the grant (budget follow-up, reports and communication)

Performance-based

Phase 2 Writing Fee

- ✓ Creation of a professional Phase 2 proposal
- ✓ Personal Kick-Off Meeting at your site
- ✓ Pre-reviews of experienced SBIR evaluators

Performance-based

Phase 2 Success Fee

Our Phase 2 Success Fee includes the Administrational Management of the grant during its entire length (budget follow-up, reports and communication)