



Non-Dilutive Funding for Industry-Academic Partnerships

FreeMind Group Webinar

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August 14th, 2012

FreeMind
Group, LLC

Join us every Tuesday at Noon EDT for
the weekly FreeMind educational
webinar.

Syllabus:

1. SBIR/STTR
 2. Details of a Detailed **Budget**
 3. Joint webinar with the **Michael J. Fox Foundation** on Parkinson's and other Neurological disorders
 4. **BARDA** – mission and current funding opportunities
 5. **Cancer**
 6. **Medical Devices** funding opportunities
 7. Industry Academic **Partnership Programs**
 8. **Biodefense** and infectious diseases, NIAID
 9. **DOD** – DARPA, DTRA, US Army, etc.
- Webinar program is subject to change

FreeMind
Group, LLC

- ✓ Est. 1999
- ✓ 25 Fulltime Employees
- ✓ Academia & Industry Clientele
- ✓ Extensive experience in submitting and winning large scale applications
- ✓ Over \$1.5B in cumulative awards

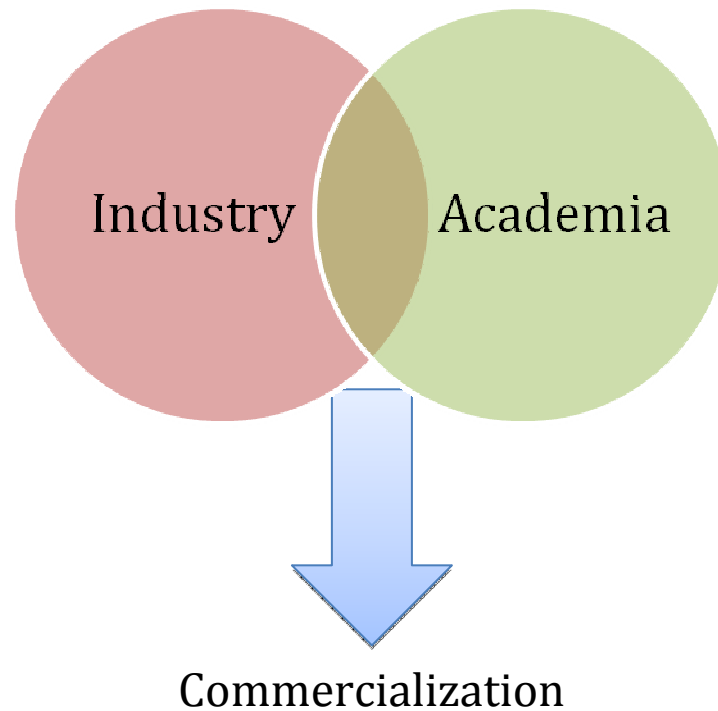
A Tool to Max. Your Funding Potential

FreeMind
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- ✓ Identifying most relevant funding opportunities
- ✓ Strategize to max. application's chances
- ✓ Manage complex project production processes
- ✓ Lead joint application writing
- ✓ Supports final contract negotiations

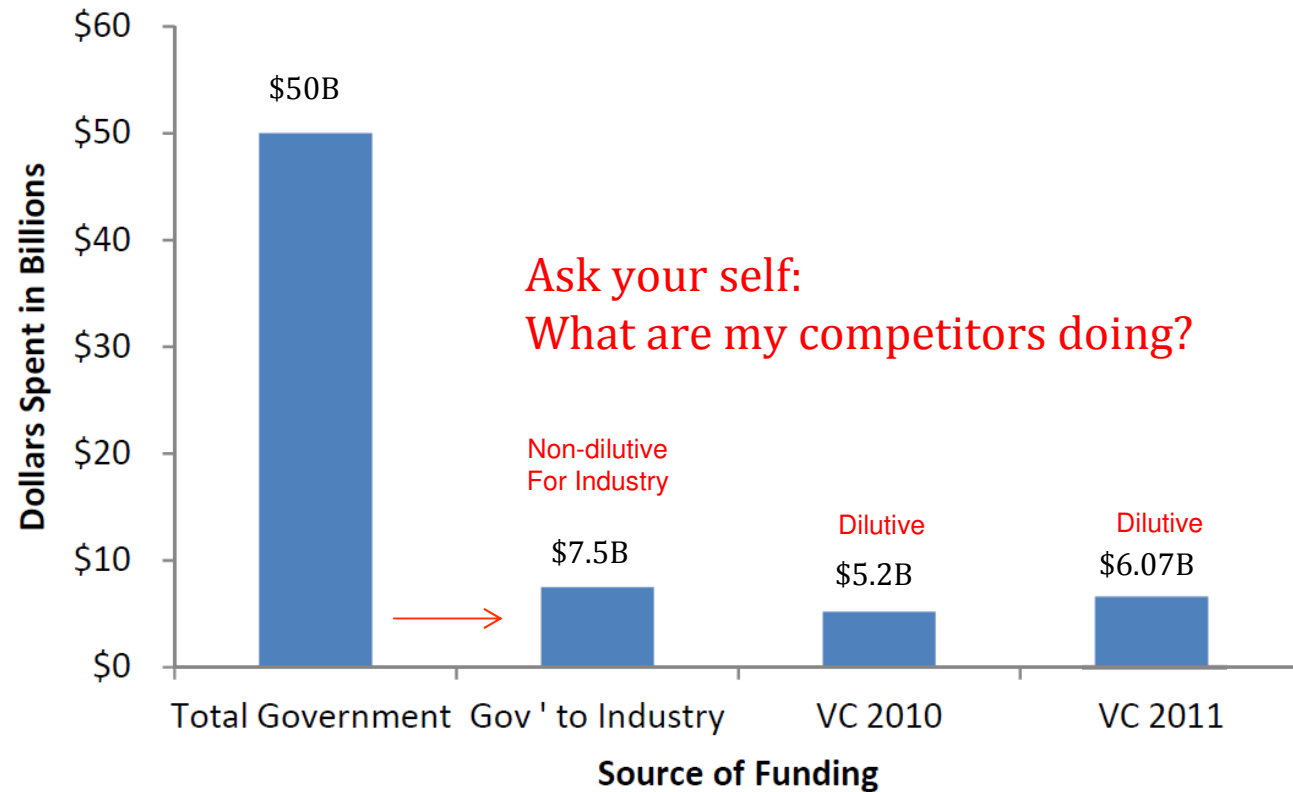
Partnerships

- Large Pharma
- Entrepreneurs
- Tech Transfer
- **Government Funding?**



VC vs. Non-Dilutive funding

Life Science companies cannot afford to ignore this pocket of money.



Adapted from the NIH Data Book, and OnBioVc trend analysis 2010, 2011

Francis Collins,
NIH Director



COMMENTARY

POLICY

**Reengineering Translational Science:
The Time Is Right**

Francis S. Collins

Realization that medical benefits of the current revolution in biology clearly cannot be achieved without vigorous and effective translation;

National Center for Advancing Translational Sciences (NCATS) - total FY2012 budget will be **\$570 million**.

“In all of these examples, partnerships with the private sector have been essential for ultimate success.”

“Through **partnerships** that capitalize on our respective strengths, NIH, academia,...and the private sector can take full advantage of the promise of translational science to deliver solutions to the millions of people”

Francis S. Collins. Reengineering Translational Science: The Time Is Right. Science Translation Medicine. Vol 3 Issue 90 Jul. 2011

NCATS

Established in 2012

2013 Budget request
\$639M

Main Goals

- Overcome translational pipeline barriers.
- Testing pipeline innovations with promising research projects.
- Cultivating strong **partnerships**.
- Increasing collaboration with the FDA
- Supporting an innovative and collaborative training program.

Some 14 different programs; examples:

- Therapeutics for Rare and Neglected Diseases (TRND) - Speed the development of new drugs for rare and neglected diseases; **Deadline: September 28th, 2012!**
- Cures Acceleration Network (CAN) - address scientific and technical challenges that impede translational research.

CAN will support the following activities:

- Rescuing and Repurposing Drugs
- Tissue Chip for Drug Screening
- Identifying and Validating Drug Targets

NIH, DoD

- Many more examples
 - Big Pharma and the FreeMind Group; Industry - Academia, Industry - Industry collaborations
 - FMG and the Seattle Structural Genomics Center for Infectious Disease – Consortium comprised of Seattle Biomed, UW, Emerald BioStructures, and Pacific Northwest National Laboratory - \$39.6M
- Not just specific solicitations – also investigator initiated programs
- Collaborations are strongly encouraged on ALL grants.

SBIR/STTR

The STTR program is intended to:

Stimulate a partnership of ideas and technologies between innovative small businesses and non-profit research institutions. The STTR program assists the small business and research communities by commercializing innovative technologies.

Does have it's core limitations, mainly eligibility as well as percent efforts by the respective parties (Small Business at least 40%, Institution at least 28%).

SBIR/STTR is 2.5% of the budget, STTR – roughly 0.85%

(Parent **STTR** [R41/R42]) [PA-12-089](#)

•Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications

And now, some specific partnership funding opportunities

NIAID - R01

Deadlines:

Letter of intent:
April 24, 2012

Full application:
May 24, 2012

Start Date:
April 2013

Funding: up to \$3.75M over 5 years in Direct costs (\$750,000 per year).

In addition, applicants may request up to a total of \$280,000 for major equipment (1st year)

Scope:

- To support preclinical research that will advance the development and/or production of lead biodefense countermeasures (vaccines, vaccine technologies, adjuvants, therapeutics, immunotherapeutics, and medical diagnostics) specific for NIAID **Category A, B, or C priority agents**.
- Applications must present a Product Development Strategy and demonstrate substantive investment by at least one industrial participant.

NIAID -
R21/R33

Deadlines:

Full application:
June 13, 2012

Start Date:
April 2013

Funding: For the **R21 phase**, direct costs can be requested up to \$275,000 over 2 years. For the **R33 phase**, direct costs can be requested up to \$900,000 over 3 years (\$280,000 per year).

Scope:

- This initiative by NIAID seeks to stimulate basic and early stage **translational research** focused on development of novel intervention strategies to clear persistent, chronic or latent infectious agents from the host.
- Responsive applications will define and address a therapeutic need specific to a targeted pathogen
- Milestones!

NIAID - RO1

Deadlines:

Full application:
June 26, 2012

Start Date:
April 2013

Funding: up to \$3.75M over 5 years in Direct costs (\$750,000 per year).

In addition, applicants may request up to a total of \$280,000 for major equipment (1st year)

Scope:

- To support **preclinical** development of candidate technologies that would improve vaccine effectiveness and/or simplify vaccine delivery during a natural outbreak or following intentional release of an infectious agent.
- Projects that would benefit production, delivery, stability and/or efficacy of non-biodefense-related vaccines are responsive provided that the targeted technology would be applicable to biodefense-related products.
- Applications must include a **Product Development Strategy** and demonstrate substantive investment by at least one **industrial participant**

NCI

Deadline:
Oct 5th, 2012

Funding: \$500,000 Direct cost/yr for up to 5 yrs.

Scope:

- Research partnerships formed by academic and industrial investigators to accelerate the translation of either animal or human in vivo imaging, image guided, and/or spectroscopic systems and methods designed to solve targeted cancer problems for cancer research, clinical trials, and/or clinical practice.
- Inter-disciplinary, multi-institutional research team to work in a strategic alliance to implement a coherent strategy to develop and translate the proposed system or methods with potential for significant impact on preclinical, single, or multisite clinical studies.
- Supports clinical trials that emphasize optimization and validation of the performance of imaging systems, including devices, agents and/or methods.
- Does not support commercial production.

NCI

Deadline:
Dec 5th, 2012

Funding: \$150,000 Direct cost for Phase I (2yr),
\$1M Direct cost for Phase II (3yr).

Scope:

- Propose the development and clinical validation of systems for image-guided interventions (IGI) for cancer.
- Provide support for: the development, optimization and validation of fully integrated cancer imaging, monitoring, and therapy systems; the development of multiple prototype integrated IGI systems as required for multisite clinical evaluations; in order to reach the research goals.

NCI

Deadline:
Oct 5th, 2012

Funding: \$500,000 Direct cost/yr for up to 5 yrs.

Scope:

- To promote research on quantitative imaging of tumor response to cancer therapies in clinical trial settings.
- Development of quantitative imaging methods, protocols and software solutions and their application in clinical therapy trials. Focus on imaging-derived quantitative measurements of responses to drugs and/or radiation therapy, and/or image-guided interventions.
- Multidisciplinary efforts - involvement of industrial partners is not required, but is strongly encouraged.

NIBIB

Deadline:
Oct 5th, 2012

Funding: No more than \$2M/year. Up to 5 years

Scope:

- BRPs for basic, applied, and translational multi-disciplinary research that addresses important biological, clinical or biomedical research problems.
- Integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. Design-directed, developmental, discovery-driven, or hypothesis-driven research
- Some BRP projects may propose research that could lead to a novel device as a product

NIAID -
R21/R33

Deadline:

Due date:
Feb 22, 2013

Funding: Not capped, should reflect the scope of the work. Preapproval for over \$500K/year.

Scope:

- Translate basic research findings into clinical tools for better human health; in areas of hearing, balance, smell, taste, voice, speech and language.
- To provide a new avenue for basic scientists, clinicians and clinical scientists to jointly initiate and conduct translational research projects.
- To encourage translation of basic research findings which will impact the diagnosis, treatment and prevention of communication disorders.
- **Multi-institutional, multi-disciplinary, and academic-industrial collaborations studies are encouraged.**

NIMH, NIAAA,
NIDA

Deadline:

Due date:
Oct 22, 2012

Funding: Not capped, should reflect the scope of the work. Preapproval for over \$500K/year.

Scope:

- To create multidisciplinary research groups or partnerships for the discovery of pharmacological agents to treat and to study mental illness, drug or alcohol addiction.
- To advance the discovery, preclinical development, and proof of concept testing of new, rationally based candidate medications to treat mental disorders or drug or alcohol addiction, and to develop novel ligands as tools to further characterize existing or to validate new drug targets.
- Partnerships between academia and industry are strongly encouraged.**

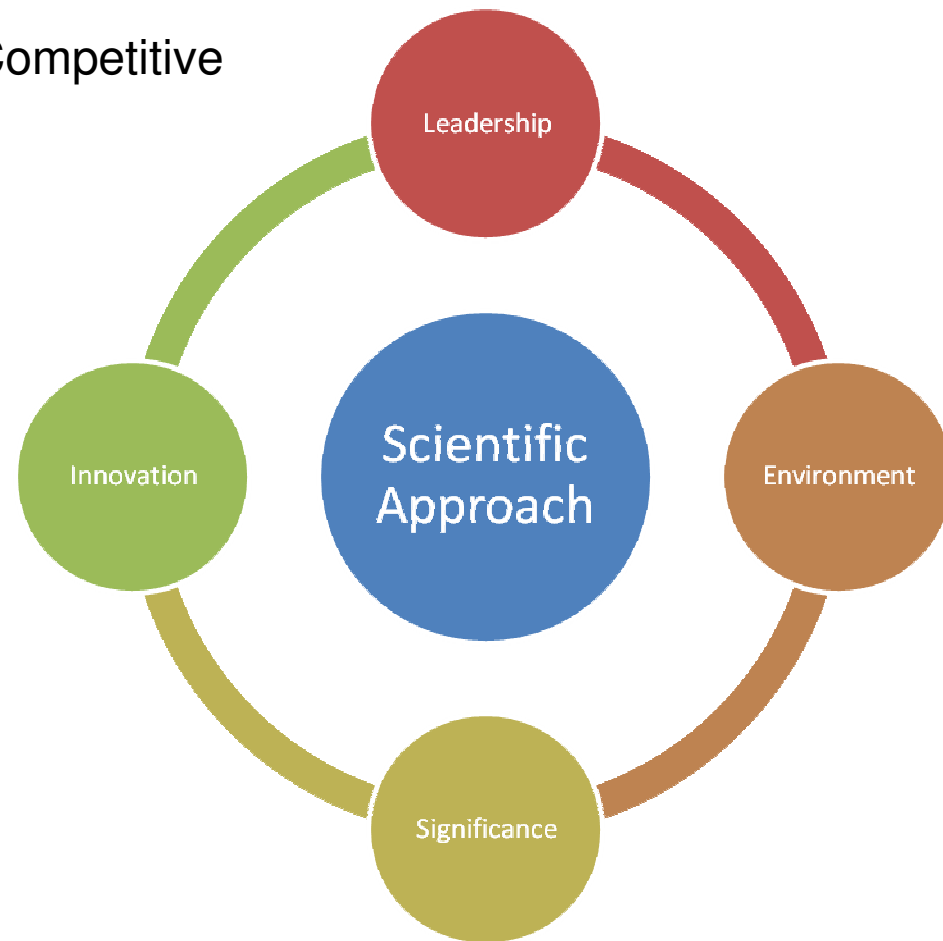
Overcoming the Challenges

Key Challenges

1. Different mechanisms with varying requirements
2. Writing and assembling the application
3. Plan for Multi PI
3. **Responsive vs. Competitive;** leadership, significance, innovative, approach, and environment.

Risk
Assessment

Responsive vs. Competitive



Key Issues

Systematic Approach

- Know the interests of the Agency
- Focus your project application
- Ask for what is necessary
- Present a complete project
- Leverage on research collaborations

Key Issues

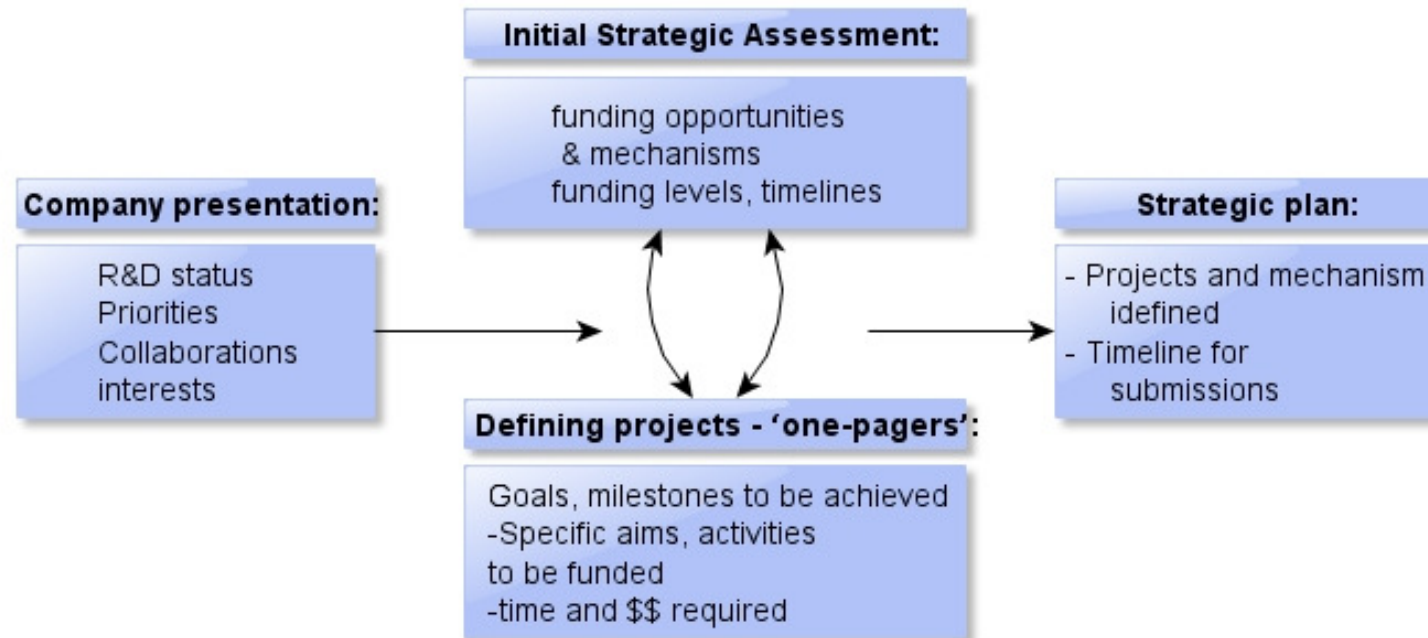
Target the Right Mechanism

- Different “pockets of money”
- Different size of award/success rates
- Some projects will not have the right target
- Conduct a thorough strategic assessment

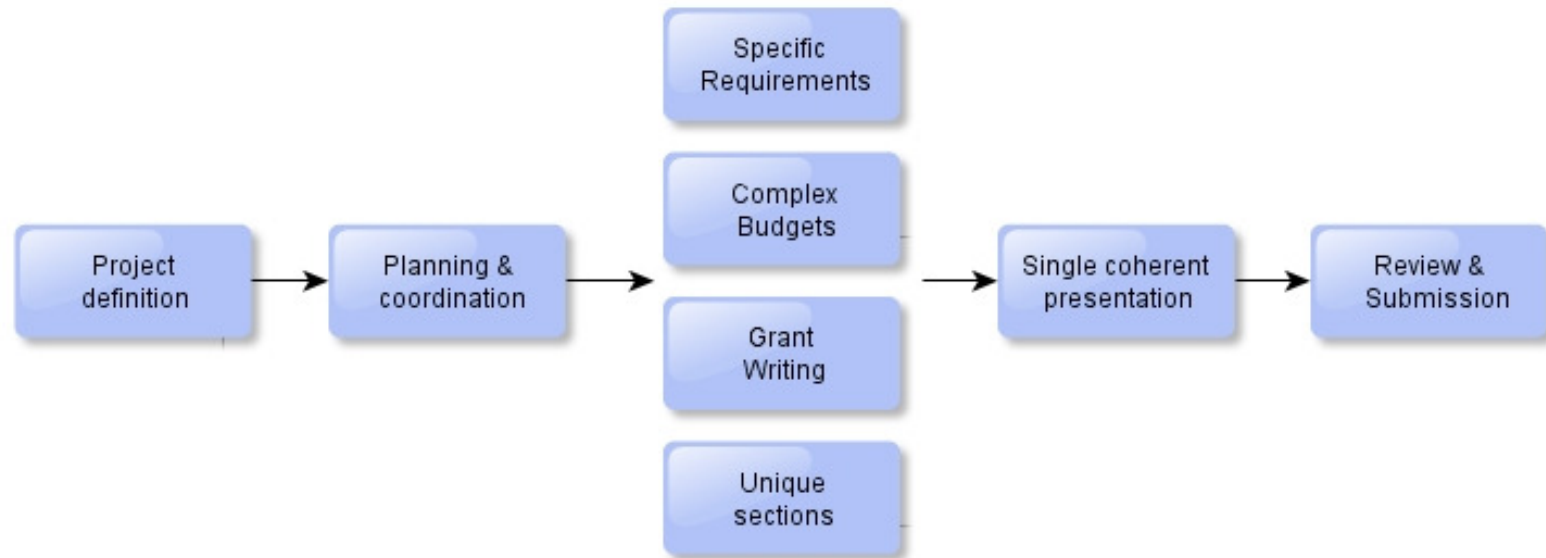
The Professional
Team

- ✓ 25 full time employees
 - ✓ Analysts
 - ✓ Managers/Writers
- ✓ Dr. Merav Geva, FreeMind's Director of the Professional Department & Chief Analyst

Strategic
Assessment



Specific Project



Thank you!

Contact Us!

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