

Medical Device Non-Dilutive Funding: Trends & Opportunities

FreeMind Group Webinar
Ayal Ronen
August 7th, 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. **Medical Devices** funding opportunities
6. **Oncology**
7. **DOD** – DARPA, DTRA, US Army, etc.
8. Industry Academic **Partnership programs**
9. **Biodefense** and infectious diseases, NIAID

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
Group, LLC

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

Trends

- Miniaturization
- Organ replacement
- Molecular and gene-based diagnostic
- Health information technology

Funding for Medical Devices

Changing Times

- More organized and structured funding for medical device development
- Rising number of specific Program Announcements and Requests-For-Applications from NIH institutions.

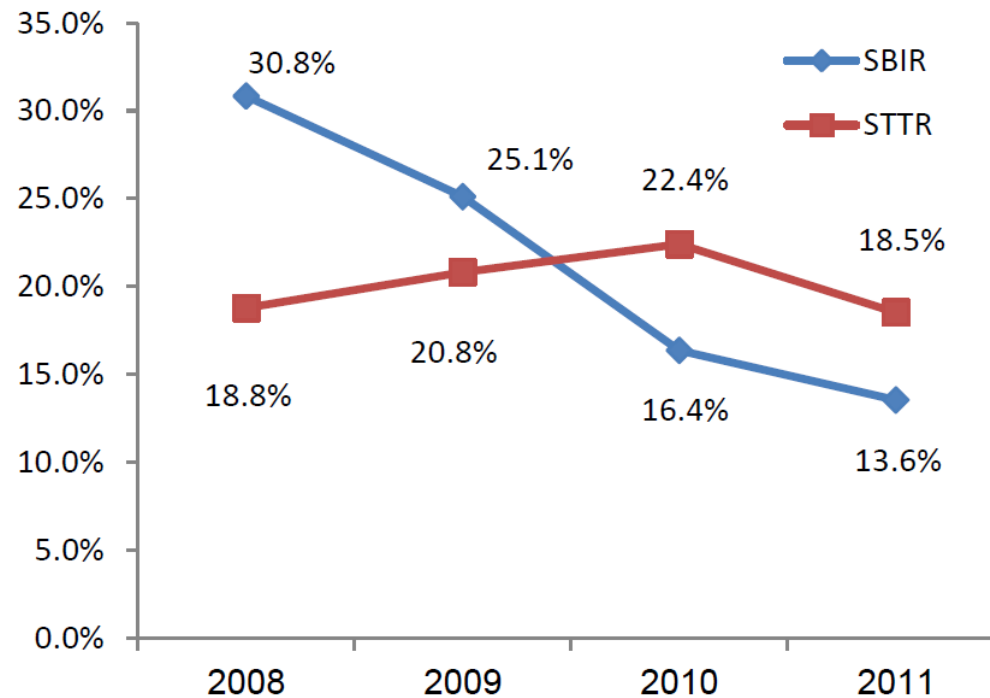
NIBIB

- *“Medical device makers should focus on creating low cost, non-invasive, mobile technologies but still work on “medical moonshots” that change the world”*
(Dr. Pettigrew, director of the NIBIB)

Declining
Success Rates

Steep decline in overall success rates for SBIR from 30% in 2008 to roughly 13% in 2011. STTR remains relatively constant

SBIR/STTR Overall Success Rates

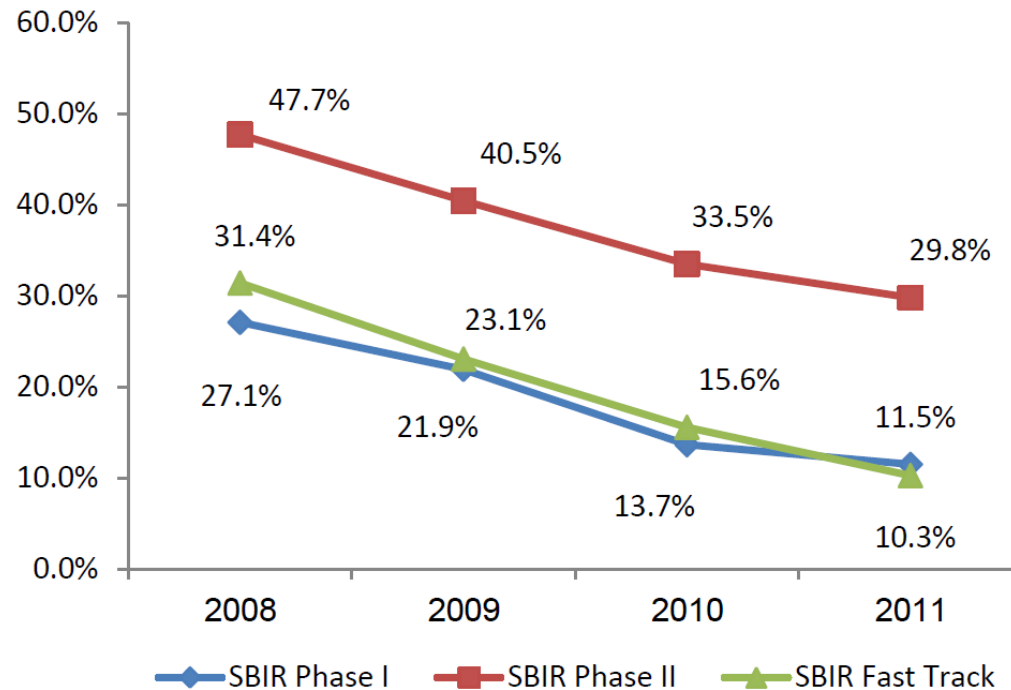


Adapted from the NIH Data Book, www.report.nih.gov

Phase
Breakdown

All Phases are affected by the decline in success rates.

SBIR Success Rates per Phase

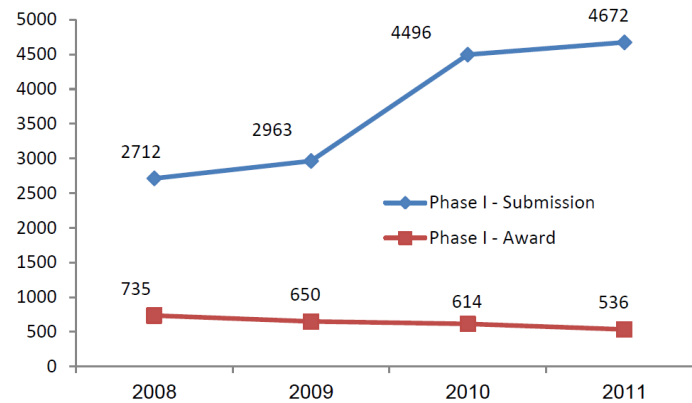


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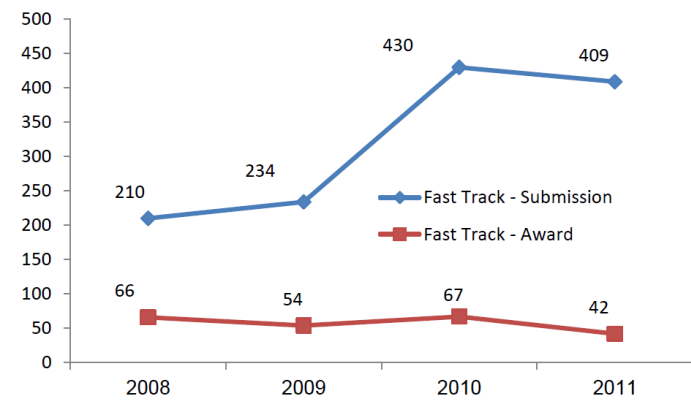
Some Interesting Statistics

Submissions vs. Awards

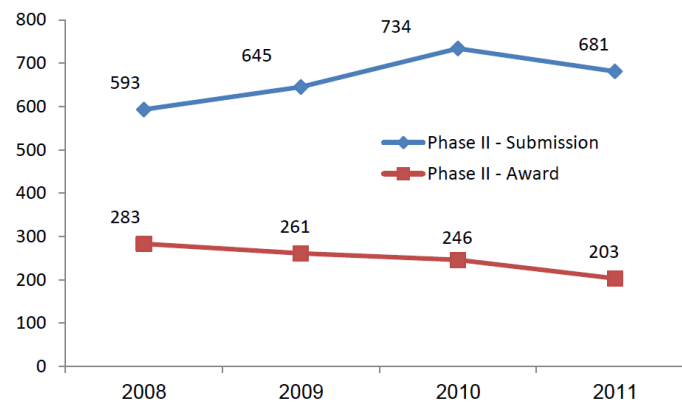
SBIR Phase I Submissions vs. Awards



SBIR Fast Track Submissions vs. Awards



SBIR Phase II Submissions vs. Awards



Record breaking number of submissions for all Phases together with fewer awards.

Phase I submissions rise 72% between 2008 and 2011!

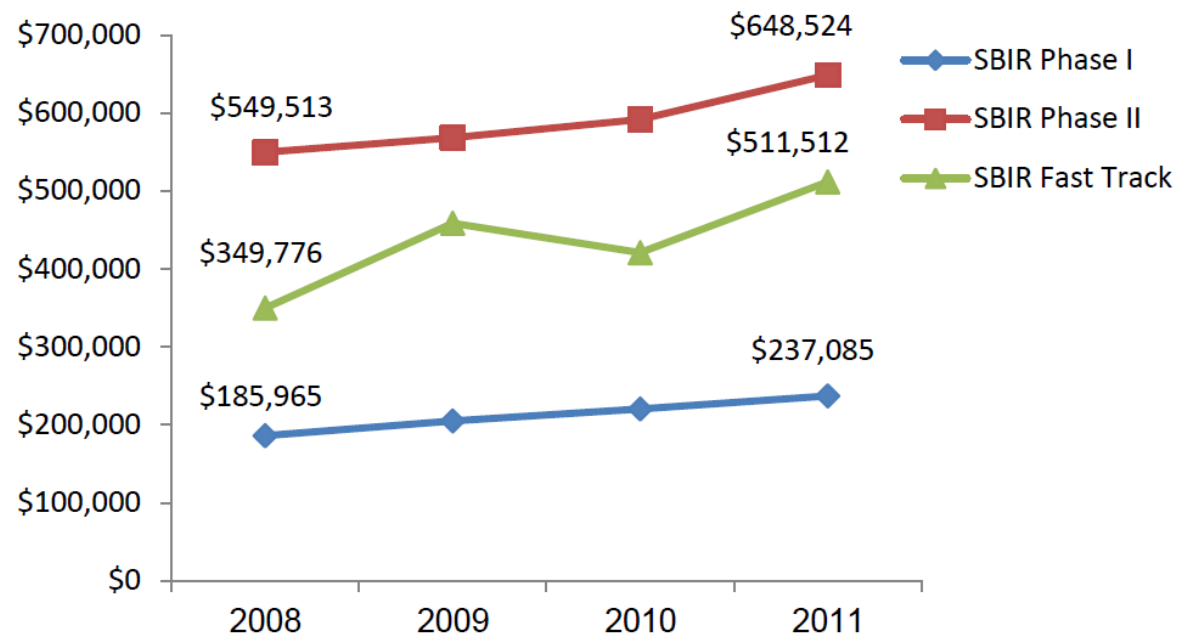
Adapted from the NIH Data Book, www.report.nih.gov

Some Interesting Statistics

The good news
(?)

Phase	% Increase 2008 -2011
Phase I	27%
Phase II	18%
Fast Track	46%

SBIR - Average Award by Phase



Adapted from the NIH Data Book, www.report.nih.gov

Some Interesting Statistics

Where is the money spent?

NIH Budget and allocation of funding remains relatively constant between 2009 and 2011

	2010	2011
Research Project Grant	\$16,598,000,000 (53%)	\$16,428,000,000 (53%)
Research Centers	\$3,026,000,000 (10%)	\$3,020,000,000 (10%)
R&D Contracts	\$3,459,000,000 (11%)	\$3,227,000,000 (11%)
Intramural Research	\$3,285,000,000 (11%)	\$3,269,000,000 (11%)

Adapted from the NIH Data Book, www.report.nih.gov

$$SBIR\ Percentage = \frac{\text{Total SBIR}}{\text{Total RPG}} = \frac{\$648,000,000}{\$16,428,000,000} \cdot 100 = 3.9\%$$

What about the remaining 96%? Are Companies Eligible? For most of it, YES!

Routes

Investigator Initiated

- Mechanism of choice – unsolicited SBIR/R21/R01
- Establish interest within the NIH before submitting
- Highly focused – remember, NIH funds projects, not companies!
- Innovative and of great Significance to public health
- Can be completed on time and within Budget

Solicited route

- Addressing a specific scientific area
- Of innovative value and great significance to public health in said scientific area
- Can be completed on time and within Budget

15 Participating
Institutes

Deadline:
Oct 16th, 2012

Funding: \$275,000 Direct cost for a 2 year R21 project period.

Scope:

- To encourage innovation and high risk/impact bioengineering research in new areas.
- No preliminary data required (encouraged)
- Hypothesis-driven, discovery-driven, developmental, or design-directed research.
- Can explore approaches and concepts new to a particular substantive area; research and development of new technologies, techniques or methods; or initial research and development of data upon which significant future research may be built.

15 Participating
Institutes

Deadline:
Oct 5th, 2012

Funding: \$500,000 Direct cost/year for up to 5 years.

Scope:

- R01 awards to support BRGs for basic and applied multi-disciplinary research that addresses important biological, bioengineering or medical research problems.
- The BRGs support integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior.
- A BRG application may propose hypothesis-driven, discovery-driven, developmental, or design-directed research.

13 Participating
Institutes

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

NINDS, NICHD

Deadline:
Dec 5th, 2012

Funding: For the phase I, direct costs normally may not exceed \$150,000 over 2 years. For the phase II, direct costs normally may not exceed \$100,000,000 over a 3 year period.

Scope:

- To develop advanced tools and technologies for cerebrospinal fluid (CSF) shunts that will lead to improved clinical treatment for patients with hydrocephalus.
- **Has an STTR equivalent too**

NINDS, NIA,
NIBIB, NICHD,
NIDCD

Deadline:
Dec 5th, 2012

Funding: For the phase I, direct costs may not exceed \$700,000 over 2 years. For the phase II, direct costs normally may not exceed \$300,000,000 over a 3 year period.

Scope:

- Projects to design and develop advanced tools and technologies that will lead to improved clinical treatment for Deep Brain Stimulation (DBS) patients .
- **Has an STTR equivalent too**

NINDS

Deadline:
Dec 5th, 2012

Has a U01
equivalent due
Oct 5th:
5 year project,
\$1M/year

Funding: Phase I - direct costs normally may not exceed \$150,000 over 2 yr. Phase II - direct costs normally may not exceed \$1,000,000 over 3 yrs.

Scope:

- Translational and pilot clinical studies for neural prosthetics.
- Milestone-driven projects for the development and demonstration of clinically-useful neural prosthetic devices.
- Clinical prototype devices, preclinical safety and efficacy testing, design verification and validation activities, pursuit of regulatory approval for clinical study, and proof-of-concept or pilot clinical studies.

NIBIB, NHLBI

Deadline:
Oct 5th, 2012

Funding: \$500,000 Direct cost/year for up to 5 years.

Scope:

- Engineering of novel, multifunctional drug and gene delivery systems that can target therapies to particular cells and intracellular compartments and can monitor delivery and determine therapeutic efficacy through the integration of advanced imaging and/or sensing technologies into the delivery system.
- Develop at least one prototype system .
- Should include PIs from both the drug/gene delivery and imaging fields (Plan for multi PI).

NCI

Deadline:
Oct 5th, 2012

Funding: suggested - \$500,000 Direct cost/year for up to 5 years. Preapproval for larger sums.

Scope:

- Partnerships (academic – industry) 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.
- Supports clinical trials that emphasize optimization and validation of the performance of imaging systems, including devices, agents and/or methods.
- Not support commercial production.

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.

16 Participating
Institutes

Deadline:
Oct 16th, 2012

Funding: \$275,000 Direct cost for a 2 year R21 project period.

Scope:

- Apply nanoscience and nanotechnology approaches to address problems in biology and medicine.
- Seeking cutting-edge nanoscience and nanotechnology research that can lead to biomedical breakthroughs and new investigations into the diagnosis, treatment and management of an array of diseases and traumatic injuries.
- Covers Devices too.
- High risk high reward

US ARMY BAA

Deadlines:

Rolling BAA:

Pre-applications
accepted year round.

Invitation to submit
full application within
90 days.

Upon invitation only:
proposals will be
accepted within 90
from invitation to
submit full proposal.

Funding: Budgets are **not capped** and must reflect the scope of the work. Funding can be requested for up to 5 years.

Scope:

- To provide solutions to medical problems of importance to the American war fighter.

Research Areas of Interest:

Military Infectious Diseases

Combat Casualty Care

Military Operational Medicine

Clinical and Rehabilitative Medicine

Medical Biological Defense

Medical Chemical Defense

Telemedicine and Advanced Technology

BARDA BAA

Deadlines:

Rolling BAA:

Pre-applications are accepted anytime.

Full applications:

Within 45 days from invitation to submit

Funding: Budgets are **not capped** and must reflect the scope of the work. We anticipate Funding can be requested for up to 5 years.

Scope:

- To address novel and emerging threats, as well as support the technological and scientific advancements of medical countermeasures for biodefense and pandemic influenza.
- Pipeline acceleration and evaluation of candidate vaccines and therapeutics.
- Product improvements to enhance safety, efficacy, ease of use, and manufacturability.
- Product repurposing to treat novel and emerging pathogens.
- *In vitro* diagnostic platforms for the rapid diagnosis of human infection.

BARDA BAA

Deadlines:

Rolling BAA:

Pre-applications
accepted on **four**
quarterly deadlines:
Sept 1, Dec 1, March
1, and June 7.

Invitation to submit
full application within
90 days.

Full application upon
invitation only, subject

Funding: Budgets are **not capped** and must reflect the scope of the work. Funding can be requested for up to 5 years.

Scope:

- BARDA encourages the advanced research, development and acquisition of medical countermeasures such as vaccines, therapeutics, and diagnostics.

Areas of interest

- 1.Vaccines Development
- 2.Antitoxins and Therapeutics
- 3.Antimicrobials and Antivirals
- 4.Radiological and Nuclear Agent Countermeasures
- 5.Chemical Agent Countermeasures
- 6.Diagnostics

Medical Device
Opportunities

Funding is available for medical devices
at all R&D stages and essentially in all
medical fields

Key Challenges

- 1. Different mechanisms with varying requirements**
- 2. Writing and assembling the application**
- 3. The ability to transfer an engineering plan into a research plan – Milestones!**

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

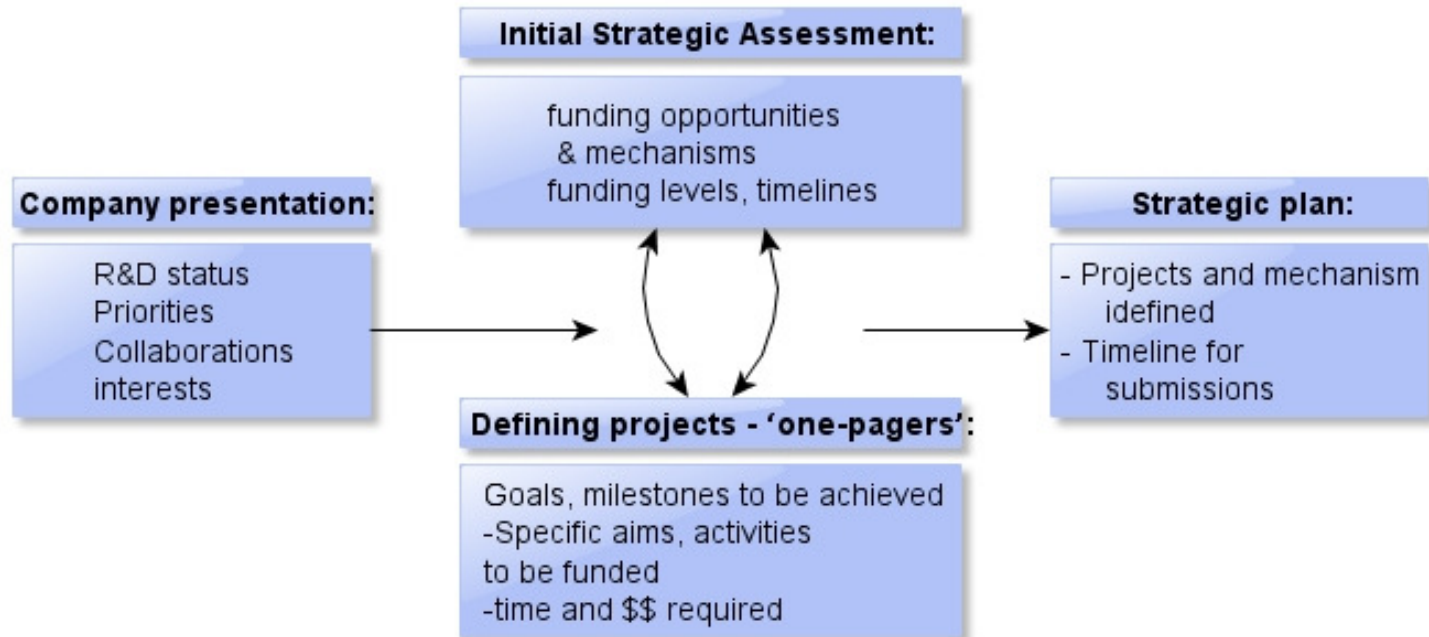
Target the Right Mechanism

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

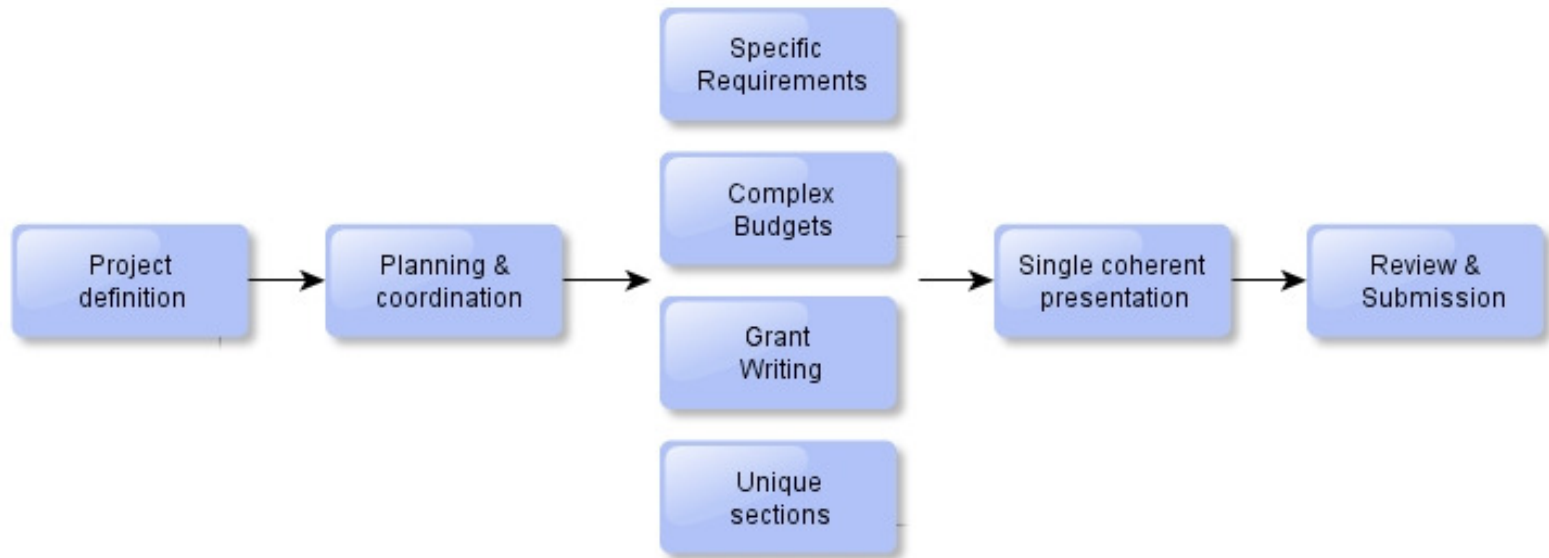
The Professional
Team

- ✓ 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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