Beyond the SBIR: Non-Dilutive Funding for Your Startup

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August 2, 2017
Est. 1999
60 Fulltime Employees

Diverse Client Base:

- Academics, University Medical Centers, and Independent Research Institutes
- Industry – Small Startups to Large Pharmaceutical Companies

~500 Applications Annually

~$100M in Awards per Year
Common Misconception

Non-Dilutive Funding for Industry ≠ SBIR
HHS- NIH

27 institutes and centers including NCI, NIDDK, NINDS, NIAID, NIBIB, NHLBI, NEI, NIA, NIMH, etc.

Other HHS Organizations

BARDA, FDA, CDC

National Science Foundation

Department of Defense (DOD)

US Army, DARPA, DTRA, CDMRP, etc.

Private Foundations

Gates, MJ Fox, JDRF, and many more
NIH 2017 Budget - $34B

- Research Project Grants: $16,442,000,000 (56%)
- Intramural Research: $3,410,000,000 (12%)
- Research Centers: $2,663,000,000 (9%)
- Research Training: $758,000,000 (3%)
- Other Research Grants: $1,803,000,000 (6%)
- R&D Contracts: $2,828,000,000 (10%)
- Research Mgmt & Support: $1,620,000,000 (5%)
- All Others: $72,000,000 (0%)

~$28,000,000,000
Categorical Spending

Cancer - ~$6B
Neurosciences - ~$6B
Infectious Diseases - ~$4B

Adapted from the NIH Data Book, www.report.nih.gov
Role of Non-Dilutive Funding in the Market

Future Returns on Investment

Historically, 50% of FDA Approved Drugs Received GOVERNMENT FUNDING During the Course of R&D.

Funding Routes

1. Solicited – Address a specific area of interest

2. Unsolicited – Investigator Initiated R21, RO1, SBIR/STTR - Try establish interest prior to submitting

3. Broad Agency Announcements – Large scale solicitations, address a wider area of research
Sources of Funding

National Institutes of Health (NIH)
Today: 1,146 Solicitations

http://grants.nih.gov/grants/guide/
Parent Announcements – Omnibus Solicitations

- **SBIR** - Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])(PA-14-071)
  
  $150,000 Direct costs, up to 12 months

- **STTR** - Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] (PA-14-072)

  $1,000,000 Direct costs, up to 2 years
Parent Announcements – Omnibus Solicitations

- **R21** - NIH Exploratory Developmental Research Grant Program (Parent R21) – PA-16-161
  
  $275,000 Direct costs, up to 2 years

- **R01** - Research Project Grant (Parent R01) – PA-16-160
  
  $500,000 Direct costs per year, up to 5 years
The NIH Exploratory/Developmental Grant supports exploratory and developmental research projects by providing support for **the early and conceptual stages of these projects**. These studies may involve **considerable risk** but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.
The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). **The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes** and Centers (ICs) based on their scientific missions.
Clinical Stage Funding Mechanisms

Mechanisms Used to Fund Clinical Stage R&D

- Phase II / Fast-Track SBIR (R44 or U44)
- Research Project Grant (R01)
- Clinical Trial Planning Grants (R34/U34)
- Research Project Cooperative Agreement (U01)
- Phased Cooperative Agreement (UH2/UH3)
- Broad Agency Announcement (BAA)
Requirements & Recommendations

- Clinical Protocol – Usually Necessary
- Investigator’s Brochure – Highly Recommended
- Clinical Sites, Site PIs – Helpful
- IND
- IRBs – Usually not required at time of submission
- Contact PO in advance!
Review Process

Responsive vs. Competitive

Risk Assessment

Scientific Approach

- Leadership
- Innovation
- Significance
- Environment

Risk vs. Strength
Sources of Funding

Biomedical Advanced Research Development Authority - BARDA
BARDA received a new budget of $920M approved to develop and procure medical countermeasures that address chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases.

Adapted from The BARDA Multi-Broad Agency Announcement Pre-Proposal Conference 2012
The mission of BARDA is to develop and procure medical countermeasures that address chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases.

Open solicitations

1. Broad Agency Announcement for the Advanced Development of Medical Countermeasures for Pandemic Influenza - BAA-13-100-SOL-00019

2. Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures - BAA-13-100-SOL-00013

3. Science and Technology Platforms Applied to Medical Countermeasure (MCM) Development - BAA-12-100-SOL-00013
Whitepaper submission is the first and one of the most crucial steps for award. Typically limited to 2 pages. Majority of applications do not make it past the whitepaper stage. To mean, if you are called to submit a full application, your chances increase dramatically. Carefully craft your whitepaper ensuring your science is well presented and represented and meets the guidelines and specification of the solicitation.
Department of Defense
USAMRMC, DARPA, DTRA, CDMRP
DTRA, DARPA, USAMRMC

DARPA:
“to maintain the technological superiority of the U.S. military.... by sponsoring revolutionary, high-payoff research that bridges the gap between fundamental discoveries and their military use.”

DTRA:
“Safeguard the United States and its allies from Weapons of Mass Destruction”

USAMRMC:
“provide solutions to medical problems of importance to the American warfighter at home and abroad”.

2015 Domestic for-Profit awards:

DARPA $79M
DTRA $200M
US Army $181M
FDA
Clinical Studies of Safety and Effectiveness of Orphan Products Research Project Grant (R01)

Funding: Up to $2M

Scope:
- Designed to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the product being developed will be superior to the existing therapy.
- Funds Phases I/II/III
Congressionally Directed Medical Research Programs (CDMRPs)
Funding: Level 3 - $4M + Indirect costs
Level 4 - $10M + Indirect costs

Scope:
• Funding Level 3: Advanced translational studies that have potential for near-term clinical investigation. Small-scale clinical trials may apply.
• Funding Level 4: Large-scale projects that will transform and revolutionize the clinical management and/or prevention of breast cancer. Near-term clinical impact is expected. PIs are expected to have experience in successfully leading large-scale projects.
CDMRP Programs 2017

CDMRP 2017 budget of $968.7M approved:
Breast Cancer: $120M
General Medical Research: $300M
Prostate Cancer: $90M
Spinal Cord Injury: $30M
Vision: $15M
Alzheimer's & Parkinson’s: $31M

Issued annually by the DOD, typically around March.
Follow: www.cdmrp.org
Funding: Application budgets are not capped, however, must reflect the scope of work.

2017 Topic Areas:

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Diarrheal Diseases
- Dystonia
- Early Trauma Thermal Regulation
- Eating Disorders
- Emerging Infectious Diseases
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Fragile X
- Guillain-Barré Syndrome
- Hepatitis B and C
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Diseases
- Influenza
- Integrative Medicine
- Interstitial Cystitis
- Malaria
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Nanomaterials for Bone Regeneration
- Non-Opioid Pain Management
- Pancreatitis
- Pathogen-Inactivated Dried Cryoprecipitate
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Sustained-Release Drug Delivery
- Tinnitus
- Tuberculosis
- Vaccine Development for Infectious Disease
- Vascular Malformations
- Women’s Heart Disease
Turn NDF into a Strategic Source of Funding

Maximize the Company’s Funding Potential
Maximize Your Chances for Award

Seek insight into the interests and goals of the funding agencies

Correlate the granting strategy with your long term R&D plan

Identify ALL relevant funding opportunities

Plan and execute a long-term, multi-submission granting strategy
Maximize Your Chances for Award

Know your weaknesses
Find the right partners (if necessary)
Know the interests of the agency/mechanism
Address the “non-important” admin parts
Establish yourself both as a top researcher as well as an experienced manager
Reduce the risk of being selected for funding
Maximize Funding Potential

What do we do?

1. Identify ALL relevant funding opportunities
2. Create a multi-submission granting strategy
3. Submit as many top quality applications as possible
Thank you!

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Watch past presentations and webinars online on our YouTube Channel

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