Biodefense and Infectious Diseases
Funding Opportunities

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FreeMind Group
Est. 1999
60 Fulltime Employees

Diverse Client Base:

• Academics, University Medical Centers, and Independent Research Institutes

• Industry – Small Startups to Large Pharmaceutical Companies

400-450 Applications Annually
Identify the most relevant funding opportunities
Strategize to maximize the application’s chance of success
Manage complex project production processes
Lead joint application writing
Support final contract negotiations

Non-Dilutive Funding – A Strategic Financial Tool
NIH 2016 Budget - $32.31B

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

NIAID Budget (Dollars in Millions)

- FY 2014 Actual
- FY 2015 Actual
- FY 2016 Enacted
- FY 2017 President’s Budget

March 1, 2017
FreeMind Group, LLC
• $5.25B in funding for Infectious diseases
• ~$1.9B in funding for Biodefense
• NIAID has one of the best success rates in the NIH with 24% success in contrast to the 19.1% average for 2016.
NIAID – Bugs of Interest

- Newly appeared in a population or
- Existed but rapidly increasing in incidence or geographic range, or
- Are caused by one of the NIAID Category A, B, or C priority pathogens.

A
- Anthrax
- Botulism
- Dengue
- Plague
- Ebola
- Tularemia
- etc...

B
- Q Fever
- Brucellosis
- Salmonella
- Hepatitis A
- West Nile Virus
- etc...

C
- Yellow Fever
- Tuberculosis
- Influenza
- Rabies
- Chikungunya
- SARS
- etc...

Funding Routes

1. **Solicited** – Address a specific area of interest

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

3. **Broad Agency Announcements** (BAAs)
NIH – Preclinical Funding
Funding:
• Direct costs of up to $750k per year over up to 5 years
• Additional $300k for purchasing equipment.
• Total award including overhead may be up to $5.25M

Scope:
• Supports milestone-driven projects focused on developing and utilizing novel predictive assays, models and/or research tools.
• Must focus on one or more of the following: CRE, MDR Acinetobacter or MDR Pseudomonas aeruginosa.
• Projects must complete assay/tool/model development prior to the end of the third year of the project period.
Funding:
• Direct costs of up to $300k per year over up to 3 years
• Total award including overhead may be up to $1.2M

Scope:
• CounterACT aims to develop new and improved therapeutics to treat and/or prevent injuries resulting from chemical threats.
• Supported activities: confirmation of molecular targets, demonstration of in vitro activity, preliminary in vivo efficacy, preliminary ADME/Tox evaluations and PK/PD data.
Funding:
• Budgets are not capped, funding for up to 5 years.
• We recommend not asking for more than $2.5M without pre-approval.

Scope:
• Supported activities: GLP IND-enabling safety studies and pivotal efficacy studies in animals, cGMP production, and human safety clinical trials.
• Viewed by BARDA as a stepping stone towards receiving BARDA support.
NIH – Clinical Funding
Funding:
• Up to ~$200k total award

Scope:
• Fundable activities include establishing the team, site & collaborator identification, study design, protocol development and various other activities.
Funding:
• Up to $1.5M for Phase II, $1.7M for Fast Track.
• Cap may be exceeded for research on specific topics, one of these is “Discovery & development of therapeutics for infectious diseases.”

Scope:
• Support for hypothesis-driven, milestone-driven clinical trials.
• Commercialization Plan must be included NIAID can decide if IND / IDE is required
**Funding:**

- No budget cap, up to 5 years of funding.

**Scope:**

- Will accept applications for implementation of investigator-initiated, high-risk clinical trials and mechanistic studies associated with high-risk clinical trials.
- Has R01 equivalent for “Low-risk” trials.
Biomedical Advanced Research and Development Authority (BARDA)
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.
• **Whitepaper / Quad Chart** submission is the first and one of the most crucial steps for award.

• Most 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.

• Very short documents, must be coherent & concise.
Funding:

- No budget cap
- Extremely high funding levels possible

Scope:

- Clinical development of Vaccines, Antitoxins and Therapeutic Proteins, Antimicrobial Therapeutics, Radiological / Nuclear Threat Medical Countermeasures, Chemical Threat Medical Countermeasures & Clinical Diagnostics.
The CARB-X Initiative

- Global public-private partnership focused on antibacterial development.
- Funded by BARDA, NIAID, Wellcome Trust, AMR Center, CLSI & MassBio.
- Accelerator that provides funding, business services and scientific services.
- $350M in funding made available over the next 5 years.
- Next cycle expected in September.
Department of Defense
(DoD)
DTRA, USAMRMC, DARPA

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”.

March 1, 2017
Defense Threat Reduction Agency (DTRA)
Funding:
• No budget cap
• You must justify what you ask for

Scope:
• Detection - Chemical and Biological
• Information Systems Capability Development
• Protection - Individual and Collective
• Hazard Mitigation
• Threat Agent Science
• Medical Pretreatments
• Medical Diagnostics
• Medical Therapeutics
• Threat Surveillance - Chemical and Biological.
US Army
**Funding:**

- No budget cap
- You must justify what you ask for

**Scope:**

- Aims provide solutions to medical problems of importance to the American war fighter.
- Military Infectious Diseases, Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, Military Biological Defense, Medical Chemical Defense, Medical Simulation & Information Sciences.
Defense Advanced Research Projects Agency (DARPA)
Funding:
• Up to $750k

Scope:
• Aim to leverage biology as a technology to solve intractable problems
• Seeks to leverage advances in engineering and computer science to drive and reshape biotechnology for national security
• Interested in a range of emerging technical areas, including human-machine interfaces, human performance, infectious disease, and synthetic biology.
• Goal: to develop, demonstrate & transition biologically based technologies as part of the national security toolkit
NIH Review Process

Risk Management

- Leadership
- Innovation
- Environment
- Significance

Risk vs. Strength
Maximizing Your Chances

Key Issues

Systematic Approach

Know the interests of the Agency
Present a complete, focused project
Ask for what is necessary
Leverage on research collaborations
Maximizing Your Chances

Key Issues

Target the Right Mechanism

Different “pockets of money”
Different size of award/success rates
Conduct a thorough strategic assessment

Multi-Submission Granting Strategy

March 1, 2017
FreeMind Group Professional Process

Core Service 1- Strategic Assessment

✓ Long term Strategic approach
✓ Outline projects
✓ Tasks to be completed
✓ Link with existing pockets of money
✓ Solicited vs. Unsolicited
✓ Map of relevant funding opportunities

Core Service 2- Project Production Process

✓ Project Management - coordinating
✓ Comprehensive templates
✓ Ongoing feedback and edits
✓ Budgets
✓ Converge information
✓ Final outcome – single coherent presentation

March 1, 2017
Thank you!

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Watch past presentations and webinars online on our YouTube Channel

Join our LinkedIn network and follow us on Twitter for updates and announcements relating to non-dilutive funding

www.freemindconsultants.com