

# Beyond the SBIR: Non-Dilutive Funding for Your Startup

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FreeMind  
Group, LLC

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

**Non-Dilutive  
Funding for Industry**  **SBIR**

Non-Dilutive  
Market



## **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**

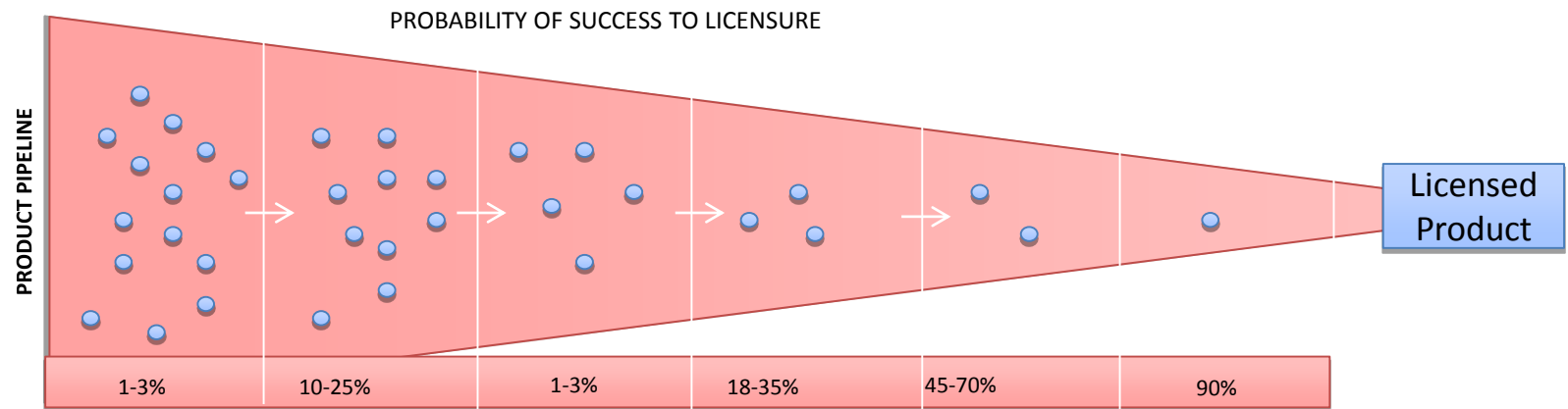
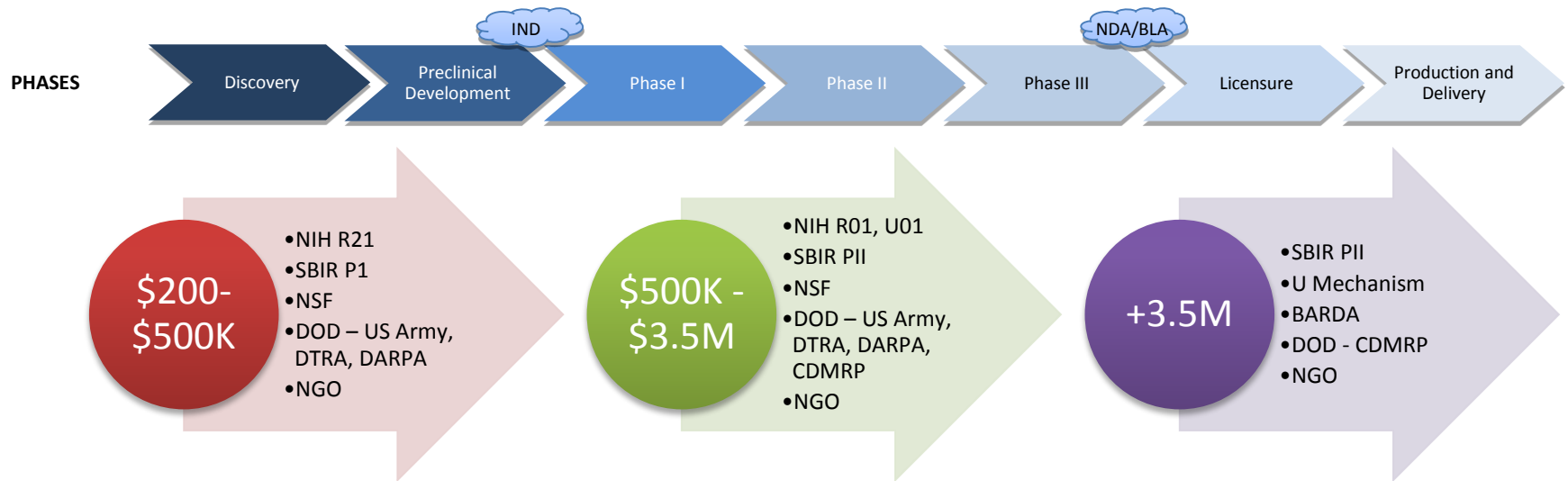
## **Department of Defense (DOD)**

US Army, DARPA, DTRA, CDMRP, etc.

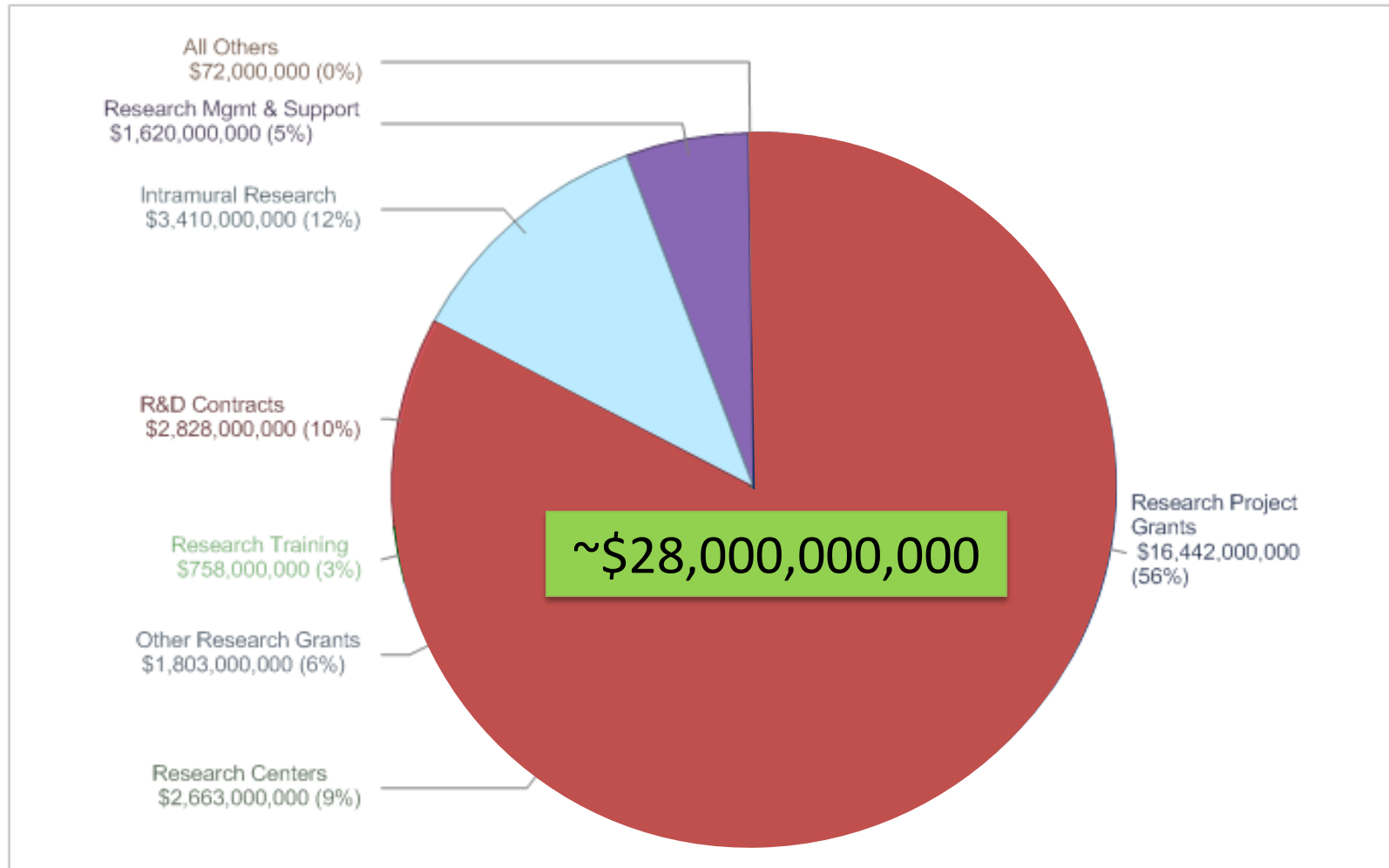
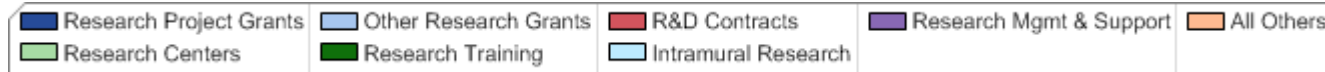
## **Private Foundations**

Gates, MJ Fox, JDRF, and many more

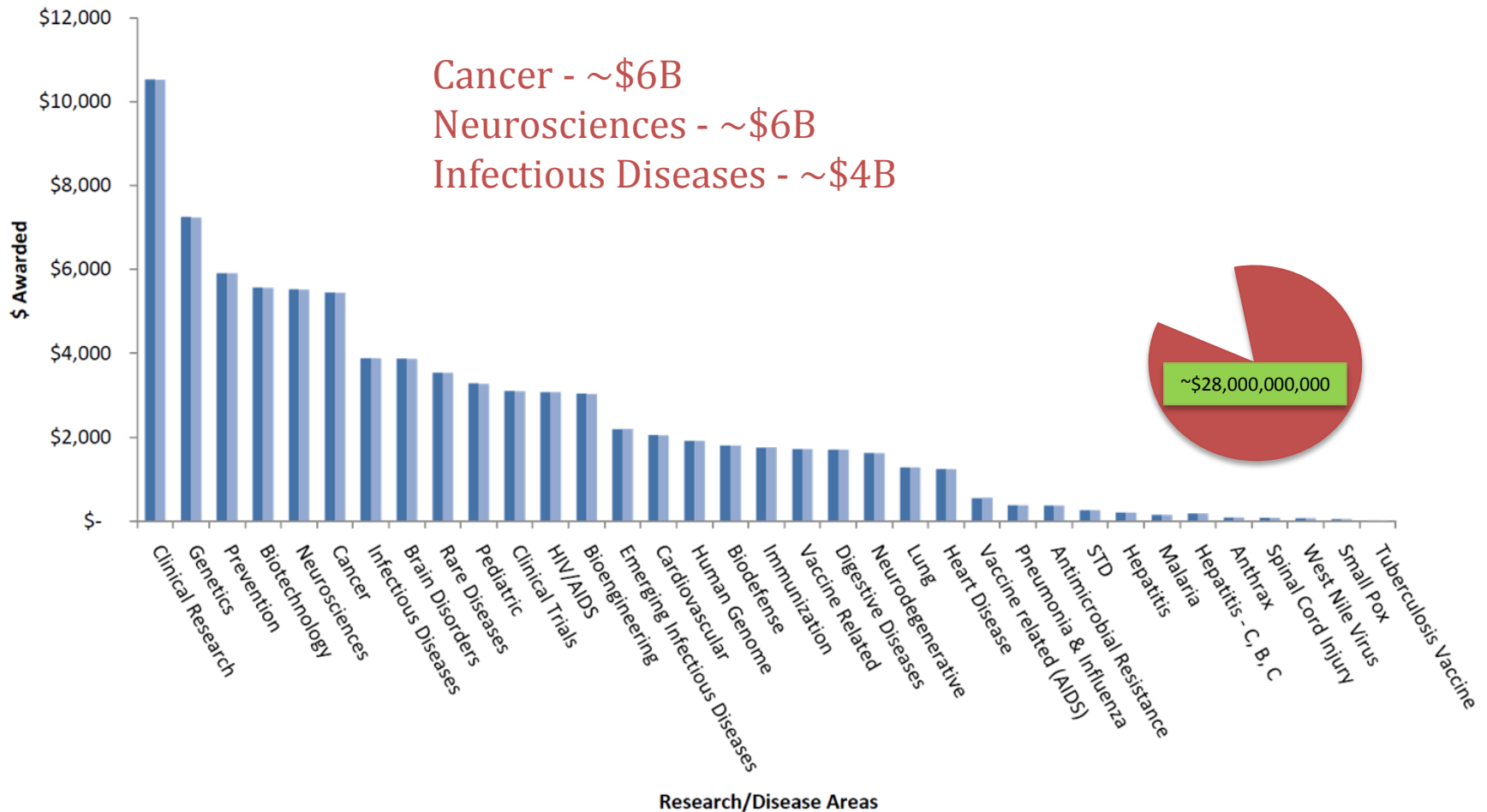
# Supports Complete R&D Process



# NIH 2017 Budget - \$34B

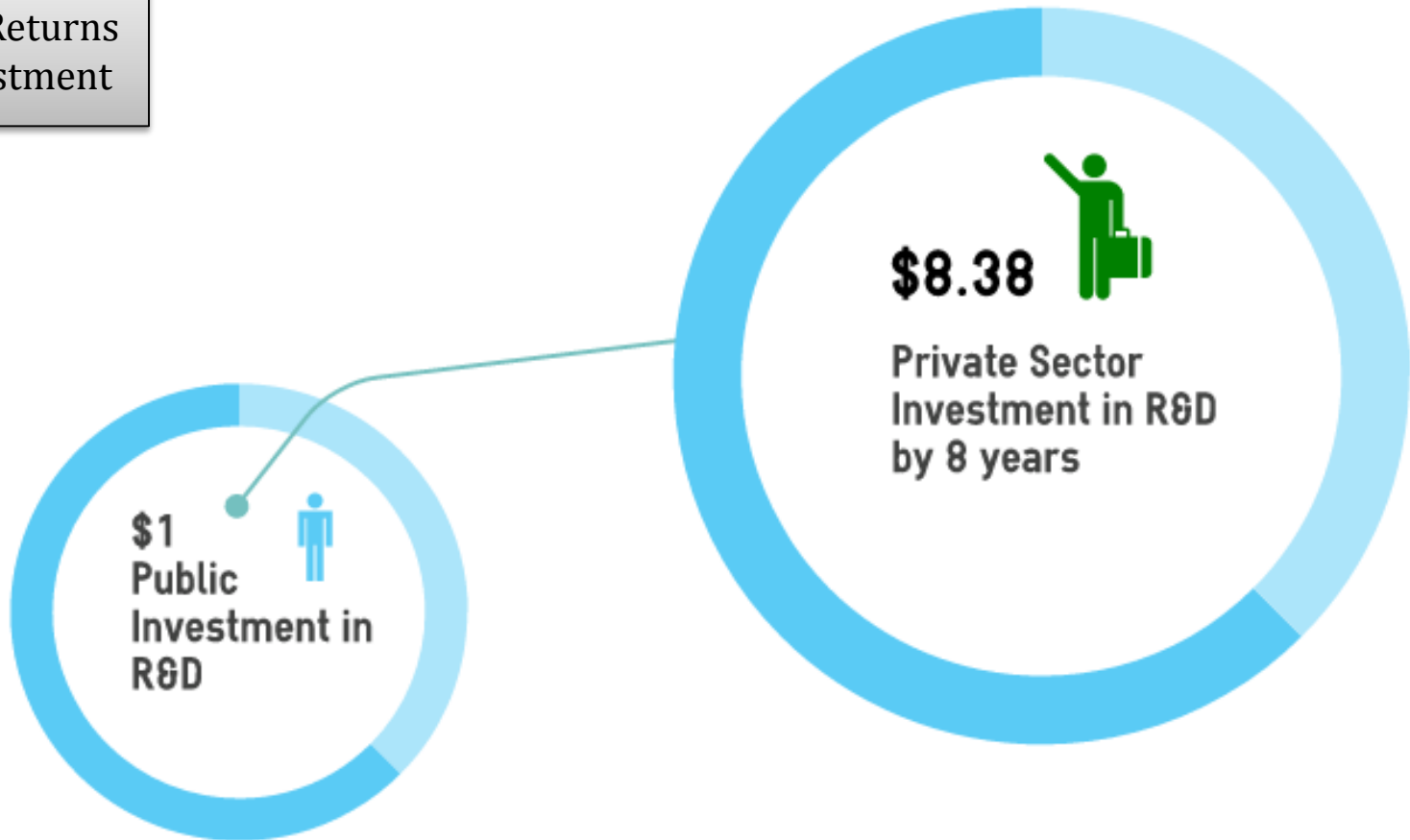


# Categorical Spending



Adapted from the NIH Data Book, [www.report.nih.gov](http://www.report.nih.gov)

Future Returns  
on Investment



Milken Institute, "Estimating Long-term Economic Returns of NIH on Output in the Bioscience." August 31, 2012.



Historically,



**50%** 

of FDA Approved Drugs Received

**GOVERNMENT  
FUNDING**

During the Course of R&D



Milken Institute, "Estimating Long-term Economic Returns of NIH on Output in the Bioscience." August 31, 2012.

## Routes

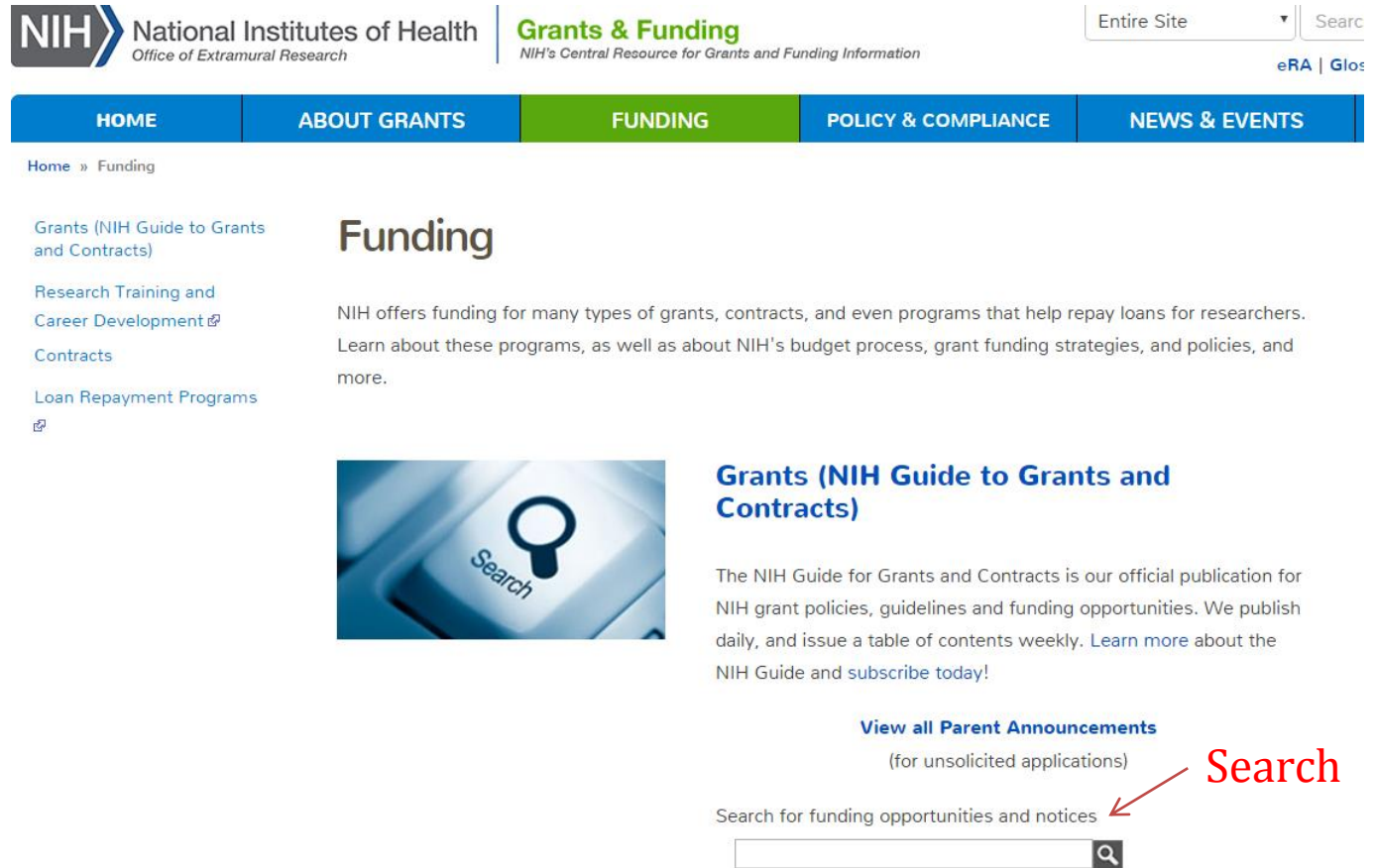
## Funding Routes

1. **Solicited** – Address a specific area of interest
2. **Unsolicited** – Investigator Initiated R21, R01, SBIR/STTR- Try establish interest prior to submitting
3. **Broad Agency Announcements** – Large scale solicitations, address a wider area of research

## National Institutes of Health (NIH)

Solicited

Today:  
1,146 Solicitations



The screenshot shows the NIH Grants & Funding website. At the top, the NIH logo and "National Institutes of Health Office of Extramural Research" are displayed. To the right, there's a search bar with "Entire Site" and a "Search" button. Below the header is a navigation bar with links: HOME, ABOUT GRANTS, FUNDING (highlighted in green), POLICY & COMPLIANCE, and NEWS & EVENTS. A breadcrumb trail shows "Home » Funding". On the left sidebar, there are links for "Grants (NIH Guide to Grants and Contracts)", "Research Training and Career Development", "Contracts", and "Loan Repayment Programs". The main content area is titled "Funding" and contains a paragraph about NIH funding opportunities. Below this is an image of a computer keyboard with a "Search" key highlighted. To the right of the image is a section titled "Grants (NIH Guide to Grants and Contracts)" with a description of the NIH Guide. Below this is a link "View all Parent Announcements (for unsolicited applications)". At the bottom, there is a search bar with the text "Search for funding opportunities and notices" and a red arrow pointing to it from the word "Search" in red text.

NIH National Institutes of Health  
Office of Extramural Research

Grants & Funding  
NIH's Central Resource for Grants and Funding Information

Entire Site Search

eRA | Glossary


HOME ABOUT GRANTS FUNDING POLICY & COMPLIANCE NEWS & EVENTS

Home » Funding

Grants (NIH Guide to Grants and Contracts)  
Research Training and Career Development  
Contracts  
Loan Repayment Programs

## Funding

NIH offers funding for many types of grants, contracts, and even programs that help repay loans for researchers. Learn about these programs, as well as about NIH's budget process, grant funding strategies, and policies, and more.



### Grants (NIH Guide to Grants and Contracts)

The NIH Guide for Grants and Contracts is our official publication for NIH grant policies, guidelines and funding opportunities. We publish daily, and issue a table of contents weekly. [Learn more](#) about the NIH Guide and [subscribe](#) today!

[View all Parent Announcements](#)  
(for unsolicited applications)

Search for funding opportunities and notices

Search

<http://grants.nih.gov/grants/guide/>

# SBIR and STTR Omnibus Solicitations

Investigator  
Initiated

Deadline:  
**SBIR – Sep 5<sup>th</sup>**  
**STTR – Sep 5<sup>th</sup>**

Standard Due  
Dates:  
SBIR – April,  
Sept, Jan 5<sup>th</sup>  
STTR – April,  
Jun, Oct 16<sup>th</sup>

## 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**

## R01 and R21 Omnibus Solicitations

Investigator  
Initiated

Deadline:  
**R01 – Oct 5<sup>th</sup>**  
**R21 – Oct 16<sup>th</sup>**

Standard Due  
Dates:  
R01 – Feb, Jun,  
Oct 5<sup>th</sup>  
R21 – Feb, Jun,  
Oct 16<sup>th</sup>

### 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**

# R21 Omnibus Solicitation

Investigator  
Initiated

Deadline:  
**R21 – Oct 16<sup>th</sup>**

Standard Due  
Dates:  
R21 – Feb, Jun,  
Oct 16<sup>th</sup>

## Department of Health and Human Services

### Part 1. Overview Information

#### Participating Organization(s)

National Institutes of Health (NIH)

#### Components of Participating Organizations

National Eye Institute (NEI)  
National Human Genome Research Institute (NHGRI)  
National Institute on Aging (NIA)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
National Institute of Biomedical Imaging and Bioengineering (NIBIB)  
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
National Institute of Dental and Craniofacial Research (NIDCR)  
National Institute on Drug Abuse (NIDA)  
National Institute of Environmental Health Sciences (NIEHS)  
National Institute of Mental Health (NIMH)  
National Institute of Neurological Disorders and Stroke (NINDS)  
National Institute of Nursing Research (NINR)  
National Institute on Minority Health and Health Disparities (NIMHD)  
National Library of Medicine (NLM)  
National Center for Complementary and Integrative Health (NCCIH)

Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the [R21 IC-Specific Scientific Interests and Contact](#) website. ICs that do not participate in this announcement will not consider applications for funding.

#### Funding Opportunity Title

NIH Exploratory/Developmental Research Grant Program ( Parent R21)

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.

# R01 Omnibus Solicitation

Investigator  
Initiated

Deadline:  
**R01 – Oct 5<sup>th</sup>**

Standard Due  
Dates:  
R01 – Feb, Jun,  
Oct 5<sup>th</sup>

## Department of Health and Human Services

### Part 1. Overview Information

#### Participating Organization(s)

National Institutes of Health (NIH)

#### Components of Participating Organizations

National Cancer Institute (NCI)  
National Eye Institute (NEI)  
National Heart, Lung, and Blood Institute (NHLBI)  
National Human Genome Research Institute (NHGRI)  
National Institute on Aging (NIA)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
National Institute of Biomedical Imaging and Bioengineering (NIBIB)  
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
National Institute of Dental and Craniofacial Research (NIDCR)  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)  
National Institute on Drug Abuse (NIDA)  
National Institute of Environmental Health Sciences (NIEHS)  
National Institute of General Medical Sciences (NIGMS)  
National Institute of Mental Health (NIMH)  
National Institute of Neurological Disorders and Stroke (NINDS)  
National Institute of Nursing Research (NINR)  
National Institute on Minority Health and Health Disparities (NIMHD)  
National Library of Medicine (NLM)  
National Center for Complementary and Integrative Health (NCCIH)  
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)

Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the [R01 IC-Specific Scientific Interests and Contact](#) website. ICs that do not participate in this announcement will not consider applications for funding.

#### Funding Opportunity Title

NIH Research Project Grant (Parent R01)

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.**



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)

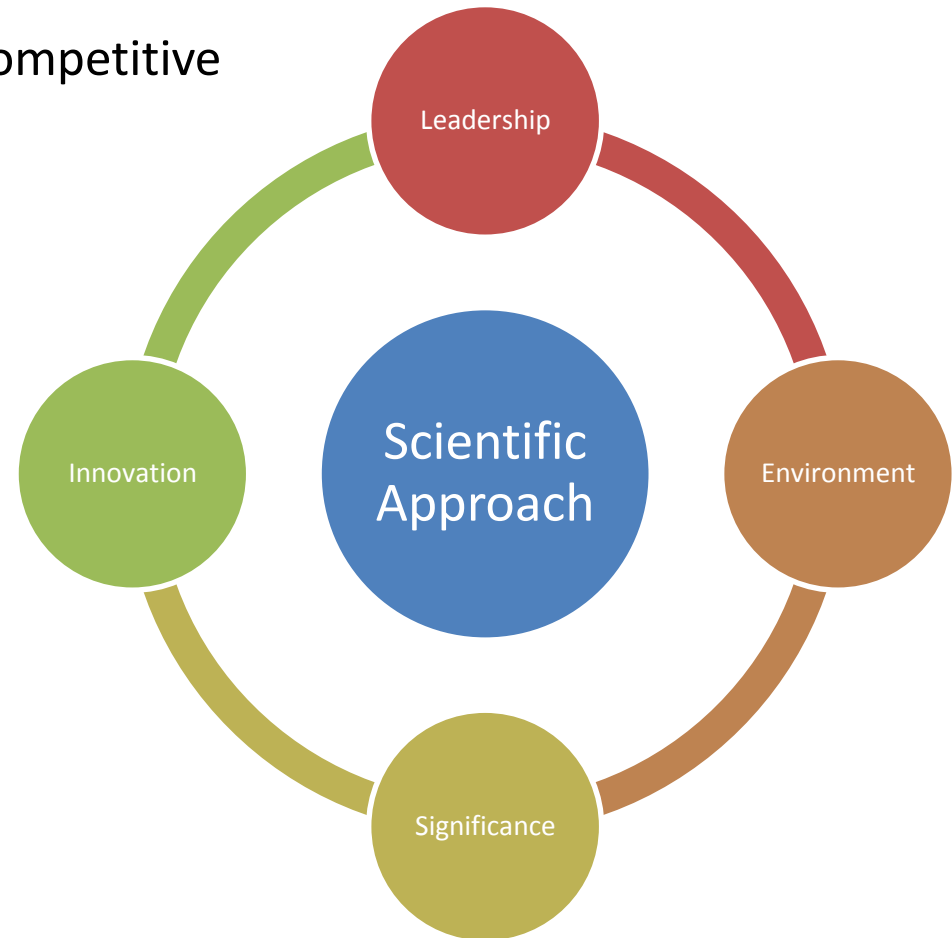
Important Notes

## 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!**

Risk  
Assessment

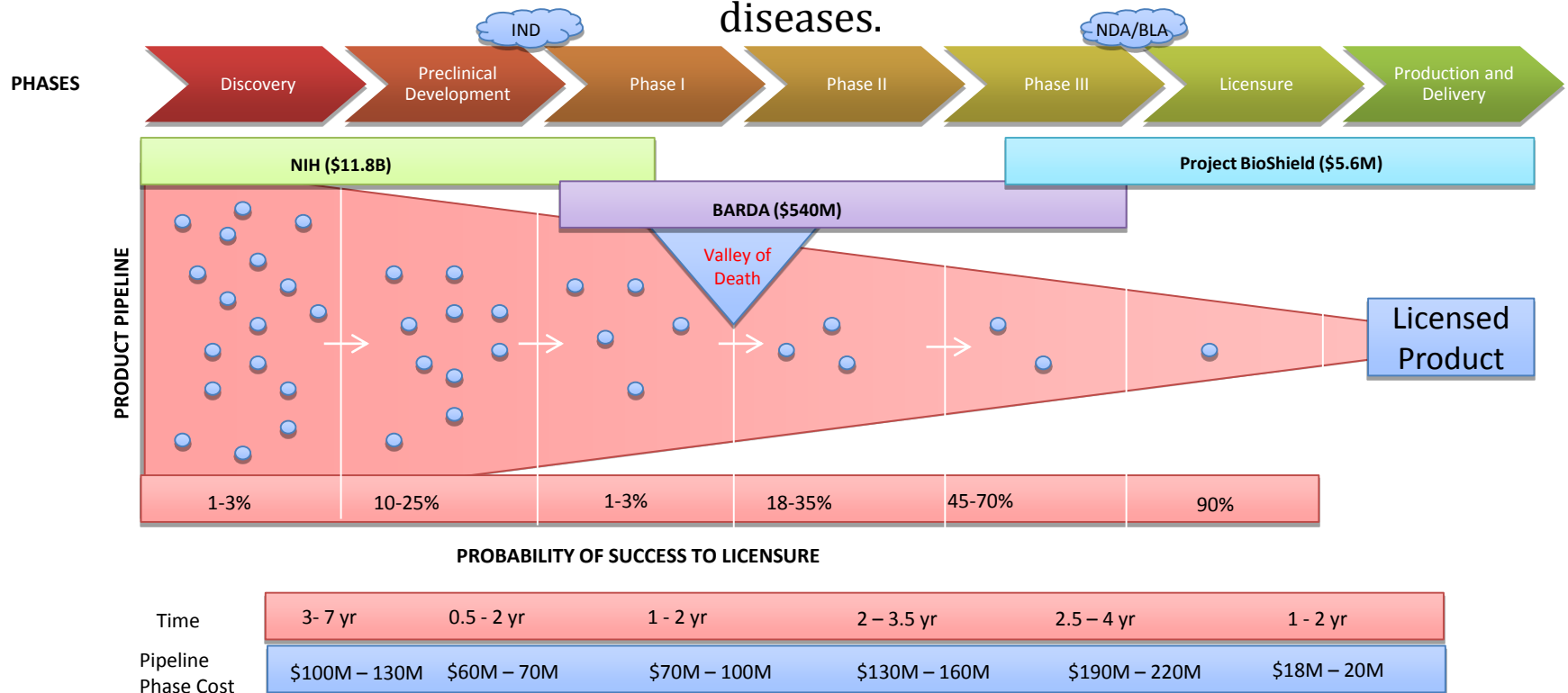
Responsive vs. Competitive



## Biomedical Advanced Research Development Authority - BARDA

# BARDA – Medical Countermeasures

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.



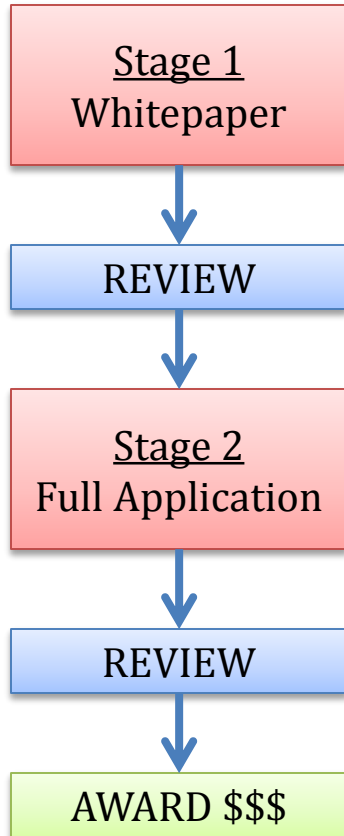
Adapted from The BARDA Multi-Broad Agency Announcement Pre-Proposal Conference 2012

## 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.

### 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

2015  
Domestic for-  
Profit awards:

DARPA  
\$79M

DTRA  
\$200M

US Army  
\$181M



*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".*

# FDA

FDA

RFA-FD-15-001

Next Due Date:  
**Feb 1, 2018**

**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)

CDMRPs

W81XWH-16-  
BCRP-  
BREAKTHROUGH\_  
FL34

Deadlines:  
Pre-Application  
**April 27<sup>th</sup>**  
Full Application  
August 11<sup>th</sup>

**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

Alcohol and Substance Abuse  
Amyotrophic Lateral Sclerosis  
Autism Bone Marrow Failure  
Breast Cancer  
Duchenne Muscular Dystrophy  
Epilepsy  
Gulf War Illness  
Hearing Restoration  
Kidney Cancer  
Joint Warfighter Medical  
Lung Cancer  
Lupus  
Military Burn  
Multiple Sclerosis  
Neurofibromatosis  
Orthotics and Prosthetics Outcomes  
Ovarian Cancer  
Parkinson's  
Peer Reviewed Alzheimer's  
Peer Reviewed Cancer  
Peer Reviewed Medical  
Peer Reviewed Orthopaedic  
Prostate Cancer  
Reconstructive Transplant  
Spinal Cord Injury  
Tick-Borne Disease  
Trauma Clinical  
Tuberous Sclerosis Complex  
Vision

## Congressionally Directed Medical Research Programs (CDMRP)

### **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](http://www.cdmrp.org)

CDMRPs

Pre-App  
Deadline  
July 20, 2017

**Funding:** Application budgets are not capped, however, must reflect the scope of work.

## 2017 Topic Areas:

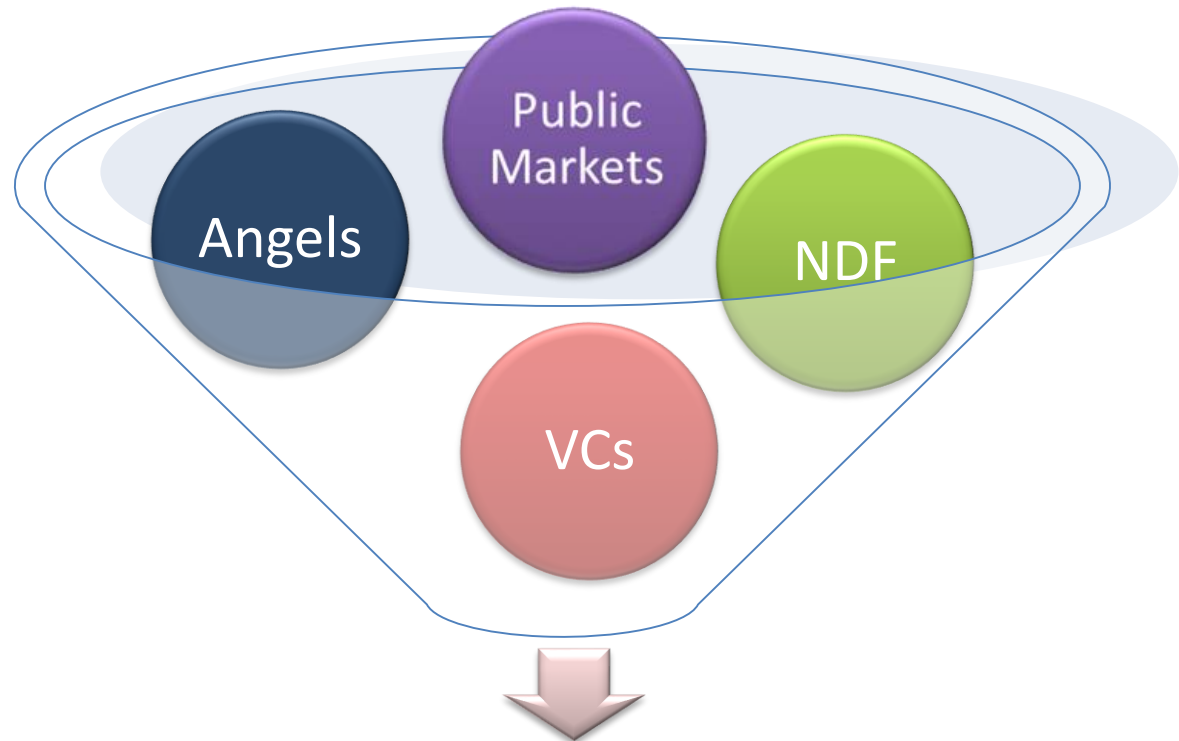
- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Diarrheal Diseases
- Dystonia
- Early Trauma Thermal Regulation
- Eating Disorders
- Emerging Infectious Diseases
- 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

Strategic  
Approach



Maximize the Company's  
Funding Potential



## Maximize Your Chances for Award

Strategic  
Approach

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**

NDF

## Maximize Your Chances for Award

Risk  
Management

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

NDF

What do we do?

# Maximize Funding Potential

1. Identify ALL relevant funding opportunities

2. Create a multi-submission granting strategy

3. Submit as many top quality applications as possible

Thank you!

Contact Us!

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