



Non-Dilutive Funding Specialists

Beyond the SBIR: Non-Dilutive Funding for Your Startup

Meytal Waiss

Director, Business Development

August 2, 2017

FreeMind
Group, LLC

Est. 1999

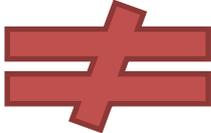
60 Fulltime Employees

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

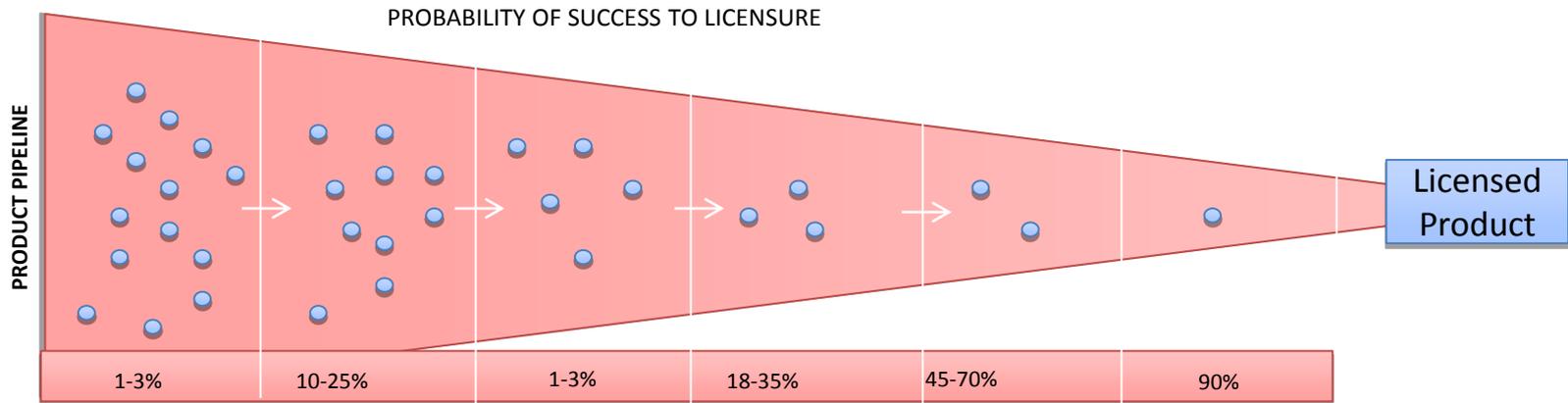
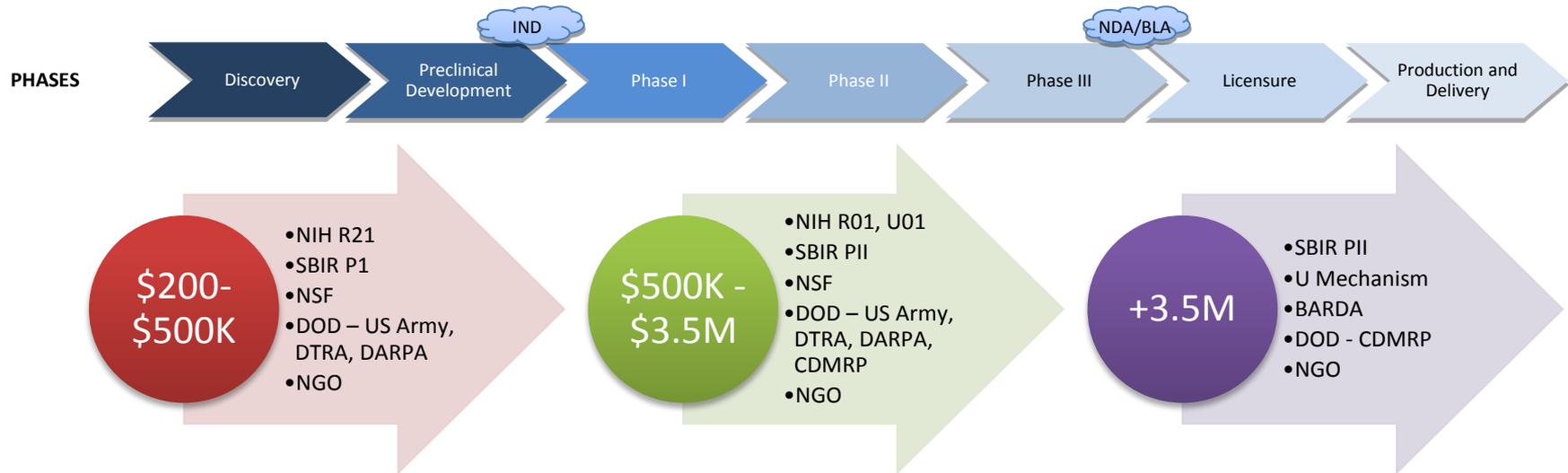
Department of Defense (DOD)

US Army, DARPA, DTRA, CDMRP, etc.

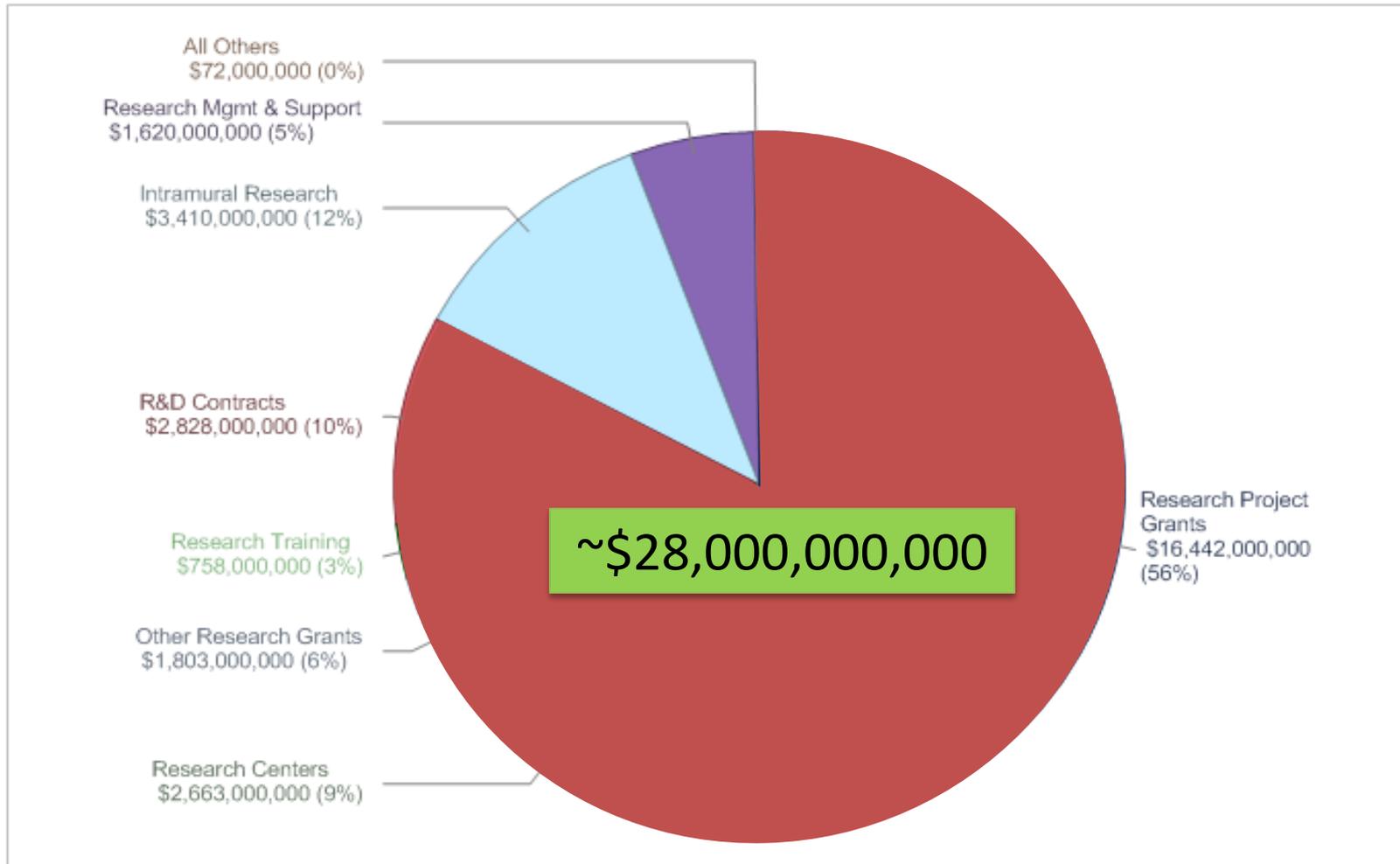
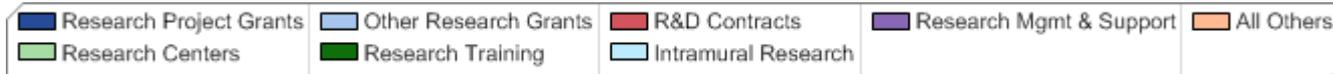
Private Foundations

Gates, MJ Fox, JDRF, and many more

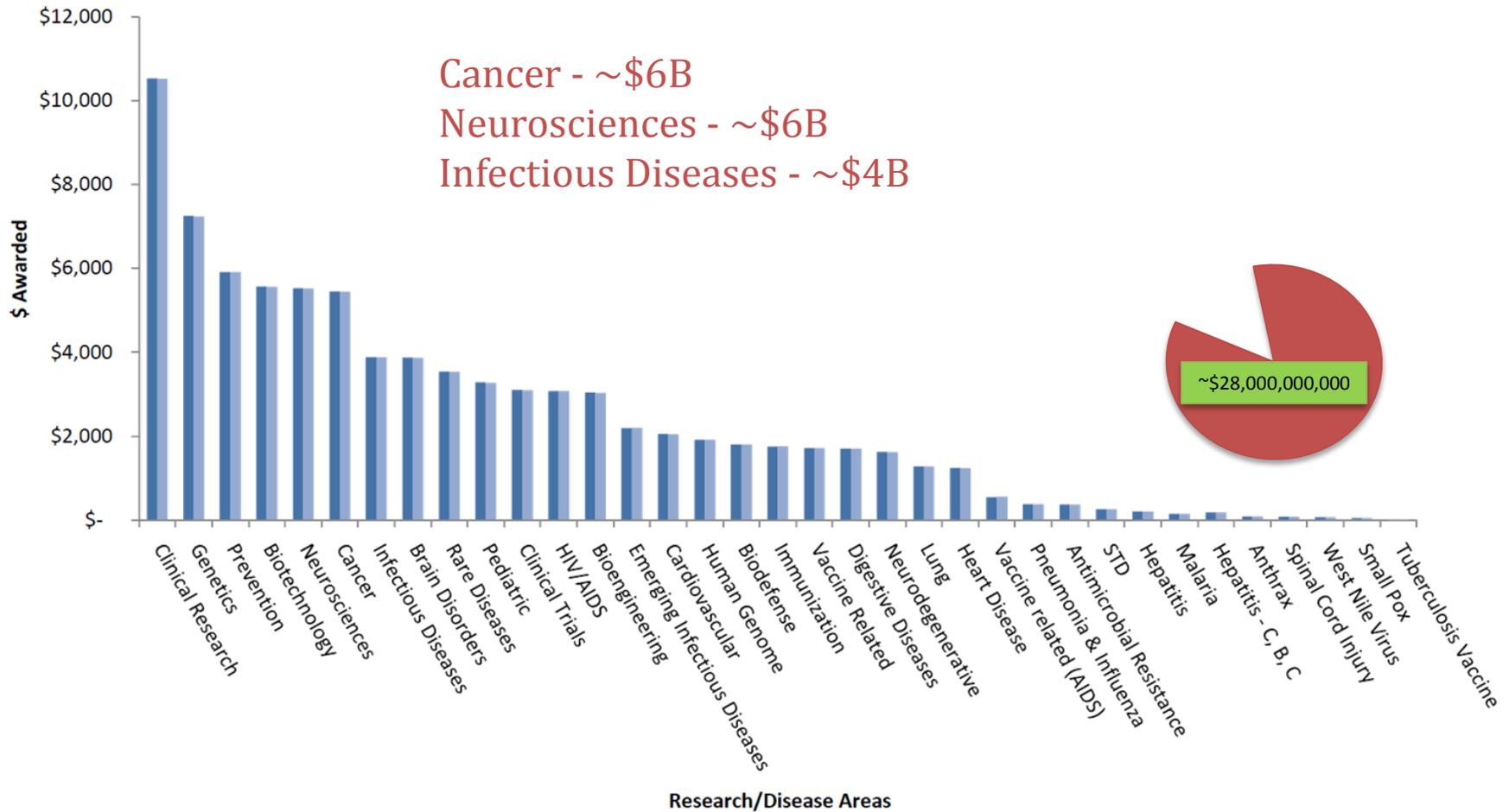
Supports Complete R&D Process



NIH 2017 Budget - \$34B

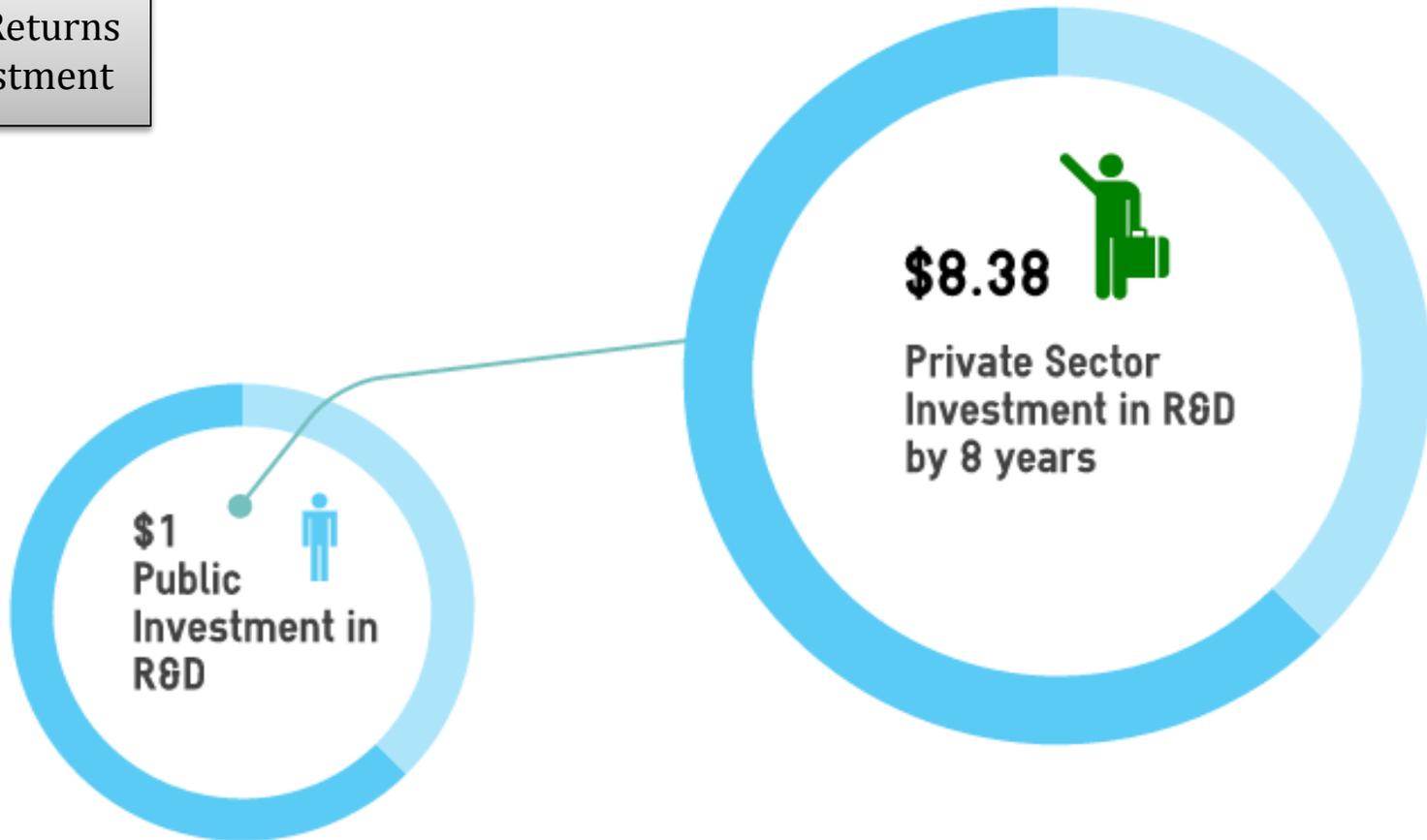


Categorical Spending



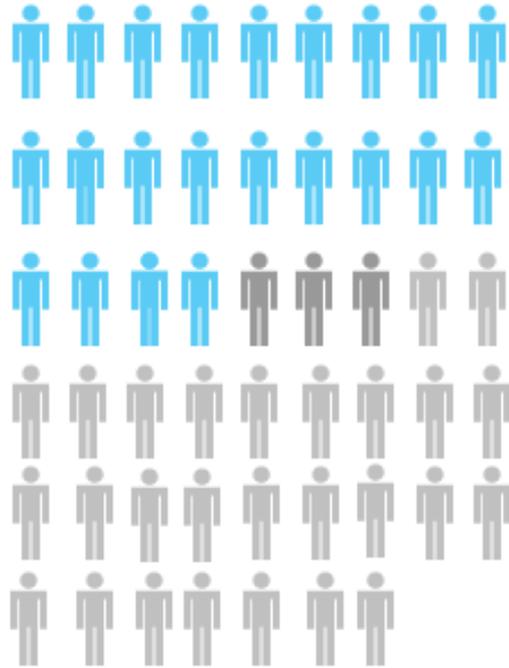
Adapted from the NIH Data Book, www.report.nih.gov

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

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/>

Investigator
Initiated

Deadline:
SBIR – Sep 5th
STTR – Sep 5th

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

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

Investigator
Initiated

Deadline:
R01 - Oct 5th
R21 - Oct 16th

Standard Due
Dates:
R01 - Feb, Jun,
Oct 5th
R21 - Feb, Jun,
Oct 16th

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 16th

Standard Due
Dates:
R21 – Feb, Jun,
Oct 16th

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	<p>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)</p> <p><small>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.</small></p>
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.

Investigator
Initiated

Deadline:
R01 – Oct 5th

Standard Due
Dates:
R01 – Feb, Jun,
Oct 5th

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	<p>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) <i>Eunice Kennedy Shriver</i> 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)</p> <p>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.</p>
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)

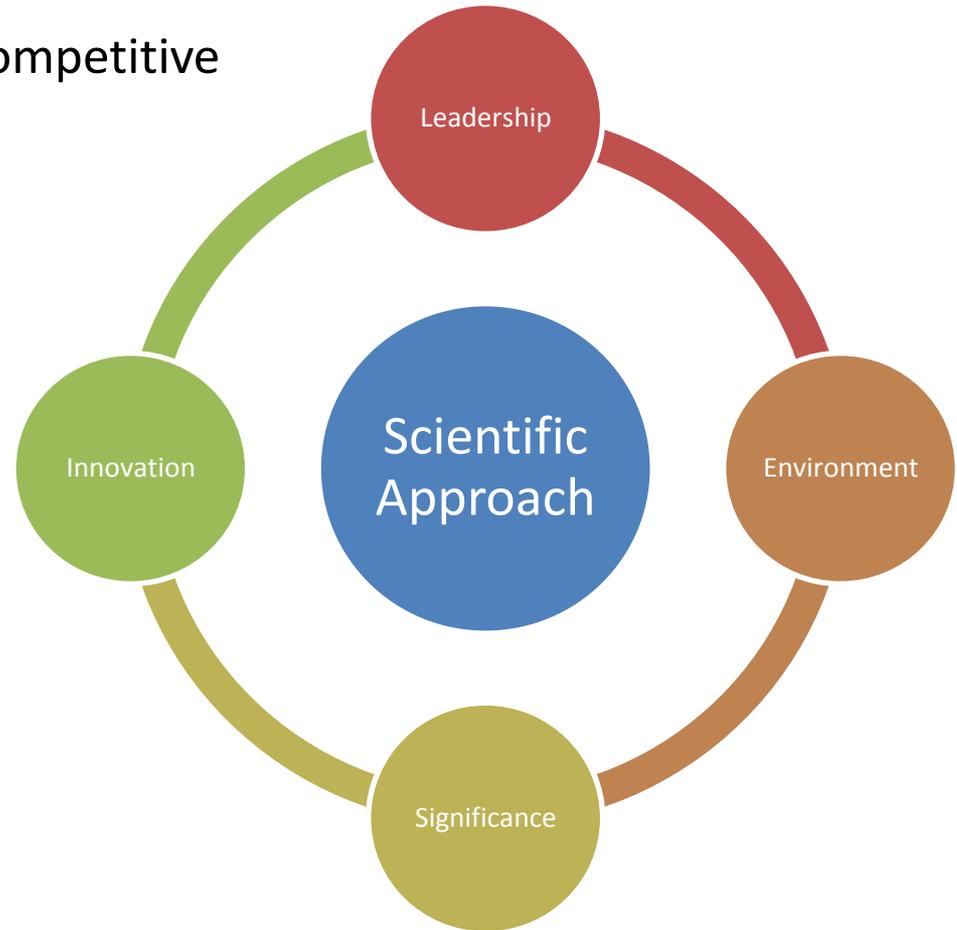
Important Notes

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

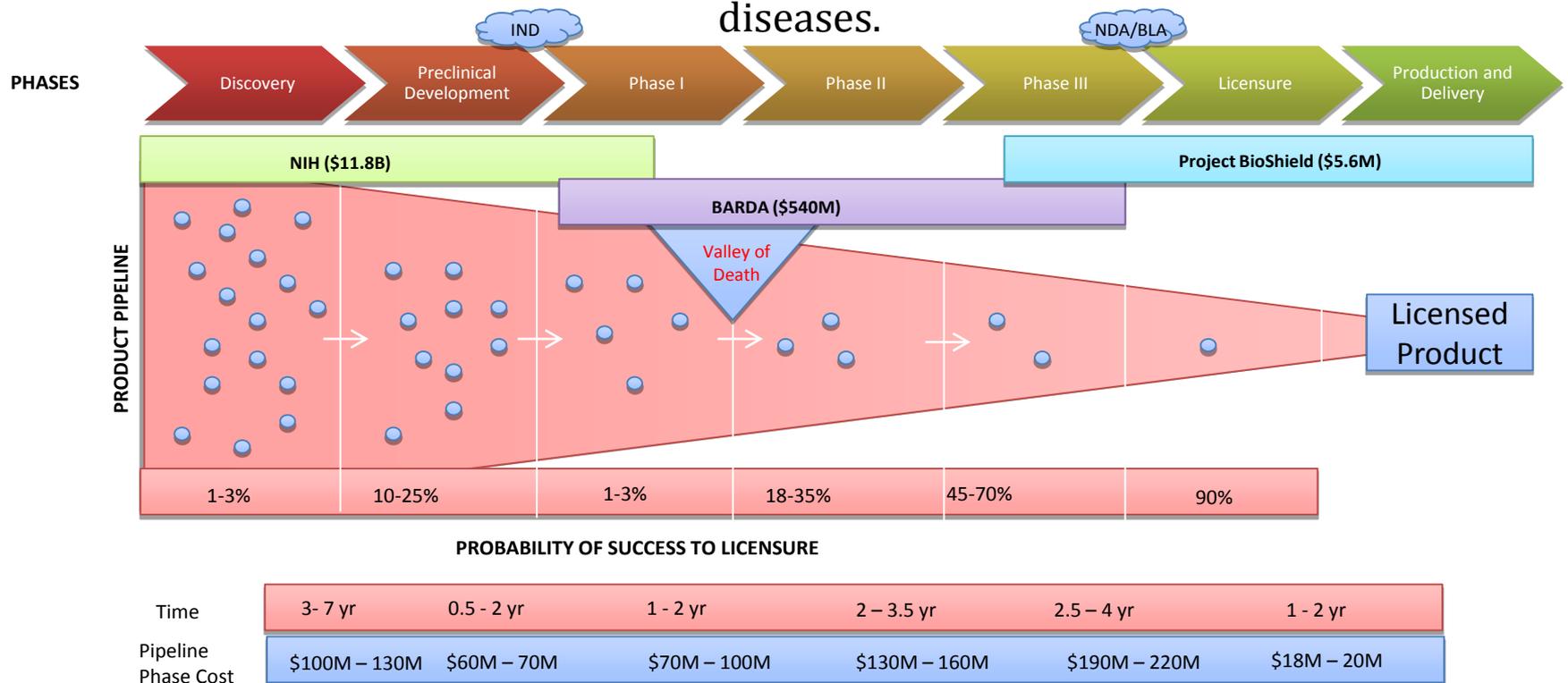
Responsive vs. Competitive



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.



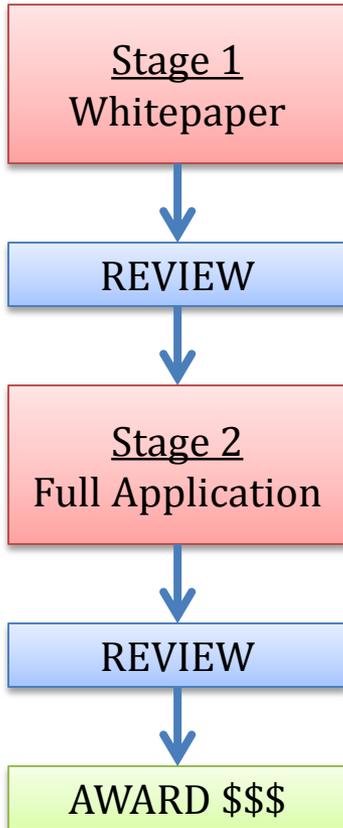
Adapted from The BARDA Multi-Broad Agency Announcement Pre-Proposal Conference 2012

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 27th
Full Application
August 11th

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
AutismBone 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.cdmp.org

CDMRPs

Pre-App
Deadline
July 20, 2017

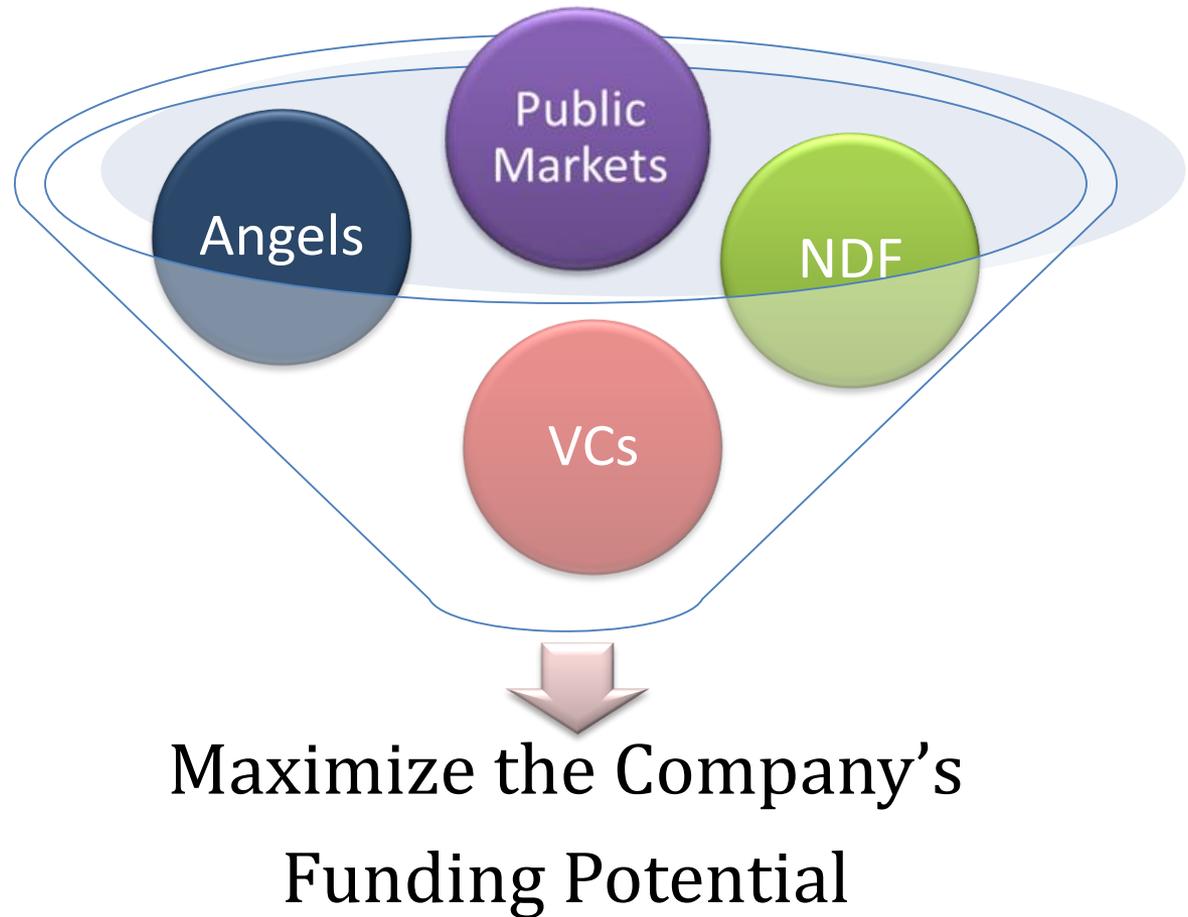
Funding: Application budgets are not capped, however, must reflect the scope of work.

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

Strategic
Approach



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**



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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FreeMindGroup

Watch past presentations and webinars online on our YouTube Channel



FreeMind Group

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



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