Life Sciences Trends & Topics
WEBCAST SERIES

Non-Dilutive Funding & Valuable Resources

STRATEGIES FOR GROWTH WITHOUT GIVING UP EQUITY

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Welcome

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With You Today

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Learning Objectives

Upon completion of this session, participants will be able to:

- Explore common challenges and pitfalls in pursuing non-dilutive funding and learn how to navigate these effectively to improve your chances of success
- Review what non-dilutive funding is, including its advantages and how it differs from traditional equity-based funding
- Identify various sources of non-dilutive funding, such as grants, awards, tax credits, and government programs tailored to support businesses in different sectors
- Discuss how to prepare compelling applications & proposals for non-dilutive funding including key elements that funding bodies look for
- Discover strategies for integrating non-dilutive funding into your overall financial planning to support sustainable growth and innovation without diluting equity

Our Agenda Today

Beyond SBIRs: NIH as a Tech Development Partner

Partnering with Frederick National Laboratory for Cancer Research

R&D Government Collaborations

ASPR/BARDA Funding Opportunities

Panel Discussion

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Beyond SBIRs: NIH as a Tech Development Partner

Beyond SBIRs:
NIH as a Tech Development Partner

Your Six Top NIH Business Tips & Opportunities

- **In-licensing of NIH technology**
- **Technology development collaborations with the NIH Intramural Research Program**
- **Getting grants & contracts from NIH**
- **Selling products / services to NIH**
- **Using pre-clinical / clinical NIH services**
- **Utilizing NIH information sources**

Common Myths About Working with NIH

- **Only basic research**
  - FACT: Translational/clinical
- **Only study “drugs”**
  - FACT: Devices/Dx/Biomarkers/Wearables/Tools
- **Only work with academia**
  - FACT: Hundreds of industry licenses and partnerships
- **Only work with U.S. companies**
  - FACT: We partner internationally
- **Only develop internal ideas**
  - FACT: Ideas can originate in company partners

What are the Advantages for Your Company/Clients?

- **Access to scientific and regulatory expertise**
- **Access to unique reagents and resources**
- **Collaborations leading to new IP**
  - ☺ 0% overhead / indirect rate *
  - ☺ Reasonable milestone payments and royalties
  - ☺ Exclusive license option to co-owned IP
  - ☺ NIH cannot spin out a company to compete for the new IP
- **Licensing w/ compelling business terms**
  - ☺ 0% equity
  - ☺ “Fair value for public dollar”

*NCI capped 15%





Case Study

Co-Founders Dr. Melissa Lim & Patrick Yam

Industry → NIH

Collaborative Agreement with NIH National Institute of Diabetes and Digestive and Kidney Diseases

Met at conference; discussed clinical collaboration

Phase 1 successfully completed

Partnership with Dept. of Veterans Affairs; evaluate vet in all 50 states – reduces VA costs 60% versus fee-for-service sleep center

SomnoRing® (improved metrics & comfort

Somnology IDTF

Launched Somnology Independent Diagnostic Testing Facility (IDTF) to address growing market for improved accessibility to sleep assessments

Plex® Sleep

2017 2018 2019 2020 2021

Won MedTech Breakthrough Award: "Best Sleep Monitoring Solution"

- Collaborate with NIDDK; clinical trial studying effect of diet and environment on sleep
- Clinical trial testing new diabetes drug
- Provided in-kind/indirect funding covering trial costs
- Provided scientific and technical support

NIH Value Proposition:
Commercialization-friendly “Business Model”

- ★ View industry as partners rather than revenue source
- ★ Truly an exchange of ideas and effort
- ★ Statutory preference for working with smaller businesses
- ★ No sponsored/fee-for-service research
- ★ Indirect/in-kind support frees up other capital – extend runway

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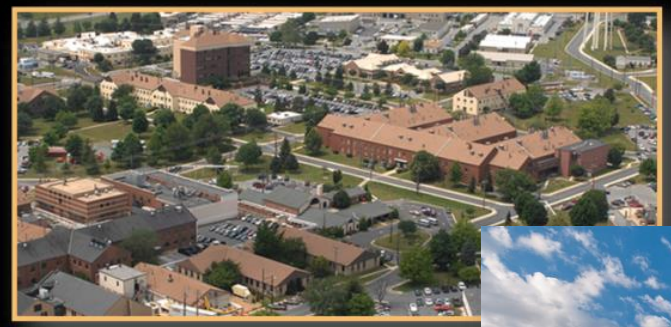
Partnering with Frederick National Laboratory for Cancer Research

Frederick National Laboratory for Cancer Research

Partnering with Frederick National Laboratory for Cancer Research



Only national laboratory fully devoted to biomedical research

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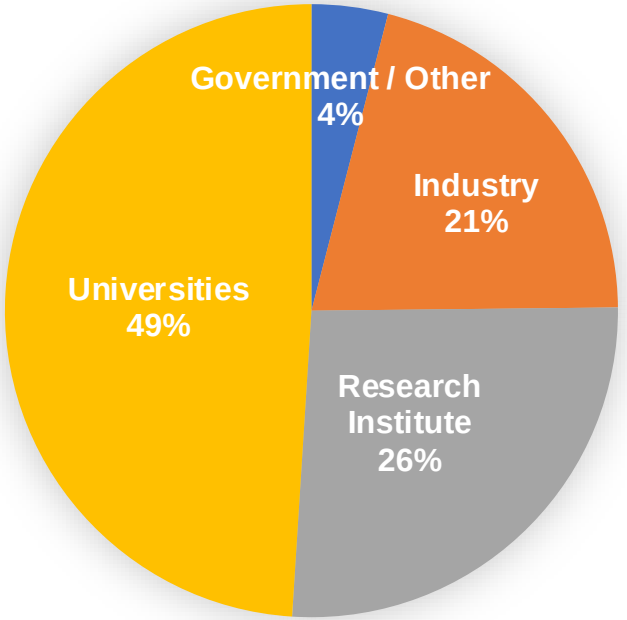
Who can we work with?

- **Universities/academics**
- **Biotech/med-tech**
- **Pharma**
- **Startups**
- **Cancer centers**
- **Nonprofits**

- Cancer
- HIV/AIDS
- Cancer-causing viruses
- Emerging infectious disease
- Nanoformulations



Only national laboratory devoted to biomedical research

From early discovery to clinical trials…

FNL consists of a wide variety of expertise, instruments, and tools.

Biomedical Computing
- Advanced Biomedical Computing Center
  - Bioinformatics
  - Simulation, Analysis, and Modeling
  - Imaging and Visualization

Virology
- AIDS and Cancer Virus Program

Genetics & Genomics
- Laboratory of Molecular Technologies
- Next Generation Sequencing Facility

Proteins & Proteomics
- Protein Expression Lab
- Protein Chemistry Lab
- Antibody Characterization Lab
- Laboratory of Proteomics and Analytical Technology

Molecular Diagnostics
- CLIA-certified Clinical Support Laboratory

Pharmaceutical Development
- Biopharmaceutical Development Program

Imaging
- Electron Microscopy Lab
- Optical Microscopy Lab

Animal Sciences
- Laboratory Animal Sciences Program
- Center for Advanced Preclinical Research
- Small Animal Imaging Program
- Pathology/Histotechnology Lab

Nanotechnology
- Nanotechnology Characterization Lab
  - Characterization
  - Reformulation
  - Method Development

FNL leads through discovery and innovation in basic and applied biomedical sciences to bring hope to people worldwide in their fight against cancer, HIV-AIDS and other infectious diseases

What is the FLC?

- The Federal Laboratory Consortium (FLC), is a nationwide network of more than 300 federal labs moving innovative technologies developed by federal labs into the marketplace.
- The FLC represents a collective strength of more than $180 billion invested annually in R&D by the federal government.
- The FLC was organized in 1974 and formally chartered by the Federal Technology Transfer Act of 1986 to promote and strengthen technology transfer nationwide.

Federal Technology Transfer Goal

Federal technology transfer benefits industry partners due to:

- Availability of unique facilities and equipment
- Experienced federal scientists and engineers

Federal technology transfer success is measured by **PARTNER** success.

Goal is for private industry partners to take federal innovations to the marketplace to manufacture, distribute, and sell.

FLC – Mid-Atlantic Region

Federal Labs in Mid-Atlantic Region

Vladimir Popov
Mid-Atlantic Regional Coordinator
Frederick National Laboratory for Cancer Research

Claudia Haywood
Mid-Atlantic Deputy Regional Coordinator
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Mid-Atlantic Regional Coordinator
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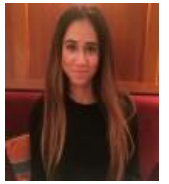
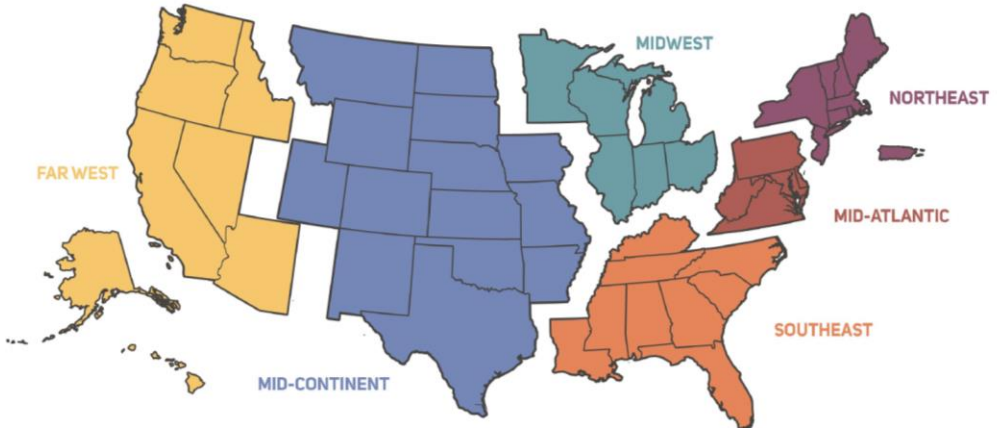


Zarpheen Jinnah
Mid-Atlantic Deputy Regional Coordinator
National Cancer Institute



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R&D Government Collaborations

R&D Government Collaborations

We have negotiated agreements with or on behalf of federal agencies that perform medical R&D, including:

- **Department of Health and Human Services**
  - Biomedical Advance Research and Development Authority / Administration for Strategic Preparedness and Response (BARDA/ASPR)
  - National Institutes of Health (NIH)
  - Centers for Disease Control and Prevention (CDC)
- **Department of Defense**
  - Defense Health Agency (DHA)
  - Army Medical Research and Development Command (USAMRDC)
  - Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)
  - Defense Threat Reduction Agency (DTRA)
  - Defense Logistics Agency (DLA)

We have experience drafting and negotiating every type of R&D legal agreement:

- **Other Transaction Authority (OTA) agreements**
  - Awarded through consortium
  - Direct agreements with Government
- Federal Acquisition Regulation (**FAR/DFARS**) Contracts for R&D and procurement of medical products
- **Grants** and **Cooperative Agreements**
- Cooperative Research and Development Agreements (**CRADAs**)
- Experimental Supply Agreements
- **Patent License Agreements** (out-license, in-license)
- Material Transfer, Clinical Trial, Quality, Non-Disclosure and other agreements

We vigorously defend and protect our client's FDA regulatory rights, intellectual property, and technical data.

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Non-dilutive Funding in DoD

- Defense Health Agency (DHA)
- U.S. Army Medical Research & Development Command (USAMRDC)
  - Congressionally-Directed Medical Research Program (CDMRP)
- Joint Program Executive Office for Chemical, Biological, Nuclear and Radiological Defense (JPEO-CBRND)
- Defense Threat Reduction Agency (DTRA), Joint Science & Technology Office (JSTO)
- Defense Advanced Research Projects Agency (DARPA)
- Uniformed Services University (USU)
- U.S. Air Force Research Laboratory (59th Performance Wing)
- U.S. Navy Medical Research Command (NMRC)

Non-dilutive Funding in DoD

- Solicitations (SAM.gov)
- Program Announcements (grants and cooperative agreements)
- Broad Agency Announcements (BAAs)
- Cooperative Research and Development Agreements (CRADAs)
- Medical Technology Enterprise Consortium (MTEC)
- Medical CBRND Defense Consortium (MCDC)
- DoD-Specific Research Foundations
  - Henry M. Jackson Foundation
  - Geneva Foundation
  - Metis Foundation

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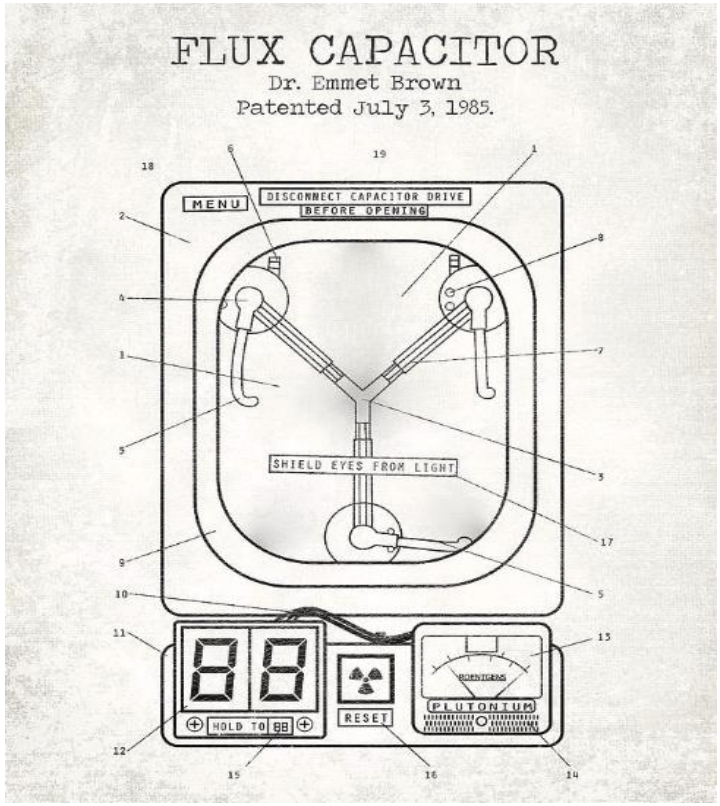
Strategic Considerations

Government R&D and Tech Transfer missions may provide substantial resources, but you must focus on your critical path and be careful not to subordinate your goals exclusively to the USG. Goals to consider:

- Proper evaluation of the FDA-regulatory landscape (sponsor responsibilities, unique approval mechanisms, marketing exclusivity, PRVs)
- Correct selection of legal instrument (assistance agreement, contract, CRADA, OTA or a combination thereof)
- Including proper terms/clauses in legal agreements to ensure protection of intellectual property (patents, copyright, trademarks, etc.), technical data and FDA regulatory rights

Failure in any one of these areas creates risk to the product development effort.



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Understanding Intellectual Property and Technical Data Rights

- The Government's goal is a "Win-Win" collaboration for successful commercialization of the technology
- Under the OTA Authority (unlike legal vehicles) – there are standard "Base Agreement" (in Consortia) or "Template terms" (in Bilaterals), but there is also **flexibility to negotiate**.
- Bayh-Dole is not required, but it is influential
  - Subject IP ("Windshield") and data vs. Background IP and data ("Rear Mirror")
    - Government will look for heightened rights to subject IP and data developed with federal funding
    - Generally, Government will not attempt to assert rights over background IP and data rights owned by company
- Aim for:
  - Clarity
  - Protection of key assets

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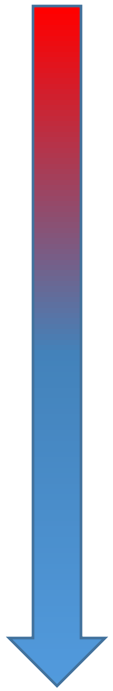
Levels of Government Rights

Greater Government rights



Lesser Government rights

Unlimited Rights

The right to use, modify, reproduce, display, release, or disclose technical data in whole or in part, in any manner, and **for any purpose whatsoever**, and to have or authorize others to do so.

Government Purpose Rights

The right to use, duplicate, or disclose technical data for Government purposes only, and to have or permit others to do so **for Government purposes only**. Government purposes include competitive procurement, but do not include the right to permit others to use the data for commercial purposes.

Limited Rights

The rights to use, modify, reproduce, release, perform, display, or disclose technical data **within the Government**. With few exceptions, the Government may not release or disclose the technical data outside the Government without the written permission of the party asserting limited rights.

Restricted Rights

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ASPR/BARDA Funding Opportunities

ASPR/BARDA

- **BAA & EZ-BAA**
- **Project BioShield**
- **BARDA Accelerator Network**
  - Provides funding to startups
  - In a Public Health Emergency, can rapidly fund and accelerate product development

- **Rapid Response Partnership Vehicle (RRPV) Consortium**
  - Product Development Life Cycle
  - Threat Agnostic Capabilities
  - Multi-Acquisition Vehicle

- **Biopharmaceutical Manufacturing Preparedness (BioMaP) Consortium**
  - Industrial base including manufacturers and providers of materials and services
  - Capacity expansion and reservation
  - Biomanufacturing technologies

ASPR Industrial Base Management and Supply Chain (IBMSC)

- Defense Production Act & Emergency Response Authorization
- Advanced Manufacturing Technologies
- Supply Chain Optimization
- Personal Protective Equipment and Durable Medical Equipment
- Testing and Diagnostics

FY 25 Funding

$970M	BARDA Advanced Research & Development
$970M	Strategic National Stockpile
$820M	Project BioShield
$328M	Pandemic Influenza
$95M	Biodefense Production of MCMs and Essential Medicines
$20M	IBMSC

Advantages/ Disadvantages

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Thank You

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