



Accelerate Innovation

June 11, 2024 – Presented by Liz Powell, Esq., MPH

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Presenter:Greg Kapcar, MPA





Agenda

- G2G Background
- Government Funding Sources & Systems
- Key Targets & Agencies
- DoD Basics Structure & Areas of Interest
- Grant Tracking GBG Reporting Service
- Case Studies
- Final Tips
- Q&A

G2G Consulting **Presenter:**Greg Kapcar, MPA





TEAM

- Bipartisan with 100+ years experience
- Raised over **\$528 M** for clients since 2007
- Secured CMS reimbursement, shaped regulations, drafted innovation policies, and led advocacy campaigns

LOCATIONS

- Capitol Hill, Washington, D.C.
- Fairfax, VA
- Cleveland & Columbus, Ohio
- Boston, MA
- Pittsburgh, PA

NICHE

- Bioscience and High-Tech Innovation
- · Women's health
- Funding Monthly GBG Report
- Legislative Updates
- Industry-related Blogs

AFFILIATES

- BIO Chapters and NCBiotech
- Defense: Women in Defense, NDIA Health Affairs, Defense Health Research Consortium
- Healthcare: HBS Healthcare Alumni Association, HSPH DC Chapter, Women's Digital Health Network
- grIP Venture Studio





Government Funding Sources

Categories:

Legislation – Appropriations & Authorizations

Grants

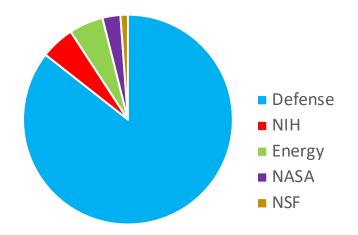
Discretionary

Procurement

Agency	FY22	FY23	FY24	FY25
DoD	\$728 B	\$797.7 B	\$825 B	\$833 B
NIH	\$45.4 B	\$48.9 B	\$49.6 B	\$50.1 B
ARPA-H	\$1 B	\$1.5 B	\$2.5 B	\$1.5 B
BARDA	\$745 M	\$950 M	\$1.015 B	\$970 M
Energy (DOE)	\$46 B	\$47.4 B	\$52 B	\$51 B
NASA	\$24 B	\$25.4 B	\$24.8 B	\$25.4 B
NSF	\$8.83 B	\$9.54 B	\$11.31 B	\$10.183 B
FDA	\$4.3 B (+user fees)	\$3.6 B (+user fees)	\$4 B (+\$3 B user fees)	\$4.5 (+\$3 B user fees)
VA	\$116.3 B	\$139.8 B	\$142.8 B	\$133.9 B

Within DoD:

\$3.28 B medical research\$21.4 B S&T\$946M Defense Innovation Unit





Government Funding Systems

White House

Budget Proposal

OMB

July - draft

January - finalize

February - introduce

Congress

Appropriations & NDAA (e.g., MOVE project)

Earmarks

Funding Levels and Directives

February-December

Departments & Agencies

Implementation of Laws & Grant Awards

Grants, BAAs,
Program
Announcements,
SBIRs, Contracts,
Pilots

All year





Federal Departments—Health and Human Services

Funding Mechanisms

- NIH SBIRs/STTRs, Ro1s, etc
- ARPA-H Program funding via Health Sciences, Scalable Solutions, Proactive Health, and Resilient Systems for:
 - ADAPT precision cancer
 - APECx broad viral efficacy with machine learning
 - ARPA-H BDF Toolbox data fabric toolbox
 - BREATHE environmental health
 - DIGIHEALS health security
 - EMBODY engineering of immune cells
 - HEROES improved outcomes
 - LIGHT lymphatic imaging, genomics and phenotyping NITRO tissue regeneration in osteoarthritis

 - PARADIGM rural access to care
 - PRINT personalized regenerative immunocompetent nanotech tissue
 - PSI precision surgery
 - SPRINT for Women's Health
 - REACT resilient extended automatic cell therapies
 - THEA human eye allografts
 - UPGRADE autonomous defense
- ASPR's BARDA BAA, DRIVe, ENACT, CARB-X active areas of interest (AOIs) include:
 - o CBRN vaccines, antivirals and antitoxins
 - Antimicrobials
 - Radiological/Nuclear threat medical countermeasures
 - Chemical threat medical countermeasures
 - Burn and blast medical countermeasures
 - Diagnostics
 - Influenza and emerging infectious diseases (IEID) vaccines and therapeutics

Conferences

- TechConnect World Innovation Conference: June 17-19 in DC
- SBIR/STTR Spring Innovation Conference: June 17-19 in DC
- BARDA Industry Days: every November in DC



Key Targets – Agencies

Federal Departments—Department of Defense

Funding Mechanisms

- SBIRs/STTRs
- Program Announcements
- Congressionally Directed Military Research Program
- Broad Agency Announcements
- Joint Warfighter Medical Research Program
- DARPA
- AFWERX: Specific Topic SBIR deadline: June 12 and includes biotechnology
- Consortiums: MTEC, BioFabUSA, MCDC, etc

Conferences

- MHSRS: August 26-30 in Kissimmee, FL
- Special Operations Medical Association Conference: every May in Raleigh, NC
- Defense TechConnect: December 3-5 in Austin, TX





Federal Departments—National Science Foundation, Department of Energy, and Veterans Affairs Department

- NSF America's Seed SBIRs/STTRs, EAGER, and RAPID
- DOE SBIRs/STTRs, ARPA-E
- Veterans Affairs pilot programs





- Military Health System (MHS) all military health care institutions and the world's preeminent military health care delivery operation
- Defense Health Agency (DHA) leads MHS integration of readiness and health and oversees research
- U.S. Army Medical Research & Development Command (USAMRDC) medical materiel developer R&D and acquisition
 - Military Infectious Disease Research Program
 - Combat Casualty Care Research Program
 - Military Operational Medicine Research Progrm
- Walter Reed Army Institute of Research (WRAIR) infectious diseases, brain health and performance optimization
- U.S. Army Institute of Surgical Research (USAISR) -- readiness and solutions for the optimal care of the combat wounded, includes Army Burn Center









DoD Key Areas of Interest

- Trauma Care Wound healing, regenerative medicine, sensors, traumatic brain injury, and PTSD
- Prolonged Field Care (PFC) managing medical and trauma patients in remote and austere locations far from medical support or logistically cannot evacuate casualties
- **VA** rehabilitation, chronic conditions, health IT, and hospital care
- Cost-savings is valued nearly as much as the improvement of care







THE ESSENTIAL GUIDE TO

Non-Dilutive Government Funding

Published by:



Questions?

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Updated Monthly





CASE STUDIES

Case Study: Cellular Therapy

CLIENT

- Wanted to work with DoD
- New to working with Congress and DoD
- In search of introductions to decision-makers and funding opportunities
- Based in OH and MA

PROBLEM

- Had never attended MHSRS or worked with government other than submitting an SBIR application to NIH
- Start-up company had 2 employees

SOLUTION

- Researched and identified funding sources
- Introduced to Capitol Hill, DoD and MHSRS
- Developed champions in Congress to deliver first dollars, then contracts with agencies for dual use development
- Secured \$120 million total for cellular therapy grants and contracts over 5 years from the Hill, USAMRDC, USAISR, DARPA and BARDA

TAKEAWAYS

- Engage in comprehensive assessment of funding landscape
- Target key Members of Congress, Program Managers and SMEs, and staff – engage repeatedly over time
- Time interactions, communications and relationship development to align with government process, timelines and needs
- Persist over time and deliver on what promise



Case Study: Orthopedic Innovation

CLIENT

- Seeking non-dilutive funding to match VC funds
- Had worked with DARPA before
- In search of new R&D funding for clinical studies
- Based in VA

PROBLEM

- Company secured some funding from DoD but didn't know how to leverage or build on that funding
- Needs funds to develop product for clinical use

SOLUTION

- Created strategy to pursue DoD relationships and funding streams specific to their stage of development
- Organized meetings at Fort Detrick, USAISR and MHSRS – MHSRS was the key tipping point
- Identified key DoD Program Managers
- Secured \$2.5 million from USAMRDC & AFWERX

TAKEAWAYS

- Work closely with DoD to meet their requirements and ensure science is novel
- Find best funding vehicles that align with stage of development
- Build relationships with DoD decision-makers
- Time interactions, communications and submissions to align with DoD process



Case Study: Cancer

CLIENT

- Cancer non-profit & for-profit
- Seeking ways to raise awareness and address gaps in rare cancer care, research, and access
- Based in TN, MA and KY

PROBLEM

- Had never worked with the government before and never engaged in advocacy
- Didn't know where to start or who to target

SOLUTION

- Created strategy for working with government
- Targeted committees, agencies and White House to educate and build champions
- Wrote legislation, advocated throughout Congress, and led grassroots campaign
- Secured policy changes and \$72 million for rare cancer research efforts over 4 years in 4 bills

TAKEAWAYS

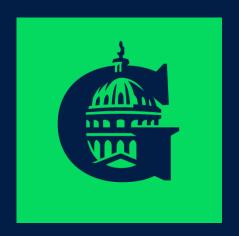
- Do comprehensive advocacy with patients & doctors
 story telling is key to advocacy
- Target Members of Congress touched by cancer
- Work with key committees of jurisdiction
- Time interactions, communications and advocacy to align with appropriations process



Final Tips



- Track funding opportunities, conferences, symposia, meetings, etc.
- Explore consortia: MTEC, ARMI, MCDC, North Carolina Center for Optimizing Military Performance (NC-COMP), etc
- Communicate effectively succinct and clear with tailored white papers and be persistent
- Build relationships with Program Managers before submitting application
- For grants, understand program goals, intent of award mechanism, and criteria; follow deadlines and budget guidelines; and register with SAM.gov, UEI, Grants.gov, eBRAP, etc
- Collaborate with government via CRADAs, MTAs, and grants whenever possible
- Engage your Members of Congress
- Sign up for G2G emails and GBG Reporting Service!



Thank You!

G₂G's BIOSCIENCE LEADS:

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