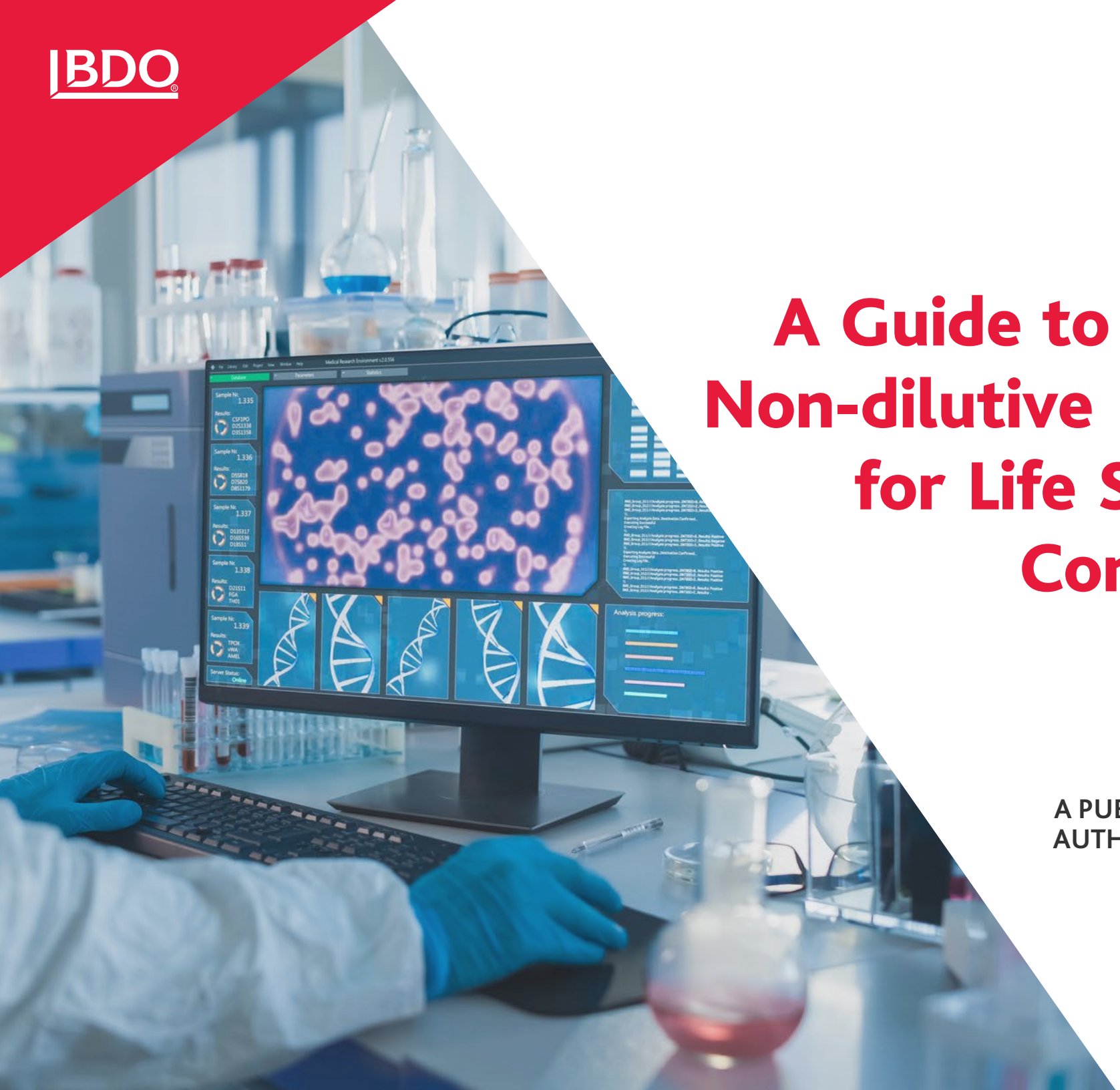

A Guide to Federal Non-dilutive Funding for Life Sciences Companies

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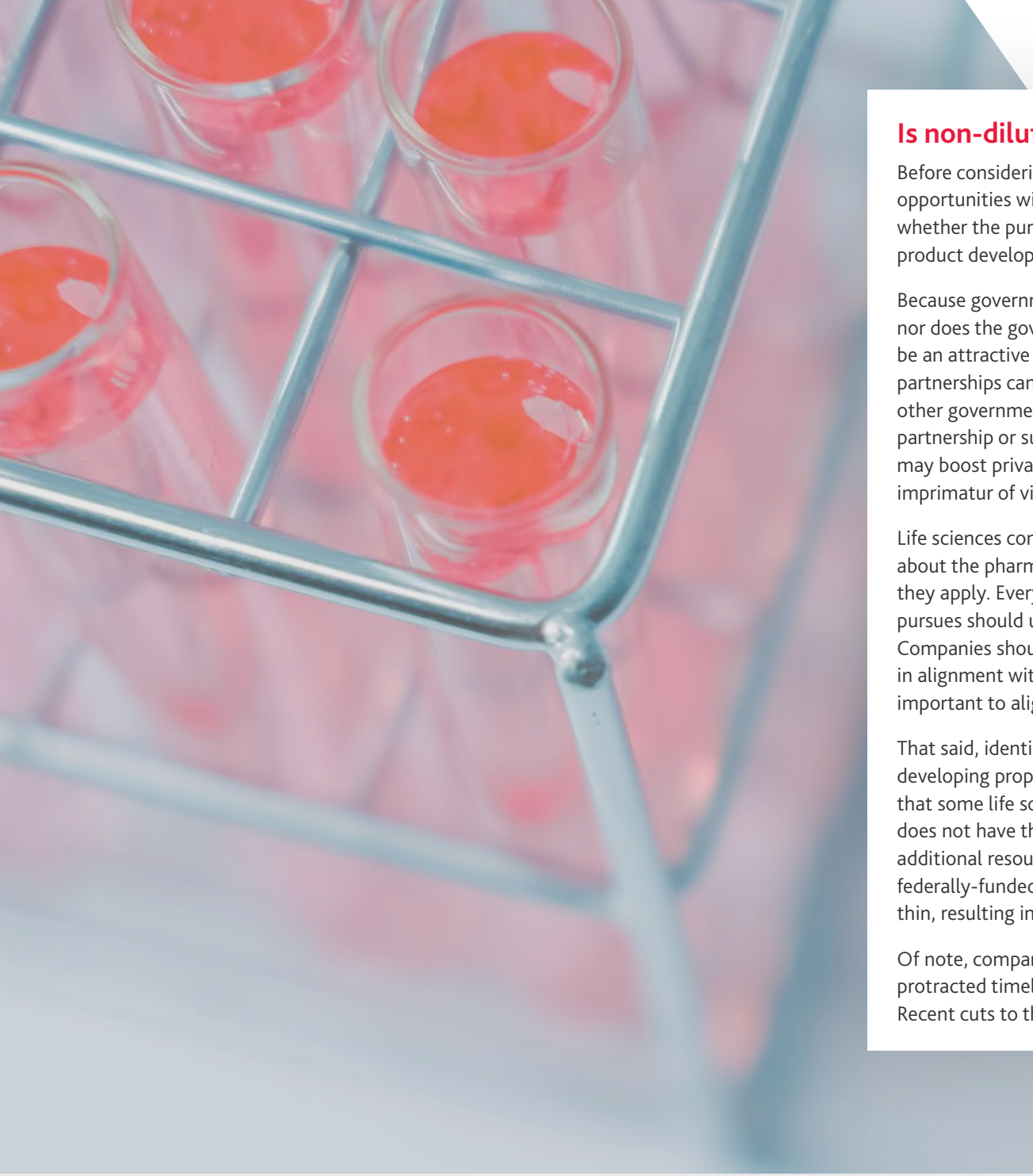
Fundraising for life sciences companies is typically a long, arduous, and evolving journey.

The U.S. government invests billions of dollars every year to help research, develop, and purchase life sciences products, which can help protect the civilian or military populations. Although the current administration is exploring cuts to the National Institutes of Health (NIH) and other agencies that provide funding for health research, federal agencies remain a key source of funds. These agencies aim to support the national interest in advancing the development of drugs, vaccines, therapeutic biologics, diagnostics, devices, and medical technology to support the population.

The federal government provides an option for life sciences companies to secure funding and continue the pace of discovery and development through non-dilutive funding. Non-dilutive funding allows companies to secure capital without sacrificing equity.

Before pursuing non-dilutive funding, company leadership must consider whether non-dilutive funding aligns with the organization's strategic goals, obtain situational awareness of which agencies are looking to partner with life sciences companies, and develop an understanding of the requirements and legal implications of government partnership.



Is non-dilutive funding right for my business goals?

Before considering the pursuit of funding, licensing, or collaboration opportunities with federal agencies, life sciences organizations must assess whether the pursuit of non-dilutive funding is the right strategy to achieve their product development goals.

Because government funding and partnerships do not require loss of equity, nor does the government take ownership of intellectual property (IP), this can be an attractive option for many companies. Further, government funding and partnerships can also open doors to additional collaborations among businesses, other government agencies, and academic institutions. Demonstrating a partnership or successful research project supported by federal funding may boost private investor confidence, as such a relationship can act as an imprimatur of viability, utility, and technical maturity of the technology.

Life sciences companies interested in non-dilutive funding should be discerning about the pharmaceutical funding and collaboration opportunities to which they apply. Every federal award, partnership, or licensing opportunity a company pursues should ultimately support its advancement toward commercialization. Companies should also be aware that while they may believe their research is in alignment with the solicitation, the government agency may not agree. It is important to align on specific requirements before accepting a funding award.

That said, identifying available funding and collaboration opportunities, developing proposals, and negotiating contracts may require skills or knowledge that some life sciences companies may not possess in-house. If an organization does not have the capacity for these tasks, an external advisor may provide additional resources and guidance. Companies should avoid assuming too many federally-funded projects at once, as doing so could potentially spread resources thin, resulting in missed performance milestones and timelines.

Of note, companies should be aware that the federal government often has a protracted timeline for execution of funding awards compared to private funders. Recent cuts to the federal workforce may further extend these timelines.

Department of Defense, Defense Health Agency (DHA)

The Defense Health agency consolidates most medical R&D under the Department of Defense (DoD), the latest addition to which is the U.S. Army Medical Research and Development Command (MRDC). The MRDC not only conducts basic and applied R&D for battlefield needs unique to the medical care of military personnel, but also conducts research on breast cancer, infectious diseases, surgical advances, and telehealth. The MRDC offers a grant program called the Congressionally Directed Medical Research program (CDMRP) that typically offers 15-20 grants per year. In addition to its mission as a basic and applied R&D apparatus, DHA is also an "advanced developer," which means it is a DoD component tasked with researching, developing and fielding medical technology to close specific medical capability "gaps." Importantly, an advanced development relationship can extend to ultimate acquisition and fielding of a company's innovative medical products.

Another notable program under the purview of the U.S. Army is the **Joint Program Executive Office for Chemical, Biological, Nuclear and Radiological Defense** (JPEO-CBNRD), which focuses on medical countermeasures such as drugs, devices, diagnostics, and vaccines that protect or treat U.S. soldiers from chemical, biological, radiological, or nuclear (CBRN) threats.

Other notable DoD agencies involved in medical R&D collaborations with industry include:

- **Defense Threat Reduction Agency (DTRA), Joint Science and Technology Office;**
- **Defense Advanced Research Projects Agency (DARPA);**
- **Uniformed Services University (USU);**
- **U.S. Air Force Research Laboratory (59th Performance Wing);** and
- **U.S. Navy Medical Research Command**

There are frequent collaborations between DoD agencies, with other federal agencies, and through public-private partnerships (P3s). To learn about funding opportunities available through the DoD, search for solicitations for contracts at **SAM.gov**.

Every agency listed above also has an open solicitation called a Broad Agency Announcement (BAA) where companies can submit research proposals to defense agencies. DoD labs also have cooperative research and development agreement (CRADA) authority, meaning they can rapidly enter into non-funded collaborative research and development agreements. CRADAs allow companies to collaborate and test their technology through the U.S. military.

Biomedical Advanced Research and Development Authority (BARDA)

The Biomedical Advanced Research and Development Authority exists to develop medical countermeasures against CBRN and pandemic influenza threats and seeks to bridge the funding gap between early research and development and licensure. As BARDA's work is centered around public-private partnerships (P3s), BARDA offers several vehicles for those partnerships:

- **BAA and EZ-BAA**
  The Broad Agency Announcement (BAA) and Easy Broad Agency Announcement (EZ-BAA) is a rolling solicitation with various Areas of Interest across vaccines, diagnostics, devices, and therapeutics. The EZ-BAA is a supporting solicitation within the BARDA **DRIVe Program**, focusing on transformative and innovative solutions to unmet needs. The EZ-BAA therefore has an interest in specific high-priority areas, such as at-home diagnostics, digital medical countermeasures (MCMs), and ImmuneChip+ technologies which can accelerate the discovery and validation of vaccines and therapeutics. Initial awards are capped at $750,000. Following the success of a project a company can apply for the BAA+ award which can amount to up to $20 million in additional funding.
- **Project Bioshield**
  Project Bioshield was established to support late-stage development and procurement of products and medical countermeasures for the Strategic National Stockpile. Funding can only be used to support medical countermeasures addressing Material Threat Determinations identified by the Department of Homeland Security.
- **BARDA Accelerator Network**
  The BARDA Accelerator Network is composed of 13 accelerators, supported by 5 hubs. The network was established to support startups assessing product feasibility and advancing development toward commercialization. The five hubs are Vaccines and Therapeutics, Diagnostics and Devices, Special Populations, Digital Health, and Enabling Technologies.
- **Rapid Response Partnership Vehicle (RRPV) Consortium**
  The RRPV Consortium is focused on accelerating partnerships and identifying solutions to various CBRN threats. Members include developers in the vaccine, therapeutics, and diagnostics community. RRPV awards primarily support threat-agnostic capabilities through all phases of the product development life cycle.
- **Biopharmaceutical Manufacturing Preparedness (BIoMaP) Consortium**
  This consortium is focused on expanding the domestic industrial base and capacity expansion of manufacturing capabilities, including raw materials and consumables.

Key government agencies offering funding and collaborations

For life sciences companies that determine non-dilutive funding is right for their research, development, and commercialization goals, here are some agencies that fund life sciences research:

National Institutes of Health (NIH)

Many companies are already aware of the National Institutes of Health (NIH) as a source of life sciences grant funding, primarily through the Small Business Innovative Research (SBIR) grant program. However, the NIH can also act as a tech development partner. Life sciences companies can:

- License NIH technology
- Develop their own technology collaboratively through the NIH Intramural Research Program; in some cases, exclusive licenses are available for co-owned IP
- Receive grants and contracts
- Sell products and services to the NIH
- Use pre-clinical/clinical NIH services, including reagents and resources such as mouse models, cell lines, antibodies, and other resources for developing technology
- Use NIH information sources

The NIH tends to work with smaller companies and offers reasonable milestone and royalty repayment rates, as rates are primarily based on getting a fair return on public dollars.

Frederick National Lab for Cancer Research

The Frederick National Lab sits under the NIH and is fully funded by the National Cancer Institute and the National Institute of Allergy and Infectious Diseases. It is the only national lab fully dedicated to biomedical research. About two-thirds of the research is focused on cancer while the other third is focused on HIV/AIDS and infectious diseases. They provide expertise, instruments, facilities, and tools from early-stage discovery to clinical trials, including:

- Virology
- Genetics and genomics
- Imaging
- Proteins and proteomics
- Animal sciences
- Pharmaceutical development
- Molecular diagnostics

Frederick National Lab for Cancer Research works with companies of any size and provides a number of facilities and technologies for free in order to advance cancer and infectious disease treatments. It is part of the federal lab consortium, which includes over 300 labs.

Legal considerations before entering an R&D government collaboration

Before entering into a non-dilutive funding agreement, companies should conduct a proper evaluation of their Food and Drug Administration (FDA) regulatory pathway, determine if the landscape could support the product, and identify the right funding agreement and legal instrument for a partnership. Some government R&D collaboration agreements include:

- Traditional research and development contracts governed by the Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulations (DFAR);
- Other Transaction Authority Agreements (OTAs) (both bilateral and consortium models are used);
- Grants and cooperative agreements;
- Cooperative research and development agreements (CRADA);
- Non-competitive experimental supply agreements;
- Patent licensing agreements; and
- Material transfer and clinical trial agreements

Companies should ensure any collaboration agreement protects their intellectual property — such as patents, copyrights, and trademarks — as well as their FDA regulatory rights, including sponsorship, priority review voucher eligibility, marketing exclusivity, and patent term restoration. In addition, protection of a company's technical data rights and how these rights will be allocated between the government and the private firm are often among the most critical terms and conditions to negotiate. Working with an external advisor who can help draft and negotiate the collaboration agreement can enable a successful and mutually beneficial collaboration.

While an agreement with a government agency will not give the government rights to any data a company brings to its research collaboration, the government will likely have rights to the data produced as part of the collaboration. This data is known as subject IP or subject technical data. Depending on how a project is funded — whether it is jointly funded, entirely funded by the government, or entirely funded by the company — the government will have a different level of rights to the technical data generated. Those rights could take the form of unlimited rights, government purpose rights (i.e. not for commercial purposes), limited rights (which allows the government to use the data, but does not permit use by others), and restricted rights.

How to get started

If non-dilutive funding or a government research partnership supports your clinical and commercial goals, the next steps are to explore available life sciences grants and collaboration opportunities on **SAM.gov** and **grants.gov**. NIH lists technology available for licensing on their **website**. If you are interested in licensing any of the available technology, you can contact a **Technology Transfer Professional**. Many of the agencies mentioned in this article also accept open solicitations through a Broad Agency Announcement (BAA), which outline areas of science the agency is interested in advancing.

For more information on non-dilutive funding and for help connecting with government resources and negotiating contracts, reach out to **BDO's Biodefense and Government Contracting** group.

To stay informed of the latest executive actions and court orders impacting federal funding for life sciences research, visit BDO's 2025 **policy hub** and Venable's **election resource center**.

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