Characterizing Private-Sector Research on Human Pathogens in the United States

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Table of Contents

1. Executive Summary

Improperly protected human pathogen research poses risks to human health and wellbeing through laboratory accidents and the malicious misuse of laboratory materials or information. A patchwork of US government policies serves to manage these risks, but private non-profit and for-profit performers of human pathogen research are subject to less oversight than government or academic research performers.

To support informed decisions about regulation, we estimated the size, nature, and oversight capacities of the US private sector in human pathogen research by using data from multiple sources, including publications, funding streams, records from comparable foreign governments, customer records from providers of research materials, and lists of organizations themselves. Each of these estimates is imperfect alone, but together forms a picture of the research community. **Overall, we estimate that about one quarter of human pathogen research performed in the United States occurs in the private sector.**

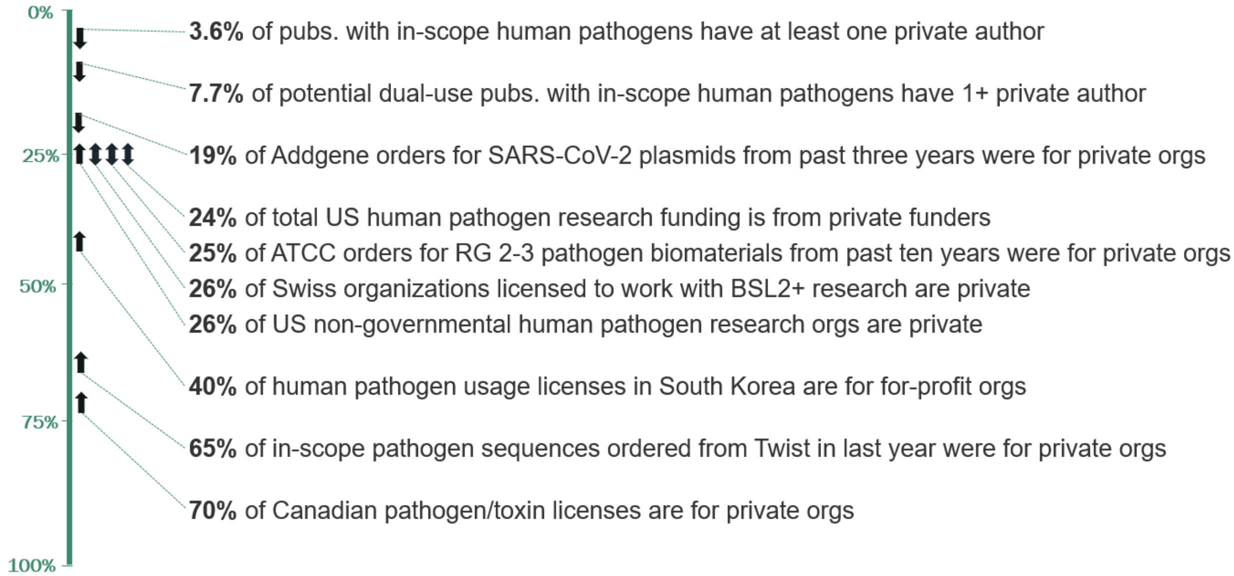

Figure 1. A continuum of estimates of the relative size of the private sector in US human pathogen research from various sources. Upward arrows indicate likely overestimates; downward arrows indicate likely underestimates; bidirectional arrows indicate that the estimate may be high or low.

Of the institutions that perform human pathogen research in the United States that are not run by the government or confer degrees, 54 of the 86 for-profits (63%) and all 19 of the non-profits that we identified had accepted federal funding in the last five years, making them subject to US government's policies for managing dual-use research of concern (DURC). The remaining 32 for-profits appeared to be unfunded by the US government and are thus only subject to OSHA workplace safety requirements.

In addition, we held discussions with representatives from six major non-profits, for-profits, and funders involved with US human pathogen research to learn more about their current oversight practices. Overall, the research funders that we spoke to relied heavily on research performers to manage day-to-day biosafety and biosecurity risks. Research performers reported strong biosafety and biosecurity practices and close alignment with US government documentation.

2. Introduction

2.1. Objective

Policy discussions and risk assessments regarding human pathogen research are typically based on data and examples from the government and academic sectors.[1,2,3,4,5] In addition, most federal policy requirements for biorisk management apply only to organizations that receive federal funding and/or work with select agents.[6] Clearly, risks involving human pathogen research can also arise from private-sector funders or performers working with non-select agents, suggesting that this regulatory gap may leave some risks with little oversight. Despite these risks, little is known about the size, activities, and internal oversight practices of the United States (US) private sector in human pathogen research.[7] Information about the scope of privately funded and performed pathogen research in the US could inform regulatory priorities for biorisk management.

The objective of this report is to characterize the role of the US private sector in human pathogen research, including its size, activities, and internal oversight.

2.2. Background

2.2.1. Private Pathogen Research in the US: Knowns, Unknowns, and Concerns

Private (non-government, non-academic) funders and performers play an increasingly large role in US life science research. In 2013, the proportion of basic research in the US funded by the federal government fell below 50% across all fields. This drop was in part because of a significant rise in corporate funding – particularly from the pharmaceutical and biotech industries.[8] The US bioeconomy is also growing rapidly. In 2021, the biggest growth year ever for synthetic biology startups, companies raised almost $18 billion in funding – “nearly as much as the entire amount in all prior years since the emergence of the field in 2009.”[9]

However, there are major open questions about the extent to which US private actors are conducting human pathogen research that could pose biosafety or biosecurity risks to the public. US government laboratories are subject to government oversight, and academic laboratories inherently maintain some visibility because their publications bring them into public view. But private non-profit and for-profit organizations conducting human pathogen research are only overseen by an incomplete patchwork of government policies (reviewed in Section 2.2.2).

As a result, there is no centralized accounting – either to the public or the federal government – of the number of US private-sector human pathogen research laboratories and what research

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[1] Bloom JD et al. (2021) Investigate the origins of COVID-19. *Science.* 372 (6543): 694-694.

[2] Casadevall A, Shenk T. (2012) The H5N1 moratorium controversy and debate. Vol. 3, e00379-00312. Am Soc Microbiol.

[3] Pannu J et al. (2022) Protocols and risks: when less is more. *Nature protocols.* 17 (1): 1-2.

[4] Reardon S. (2014) Forgotten NIH smallpox virus languishes on death row. *Nature.* 514 (7524): 544.

[5] Sandbrink J et al. (2022) Mitigating biosecurity challenges associated with zoonotic risk prediction. *Available at SSRN 4035760.*

[6] Government U. (2014) United States government policy for institutional oversight of life sciences dual use research of concern. Government Printing Office Washington, DC.

[7] National Academies of Sciences E, Medicine. (2017) Managing Dual Use Research of Concern. In *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*. National Academies Press (US).

[8] Mervis J. (2017) Data check: US government share of basic research funding falls below 50%. *Science Funding.*

[9] Bünger M, Upton L. (2022) 4Q 2021 Synthetic Biology Venture Investment Report. *Built with Biology.*

they are performing. For example, research on certain virulent and transmissible human pathogens is performed in specialized biosafety level 3 (BSL-3) laboratories. However, current public lists of BSL-3 laboratories are incomplete and primarily rely on identifying laboratories through publications.[10] Private laboratories that do not publish may not be included in these lists.

The recent discovery of an unlicensed lab operating in Reedley, California serves as a vivid reminder of the risks of unregulated private research. The lab, which was owned by a Chinese company called Prestige Biotech, held improperly-managed stocks of almost 1,000 laboratory mice and infectious diseases including COVID-19, rubella, malaria, dengue, chlamydia, hepatitis, and HIV. It could have accidentally released Risk Group 2 and 3 pathogens, potentially sparking an outbreak. However, the lab was able to acquire pathogens and operate without any local or federal oversight, and it was apparently unknown to the federal government or regional authorities. If it were not spotted by an observant city official on a chance visit, it could have continued to operate for a long time.

Existing data provide some limited information about the relative size of the private sector. The domestic biotech sector grew rapidly over the last decade and spent approximately $94 billion on research in 2021, but the fraction of this sum focused on human pathogens is unknown.[11] Recent surveys of biosafety officers (BSOs), who oversee biosafety in life-science laboratories, provide more clues. A recent international survey of BSOs found that about 21% reported working in the commercial, nonprofit, or “other” (neither academia nor government) sectors.[12]

Another currently-unpublished survey examined BSOs in the US who reported working with dual-use research of concern (DURC), defined by the federal government as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”[13] This survey found that 22% self-identified as working in the private sector. Thus, we might estimate that approximately 20% of human pathogen research performed in the US is conducted by the private sector.

Those who specifically focus on research oversight have disagreed on the nature of the practices adopted by the private sector to manage risks. For example, in a 2018 workshop on dual-use research governance hosted by the National Academies of Science and Medicine, participants disagreed about the extent to which the private sector voluntarily and competently practiced oversight of the dual-use risks of its own work, noting that “this remains an area in which future work or further discussions may be useful.”[14]

There have been repeated calls to extend, strengthen, and unify federal oversight of private human pathogen research. In 2016, the National Science Advisory Board for Biosecurity (NSABB) recommended that especially concerning instances of gain-of-function research

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[10] Young A, Penzenstadler N. (2015) Inside America’s secretive biolabs. *USA Today.* 28.

[11] DeFrancesco L, Lähteenmäki R. (2022) Public biotech in 2021-the numbers. NATURE PORTFOLIO HEIDELBERGER PLATZ 3, BERLIN, 14197, GERMANY.

[12] Gillum D et al. (2022) Experiences during the COVID-19 pandemic: a survey of biosafety professionals. *Applied Biosafety.* 27 (3)**:** 127-143.

[13] Health NIo. (2002) NIH guidelines for research involving recombinant DNA molecules (NIH guidelines).

[14] National Academies of Sciences E, Medicine. (2017) Managing Dual Use Research of Concern. In *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*. National Academies Press (US).

should be subject to federal oversight, whether publicly or privately funded.[15] More recently, a letter to the NSABB signed by 34 scholars and practitioners in the life sciences and biorisk management recommended expanding regulatory oversight to include non-federally-funded research.[16] The NSABB agreed, releasing an updated set of recommendations that include expanding oversight to "all relevant research activities, regardless of the funding source."[17]

It is essential to understand the extent of pathogen research that is being funded and performed in the US outside of government oversight, and what (if any) oversight it receives internally. If a great deal of such research is occurring without substantial oversight, then a revision of biorisk management policy to cover this sector is more urgently necessary, and systems to coordinate data-sharing and data-management between the public and private sectors should be put into place to protect sensitive research data.[18,19,20] Oversight of private research may be lax because private actors lack external supervision and are incentivized to conduct research quickly, or it may be strong because they perceive reputational or business risks from accidental or deliberate misuse.

2.2.2. Policy Landscape

Private pathogen research in the US is overseen by a patchwork of policies, most of which only apply to projects or organizations receiving government funding:

- The National Institutes of Health (NIH) maintains extensive biosafety and biosecurity guidelines for institutions that receive federal funding for research involving recombinant DNA.[21]
- The US government maintains policies for overseeing DURC. These policies only apply to US government (USG) departments and agencies that fund or conduct life sciences research, and to US organizations that receive federal funds to conduct or sponsor life sciences research and conduct or sponsor research that involves one or more of a list of 15 agents and toxins.[22]
- Government funding agencies also consider the risks of human pathogen research as part of their funding decisions. For example, the US Department of Health and Human Services (HHS) maintains a "Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens," also known as the P3CO

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15 Biosecurity NSABf. (2016) Recommendations for the evaluation and oversight of proposed gain-of-function research. *Office of Science Policy.*

16 Bloom B et al. Recommendations to Strengthen the US Government's Enhanced Potential Pandemic Pathogen Framework and Dual Use Research of Concern Policies. https://osp.od.nih.gov/wp-content/uploads/2023/05/Written_Comments_12_July_2022.pdf. Archived: https://web.archive.org/web/20230716003443/https://osp.od.nih.gov/wp-content/uploads/2023/05/Written_Comments_12_July_2022.pdf. Last Updated 07/12/22. Accessed 12/23/22.

17 National Science Advisory Board for Biosecurity. (2023) Proposed Biosecurity Oversight Framework for the Future of Science. Prepared for. https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf. Archived: https://web.archive.org/web/20230716003955/https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

18 Peters A. (2018) The global proliferation of high-containment biological laboratories: understanding the phenomenon and its implications. *Rev Sci Tech.* 37 (3)**:** 857-883.

19 Koblentz G. The Evolving Global Biosecurity Landscape. https://armscontrolcenter.org/wp-content/uploads/2022/04/Koblentz-Evolving-Global-Biosecurity-Landscape.pdf. Archived: https://web.archive.org/web/20230716004402/https://armscontrolcenter.org/wp-content/uploads/2022/04/Koblentz-Evolving-Global-Biosecurity-Landscape.pdf. Last Updated 03/22/22. Accessed 07/15/23.

20 George AM. (2019) The national security implications of cyberbiosecurity. *Frontiers in bioengineering and biotechnology.* 7**:** 51.

21 Health NIo. (2002) NIH guidelines for research involving recombinant DNA molecules (NIH guidelines).

22 National Academies of Sciences E, Medicine. (2017) Managing Dual Use Research of Concern. In *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*. National Academies Press (US).

framework.[23] Unlike the DURC policies, the P3CO framework only requires oversight on a project-by-project basis, not for entire organizations that host potentially concerning projects.

Oversight of non-government-funded research is less substantial. The most restrictive measures apply to select agents and toxins (often abbreviated as "select agents"), which are biological agents and toxins judged by the US government "to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products".[24] The Federal Select Agent Program (FSAP) mandates government oversight of any laboratories that conduct research with any of a publicly-available list of select agents. However, many serious human pathogens are not included on the select agent list, including *Mycobacterium tuberculosis*, hantaviruses, and West Nile virus.

Beyond the select agent program, all public and private laboratories in the US are also required by law to follow a set of general safety standards from the Occupational Health and Safety Administration (OSHA). These standards include requirements for personal protective equipment and management of bloodborne pathogens, but they are mostly not tailored for protection against human pathogens, and they do not mandate review of the potential information hazards or biosecurity risks of research.[25]

In addition, because of the patchwork nature of existing regulations, some projects at federally-funded institutions may receive more government-mandated oversight than others. For example, researchers at Boston University (BU) recently conducted a study that involved the creation of a novel chimeric SARS-CoV-2 virus that combined elements of two existing strains. Because BU is an academic institution receiving federal funds, the study was subject to and received standard Institutional Biosafety Committee (IBC) review, but controversy erupted over whether the study constituted gain-of-function research and required federal oversight under the P3CO framework. After a preprint of the paper was released, a representative from the NIH reported that they were unaware of the study. The paper was eventually published with a statement from the NIH explaining that "after careful review," the experiments "were funded with private funds and were not subject to NIH review."[26]

In summary, government-funded private research is overseen to varying degrees depending on the nature of the project, but oversight is primarily focused on research involving enhanced potential pandemic pathogens or DURC. Privately funded human pathogen research in the US is only required to comply with government oversight for general laboratory workplace safety and for work with select agents. Privately-funded work with non-select agents, including the vast majority of Risk Group (RG) 1-3 pathogens, is exempt from oversight.

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[23] Health Do, Services H. (2017) Framework for guiding funding decisions about proposed research involving enhanced potential pandemic pathogens.

[24] Program FSA. (2014) Select agents and toxins list. *CDC website.*

[25] National Research Council Committee on Prudent Practices in the Laboratory. (2011) OSHA Laboratory Standard. In *Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards: Updated Version*. National Academies Press (US).

[26] Branswell H. (2022) BU lab wasn't required to clear potentially controversial study with NIH, director says. *STATnews*.

2.3. Our Approach

2.3.1. Scope and Goal

2.3.1.1. Scope of Pathogens

The purpose of this project was ultimately to reduce risks from research on pathogens that have the capacity to cause significant harm from natural, accidental, or deliberate spread. Therefore, we defined the scope of pathogens included in this project as meeting ANY of the criteria below, because of their capacity for harm and disruption:[27,28]

- Pathogens in Risk Groups 2 or higher[29]
- Pathogens that have a case fatality rate (CFR) greater than or equal to 1%
- Pathogens that are subject to routine immunization (e.g., measles virus)

We excluded sexually or fecal-oral transmitted pathogens, such as norovirus, whose spread relies on behaviors and or interrupted by modern sanitary infrastructure. We also did not gather information on research on the select agents themselves, because research on these pathogens is already subject to oversight from the federal government regardless of the entity that is conducting it.

2.3.1.2. Scope of Organizations

We defined the scope of organizations included in this project as follows (Figure 2):

- The organization must be currently performing in-scope human pathogen research (as defined above) in the US.
- The organization must not itself be part of the federal government.
- The organization must not be an academic research institution or a research organization that is directly affiliated with academia (e.g., university hospitals), that has staff holding non-adjunct positions in academia, or that confers academic degrees, because they likely submit their research to public scrutiny through the publication process.

We acknowledge that federal oversight policies and regulations based on funding can apply to varying degrees depending on the technical details of funding source, recipient, and the nature of the research. An organization that simply receives no federal funding is almost certainly less visible to the federal government. Consequently, we provided separate results when possible for organizations that receive any federal funding and those that do not.

We also acknowledge exceptions and edge cases for our scoping categories, including entirely government-funded labs that are effectively government-controlled, academic labs that choose

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[27] Woolhouse M et al. (2012) Human viruses: discovery and emergence. *Philosophical Transactions of the Royal Society B: Biological Sciences.* 367 (1604)**:** 2864-2871.

[28] Woolhouse ME et al. (2008) Temporal trends in the discovery of human viruses. *Proceedings of the royal society B: biological sciences.* 275 (1647)**:** 2111-2115.

[29] In the United States, most human pathogens are classified into one of four Risk Groups (RGs) - classifications that describe the relative hazard posed by infectious agents or toxins in the laboratory ranging from 1 to 4 in increasing severity. Risk Groups are not to be confused with biosafety levels (BSLs), which are combinations of facility design features and safety equipment (primary and secondary barriers), facility practices and procedures, and personal protective equipment intended to ensure safe work with biological agents. Like Risk Groups, BSLs range from 1 to 4, with 4 involving the greatest degree of precaution, but there is no simple mapping between Risk Groups and BSLs.

not to publish, private labs that do choose to publish, institutions that are only weakly academically-affiliated, and individual DIY actors.

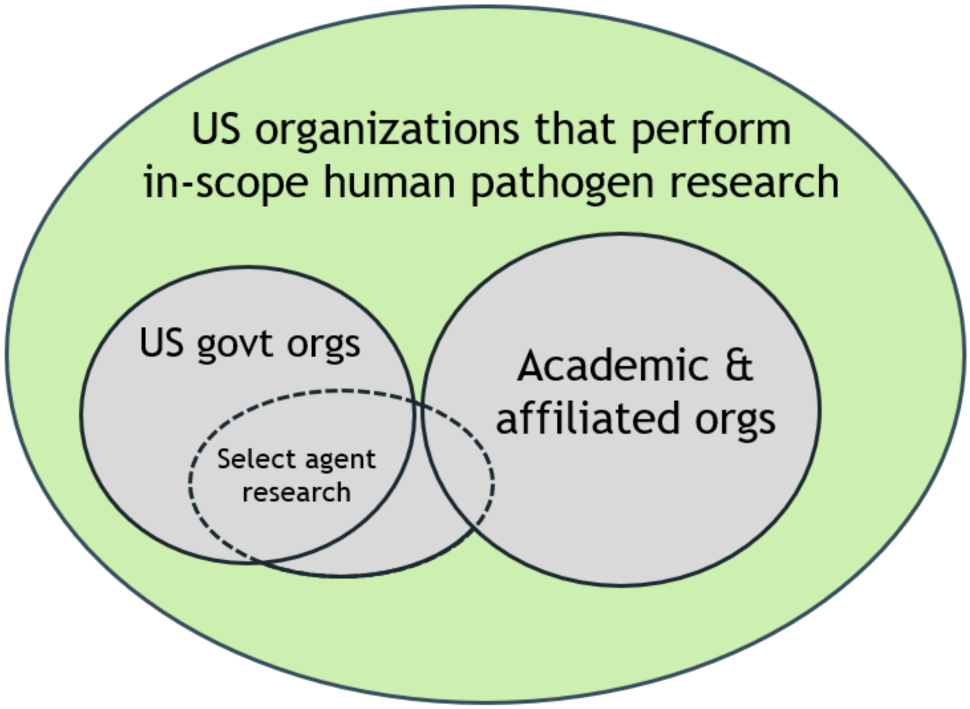

Figure 2. Scope of organizations included in this project. Gray regions are out of scope and green regions are in scope. Note: relative sizes of bubbles are for rough illustrative purposes and do not necessarily reflect real numbers of organizations or quantities of funding or publications.

2.3.1.3. Summary and Goal

In summary, this project focused on non-profit and for-profit organizations that are unaffiliated with academia and that perform research in the US with human pathogens that are in Risk Groups 2 or 3 (but are not select agents), have a CFR over 1%, or are subject to routine immunization. We refer to these organizations here in shorthand as the “private pathogen research sector.” The goal of this project was to characterize the size and oversight practices of the private pathogen research sector to inform federal policymaking and oversight.

2.3.2. Tasks

Any individual metric of the size of the private pathogen research sector will be imperfect. For example, publication-based metrics are imperfect if many private research organizations choose not to publish, counting institutions is misleading if some are much more productive than others, and identifying organizations through the funding of well-known external donors will overlook those that are funded by less-well-known donors or through profit.

To balance the limitations of any single approach, we pursued eight related approaches, or tasks, that collectively provide a fuller picture of private pathogen research (Table 1).

- The first two tasks characterized pathogen research *publications*. We examined a sample of publications involving in-scope pathogens and a smaller set of publications previously identified as holding dual-use potential.
- The next four tasks focused on characterizing key *organizations* involved with private pathogen research – funders, for-profits, and non-profits. We relied on publicly available data and discussions with organizational representatives to describe their funding sources, research areas, and degree of external and internal oversight.
- Finally, we considered two other complementary data sources. We reviewed available data from *foreign governments* on the fractions of their pathogen research that are private, and we summarized data on the private customers of bioeconomy *service providers* that supply biomaterials to research labs.
- When possible, we used the results of some tasks as data sources for other tasks to ensure that we completely identified relevant organizations (Figure 3).

Table 1. Summary of Tasks Undertaken for This Project

Name	Description of Task
Bibliometric Analysis	Conduct bibliometric analysis of published literature involving pathogens of interest, identify associated private-sector researchers and funders
Dual-Use Literature Analysis	Review 1,245 references from seven reports on dual-use research, identify associated private-sector researchers and funders
Analysis of Private Funders	Identify major private pathogen research funders, investigate their funding recipients via internet research
Analysis of Non-Profit Research Organizations	Identify major non-profit pathogen research institutions, investigate their funding sources internet research
Analysis of For-Profit Research Organizations	Identify major for-profit pathogen research institutions, investigate their funding sources via internet research
Oversight Discussions with Funders, Non-Profits, and For-Profits	Characterize the internal biosafety and biosecurity oversight practices of research funders and performers via discussions with organization representatives
Analysis of Foreign Programs	Infer the proportion of US private research on pathogens of interest by collecting similar information about proportions from foreign countries that track these pathogens
Analysis of Research Materials	Gather data from major providers of shared resources for pathogen research, such as cell lines, synthetic DNA, and plasmids, to estimate the fraction of their clients that are private

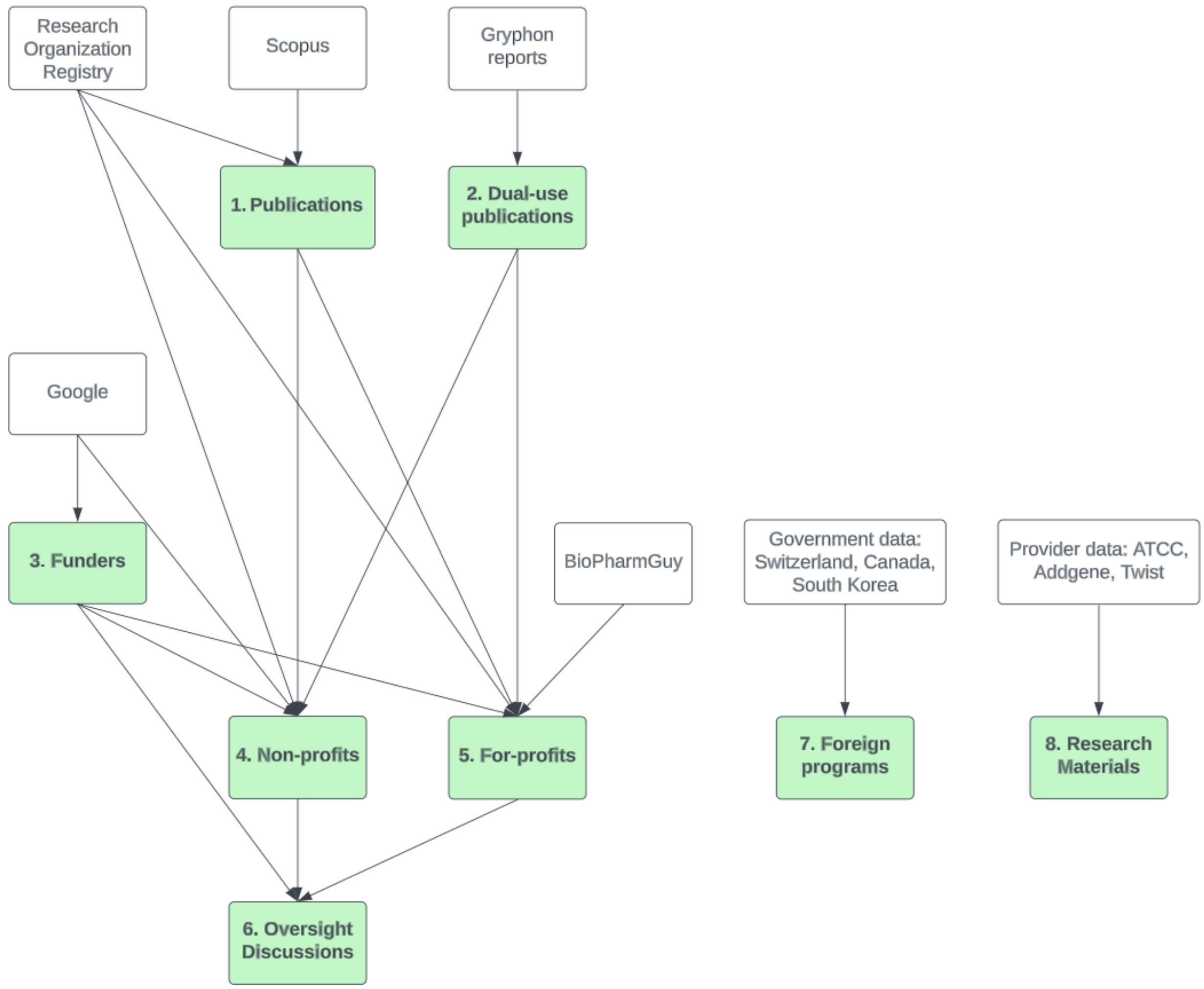

Figure 3. Primary Data Sources Used for Each Task

3. Bibliometric Analysis

3.1. Objective

The objective of this task was to analyze published literature on in-scope pathogens (see Section 2.3.1.1) to determine the proportion of US research that was conducted in private institutions and/or received private funding.

3.2. Methods

To identify relevant literature, search strings were developed for the in-scope pathogens to search in the literature database Scopus. In contrast to other databases such as PubMed or Google Scholar, Scopus was selected because it contains extensive extractable metadata for each paper, including authors' institutional affiliations and funding sources.

3.2.1. Search String Development and Literature Searches

An initial list of pathogens was drawn from a database and two reviews of human pathogens, following the scope criteria described in Section 2.3.1.1 (human pathogens that are in Risk Group 2 or 3, have a CFR over 1%, or are subject to routine immunization). Table 7 in the Appendices contains the final list of pathogens that met the inclusion criteria described above.

Scopus search strings were constructed using a template with four clauses:

1. Pathogen names and variations (e.g., "MERS coronavirus" and "MERS-CoV"). The names of pathogen-associated diseases were not included in this clause in an effort to exclude epidemiological or other studies that would not involve direct/lab-based pathogen research.
2. Date limitation term. Searches were restricted to studies published between 2012 and 2022 to obtain a more accurate picture of the current state of US private sector research.
3. Document limitation term. Searches were restricted to articles, excluding book chapters and books, conference papers and reviews, editorials, letters, press releases, and reviews.
4. Author affiliation limitation term. Searches were restricted to articles containing "United States" in the author affiliation field, which means that at least one author had a US affiliation.

As Scopus does not allow more than 2,000 search results to be exported with all metadata fields (including affiliation and funding information), pathogens were grouped into categories in order to construct search strings that returned fewer than 2,000 results: first, through splitting bacteria and viruses, then, through making separate search strings for different pathogen genera and species.

3.2.2. Bibliometric Analysis of Literature Search Results

To analyze the high volume of literature captured in the Scopus searches (more than 50,000 studies), we performed a bibliometric analysis using Python and PostgreSQL. This is a statistical research methodology that attempts to quantitatively assess characteristics of a body of literature, such as trends in author and funding affiliations. The first step of the bibliometric analysis involved parsing the Scopus export files to extract all fields containing author affiliations and funding details. Next, this list was de-duplicated and disambiguated, as the same organizations were often referred to with multiple titles in the metadata (e.g., Center for Disease Control and Prevention versus CDC). To do this, the list of author affiliations and funding organizations from the Scopus exports was compared to a list of organizations from a self-hosted Research Organization Registry (ROR) API.[30]

Once the author affiliations and funding organizations for each study captured from Scopus were standardized to the reference list, these organizations were classified as private or non-private according to the scope of this report. The majority of author and funding organizations for Scopus results were classified automatically, using the de-duplicated and disambiguated reference list created with the ROR database. Manual review was used to classify a small number of results that could not be automatically categorized.

3.3. Results

3.3.1. Search String Development and Literature Searches

The search strings used are listed in

[30] Lammey R. (2020) Solutions for identification problems: a look at the Research Organization Registry. *Science Editing.* 7 (1): 65-69.

Table 8 in the Appendices along with the dates that searches were conducted and the number of results. Searches were completed in September and October 2022, returning a total of 52,809 studies. After de-duplicating results between searches, a total of 42,175 unique articles were identified.

3.3.2. Bibliometric Analysis of Literature Search Results

Of the 42,175 unique studies captured from all Scopus searches, 40,676 (96.5%) had authors with entirely non-private institutional affiliations. The remaining 1,499 studies (3.6%) had at least one author with a private affiliation: 1,123 studies (2.7%) had a combination of authors with private and non-private affiliations, while 376 (0.9%) had authors with entirely private affiliations. Table 2 below displays these author affiliation breakdowns for each query used (generally split by pathogen genus).

Table 2. Author Affiliations for Publications Matching Pathogen List.

Pathogen Queries	Has Private		Only Private		Has Both		Only Non-Private		EIDs*
	%	n	%	n	%	n	%	n	n
Summary Totals									
All queries**	3.6%	1,499	0.9%	376	2.7%	1,123	96.5%	40,676	42,175
All pathogen queries***	3.6%	1,494	0.9%	376	2.7%	1,118	96.4%	40,498	41,992
Pathogen queries with ≥100 EIDs	3.6%	1,489	0.9%	375	2.7%	1,114	96.4%	40,233	41,722
Pathogen queries with <100 EIDs****	2.8%	9	0.6%	2	2.2%	7	97.2%	314	323
By Individual Pathogen Query									
Influenzaviruses	13.1%	552	4.1%	173	9.0%	379	86.9%	3,669	4,221
Lymphocryptoviruses	12.0%	3	0.0%	0	12.0%	3	88.0%	22	25
Mammarenaviruses	7.4%	30	2.5%	10	4.9%	20	92.6%	375	405
Lentiviruses (Others)	6.0%	52	0.7%	6	5.3%	46	94.1%	822	874
Lyssaviruses	4.3%	42	1.3%	13	2.9%	29	95.7%	944	986
Rubulaviruses	4.1%	3	1.4%	1	2.7%	2	96.0%	71	74
Vesiculoviruses	3.9%	28	0.6%	4	3.3%	24	96.2%	700	728
Flaviviruses (Zika)	3.8%	89	0.5%	12	3.3%	77	96.2%	2,230	2,319
Risk Group 3 Bacteria (M. tuberculosis)	3.7%	179	0.8%	40	2.9%	139	96.3%	4,638	4,817
Flaviviruses (Dengue)	3.5%	66	1.0%	19	2.5%	47	96.5%	1,796	1,862
Risk Group 3 Bacteria (M. bovis)	3.5%	17	1.2%	6	2.3%	11	96.5%	465	482
Orthopoxviruses	3.2%	1	0.0%	0	3.2%	1	96.8%	30	31
Coronaviruses (MERS)	3.1%	20	1.1%	7	2.0%	13	96.9%	617	637
Rubiviruses	3.1%	3	2.0%	2	1.0%	1	96.9%	95	98
Varicelloviruses	2.5%	17	0.9%	6	1.6%	11	97.5%	668	685
Alphaviruses	2.5%	24	0.4%	4	2.1%	20	97.5%	952	976
Coronaviruses (SARS-CoV-2)	2.1%	274	0.5%	68	1.6%	206	97.9%	12,511	12,785

Deltaretroviruses	2.0%	2	0.0%	0	2.0%	2	98.0%	98	100
Flaviviruses (Others)	1.9%	31	0.4%	7	1.4%	24	98.2%	1,649	1,680
Lentiviruses (HIV)	1.7%	152	0.2%	14	1.5%	138	98.3%	8,824	8,976
Morbilliviruses	1.5%	5	0.3%	1	1.2%	4	98.5%	331	336
Orthohantaviruses	1.0%	3	0.0%	0	1.0%	3	99.0%	310	313
Orthobunyaviruses	0.7%	1	0.7%	1	0.0%	0	99.3%	140	141
Risk Group 3 Bacteria (Others)	0.6%	6	0.1%	1	0.5%	5	99.4%	951	957
Bandaviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	87	87
Thogotoviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	16	16
Seadornaviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	1	1
BSL3 Query									
BSL3**	4.3%	12	1.4%	4	2.9%	8	95.7%	269	281

*EID = Electronic identifier, used to uniquely identify publications.
**EIDs can be categorized under multiple pathogen queries.
***The "BSL3" query was not included in the pathogen queries totals.
****Rows colored in dark grey denote pathogen queries with <100 EIDs.

Funder information was captured for 1,152 out of the 1,499 studies with at least one private author affiliation. Within these 1,152 studies, 44 (3.8%) were funded by a private organization, and 3 (0.3%) had only private funders. There were no studies that had a combination of only private author affiliations and only private funders. Eight unique private funders were found: Battelle, J. Craig Venter Institute, Jackson Laboratory, Oklahoma Medical Research Foundation, St. Jude Children's Research Hospital, Texas Biomedical Research Institute, Wistar Institute, and Trudeau Institute. Table 9 in the Appendices displays these funder breakdowns for each query used (generally split by pathogen genus).

4. Dual-Use Literature Analysis

4.1. Objective

The objective of this task was to identify US private-sector authors and institutions involved in pathogen research with substantial "dual-use" potential. In this context, "dual-use" refers to research that has both peaceful and offensive applications.

4.2. Methods

References were collated from seven reports prepared by Gryphon Scientific for the Department of Homeland Security on subjects related to the potential offensive use of biotechnologies by adversaries (references available for US government personnel upon request). Across these seven reports, there were 2,310 references to screen and review. Out of this total, 1,065 were duplicates, were dated earlier than 2000, or were irrelevant footnotes not citing sources. An additional 251 references had no individual authors and simply linked to a non-private website, such as references to a generic Centers for Disease Control and Prevention page, and were excluded. This down-selection left 994 unique relevant references (*Figure 4*).

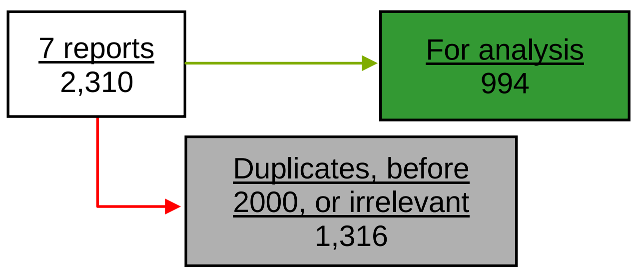

Figure 4. Summary of Reference Downselection for Dual-Use Literature Analysis

Each remaining reference was categorized based on its author affiliation status. A reference was marked as "private sector" if at least one individual with a US private sector affiliation was listed. If an individual had a private affiliation and a non-private affiliation, they were not included. Some authors were affiliated with institutions that had gone out of business and closed since the report was written, and those references were marked accordingly.

4.3. Results

Of 994 relevant references, 77 (7.7%) had at least one US private author. Out of these references, 33 (3.3%) had authors entirely from the US private sector.

Table 3. Frequency of References with or without US Private Sector Authors

Classification	Frequency	Percent of Relevant Results
Yes (at least one US private sector author)	77	7.7%
No (only public/government/academic/non-US affiliations)	914	92.0%
Closed (US institution is private, but has since closed)	3	0.3%
Total Relevant Results	994	

From the 994 relevant references, we identified 52 unique US private institutions. Several of these institutions were identified in multiple references; for example, St. Jude Children's Research Hospital came up seven times. Many others were only referenced once – most commonly smaller research laboratories, biotechnology companies, and pharmaceutical companies, such as Zalgen Labs and CytoDel Inc.

Table 4. Private Research Organizations Found in Relevant References and Their Frequencies

Organization	Frequency
J. Craig Venter Institute	7
St. Jude Children's Research Hospital	7
List Biological Laboratories, Inc.	6
Battelle Memorial Institute	5
Integrated DNA Technologies	4
Translational Genomics Research Institute	4
EcoHealth Alliance	3
Hardy Diagnostics	2
La Jolla Institute for Allergy and Immunology	2
(43 additional organizations – see Table 10 in the Appendices)	1

5. Analysis of Private Funders

5.1. Objective

The objectives of this task was to characterize all the major private funders of in-scope human pathogen research in the US, to estimate the fractions of their total funding that are given to private recipients, to identify their major recipients, and to estimate the average amount of annual funding that goes to those recipients. Research that is both funded and executed by private entities proceeds without federal oversight unless it involves regulated agents.

5.2. Methods

Funders of in-scope pathogen research in the US were found via an internet search (see Table 11 in the Appendices for search strings). We searched until no new in-scope funders could be found with a new search string. For each funder, we searched for publicly-available information on total and/or annual funding, average funding amounts per grant, examples of large grants, and lists of private and non-private grant recipients. When possible, we reviewed publicly-available records from the past three years to estimate the fractions of annual funding that each funder directed to private versus non-private (primarily academic) recipients. We did not include regrants if the recipient of funding was another large funder that we had already identified.

5.3. Results

We identified 37 private funders that contributed to in-scope human pathogen research in the US (see Table 12 in the appendices for a full list). Of these 37 funders, only 14 were identified that plausibly contributed more than $1,000,000 per year on average, though in some cases data were not available and could only be roughly estimated. In alphabetical order, they are: the AMR Action Fund, Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations, Drugs For Neglected Diseases Initiative, Foundation for Innovative New Diagnostics, Medicines For Malaria Venture, Steven & Alexandra Cohen Foundation, TB Alliance, AmFAR: The American Foundation for AIDS Research, Creutzfeldt-Jakob Disease Foundation, Gilead Foundation, Howard Hughes Medical Institute, Pediatric Infectious Disease Society, and Thrasher Research Fund.

Collectively, these organizations contributed an average of about $1.2 billion annually toward in-scope human pathogen research in the US. For comparison, the National Institute of Allergy and Infectious Diseases (NIAID), the largest US government funder of infectious-disease research, contributed about $3.9 billion to research grants in 2022.[31] If we treat $3.9 billion as a rough estimate of total US government funding for human pathogen research, we find that private funding accounts for roughly 24% of the national total ($1.2 billion / [$1.2 billion + 3.9 billion] = 24%). However, this estimate is uncertain because it excludes overlooked sources of private funding (e.g., venture capital funding and internal profit) and government funding (e.g., National Science Foundation, Department of Defense, Biomedical Advanced Research and Development Authority).

About half of the $1.2 billion from private funders – $635 million – was also directed to private recipients. However, the fraction of funding sent specifically to private research performers varied widely between funders. For example, approximately 75% of the $600 million annual US

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[31] National Institutes of Health. Budget and Spending. https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/budget-and-spending. Archived: https://web.archive.org/web/20230716005123/https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/budget-and-spending. Accessed 07/15/23.

pathogen research funding from the Coalition for Epidemic Preparedness Innovations (CEPI) is provided to private organizations, while virtually none of the $300 million from the Howard Hughes Medical Institute appears to be directed to private organizations.

Overall, the largest private contributors to privately-performed US pathogen research by far were CEPI (~$450 million/year to private recipients) and the Bill & Melinda Gates Foundation (~$100 million/year to private recipients). With the exception of the non-profit Institute for Systems Biology and the Bill & Melinda Gates Medical Research Institute, the largest private funding recipients were all for-profit companies.

6. Analysis of Non-Profit Research Organizations

6.1. Objective

The primary objective of this task was to identify all major US research organizations performing in-scope pathogen research that are not for-profit and not affiliated with government or academia.

6.2. Methods

To identify relevant organizations, we identified keywords from the websites of two prominent US pathogen research nonprofits – St. Jude's Children's Hospital and the Texas Biomedical Research Institute – and searched these keywords on Google with keywords such as "funders" and "grants" to find awards given to institutes that matched the search criteria (see Table 13 in the Appendices). To ensure a more comprehensive search, we also systematically identified non-profit entites from the Research Organization Registry (ROR), a community-led, publicly available registry for identifying research organizations.[32] We also included non-profits that we had previously identified in our review of pathogen research publications.

From our search results and the ROR, we filtered out academic organizations and organizations that were not located in the US, leaving 22,414 organizations. We then manually reviewed these remaining organizations and filtered out the large majority that obviously did not engage in wet-lab human pathogen research, such as the Phi Theta Kappa Honor Society.

Next, we researched the remaining organizations to verify that they were not affiliated with an academic institution. If the majority of the research faculty in these insititutions held positions in another academic institution (for example, researchers at the Whitehead Institute are faculty at MIT), then the entity was considered academic. We did not consider adjunct academic positions. If the affiliation of the research faculty was not clearly listed on the website, we used LinkedIn and the author affiliations listed on recent publications. This step was essential in evaluating institutions that described themselves as independent research institutes but were affiliated with academia and hospitals that conducted research and were affiliated with a medical school.

Finally, we reviewed the website of each organization for information about the specific pathogens that it studied to verify whether it likely worked with any select agents (and would therefore be subject to federal oversight). We also searched USASpending.gov, a federal website listing information about federal spending, for the name of each organization to check whether it had received federal funding in the past five years.[33]

6.3. Results

Figure 5 below summarizes our results. The internet search, ROR, and bibliometric analysis collectively yielded 42 non-profit organizations working with relevant pathogens. Of these, 16 were excluded because of academic affiliations. Seven were excluded because they likely work with select agents and are thus subject to federal oversight. 100% of the remaining 19 organizations received at least some federal funding between 2019 and 2023 and are thus

[32] Lammey R. (2020) Solutions for identification problems: a look at the Research Organization Registry. *Science Editing.* 7 (1)**:** 65-69.

[33] United States Government. USASpending.gov. USASpending.gov. Archived: https://web.archive.org/web/20230716005917/https://www.usaspending.gov/. Last Updated 2023. Accessed 07/15/2023.

subject to some federal oversight. The full set of organizations is listed in Table 14 in the Appendices.

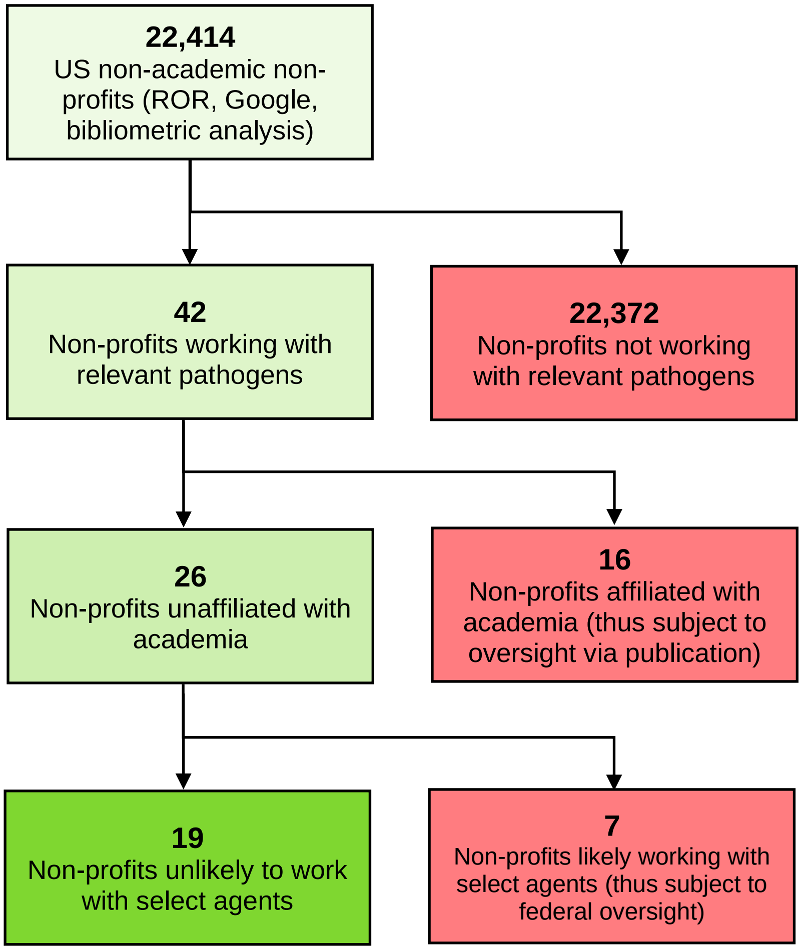

Figure 5. Flowchart of Process to Identify Non-Profit Research Organizations

7. Analysis of For-Profit Research Organizations

7.1. Objective

The objective of this task was to identify all major US research organizations performing in-scope pathogen research that are for-profit and not affiliated with government or academia.

7.2. Methods

We used two sources to identify for-proift research entities. The first was BioPharmGuy, an online directory of biotechnology companies.[34] BioPharmGuy contains listings for companies in 37 biotechnology-related business categories around the world and is updated almost daily to add new companies and remove outdated information. The directory can be sorted by various company characteristics, including the business type (e.g., diagnostics or vaccines) and location. We downloaded the sub-directory of all biotechnology companies in the US and filtered to those business types that might plausibly involve pathogen research (Antibodies; Contract research and development; Contract manufacturing; Equipment and machines; Non-pharmaceutical biotechnology; Small molecule pharmaceuticals; Vaccines; Viral technology). We then eliminated the clearly irrelevant companies based on the one-line description provided in the directory (e.g., diabetes pharmaceutical companies).

In addition to BioPharmGuy, we included for-profit organizations that we had previously identified from the Research Organization Registry in the previous section. All for-profit companies identified in the ROR were also in BioPharmGuy, with four exceptions. We also included for-profits that we had previously identified in our review of pathogen research publications, all of which had already been captured by BioPharmGuy and the ROR.

Once we had a list of candidate for-profit organizations, we carefully reviewed their websites for evidence that they were studying an in-scope pathogen. We also noted whether the company studies any select agents. Finally, we again searched USASpending.gov, a federal website listing information about federal spending, for the name of each organization to check whether it had received federal funding in the past five years.

7.3. Results

Figure 6 below summarizes our results. Overall, we found 6,920 unique companies located in the US via the BioPharmGuy directory. BioPharmGuy classifies companies into 37 different categories; of these, we reviewed 2,989 companies falling into the eight categories that seemed most likely to potentially involve research into in-scope human pathogens.

We ultimately identified 107 for-profit research organizations that study pathogens. Of these, 21 were excluded because they likely work with select agents and are thus subject to federal oversight. Of the 86 remaining organizations, 54 received at least some federal funding between 2019 and 2023 and 32 did not. The full set of organizations is listed in Table 15 in the Appendices.

[34] Wilson A. BioPharmGuy. https://biopharmguy.com/. Archived: https://web.archive.org/web/20230716010124/https://biopharmguy.com/. Accessed 07/15/23.

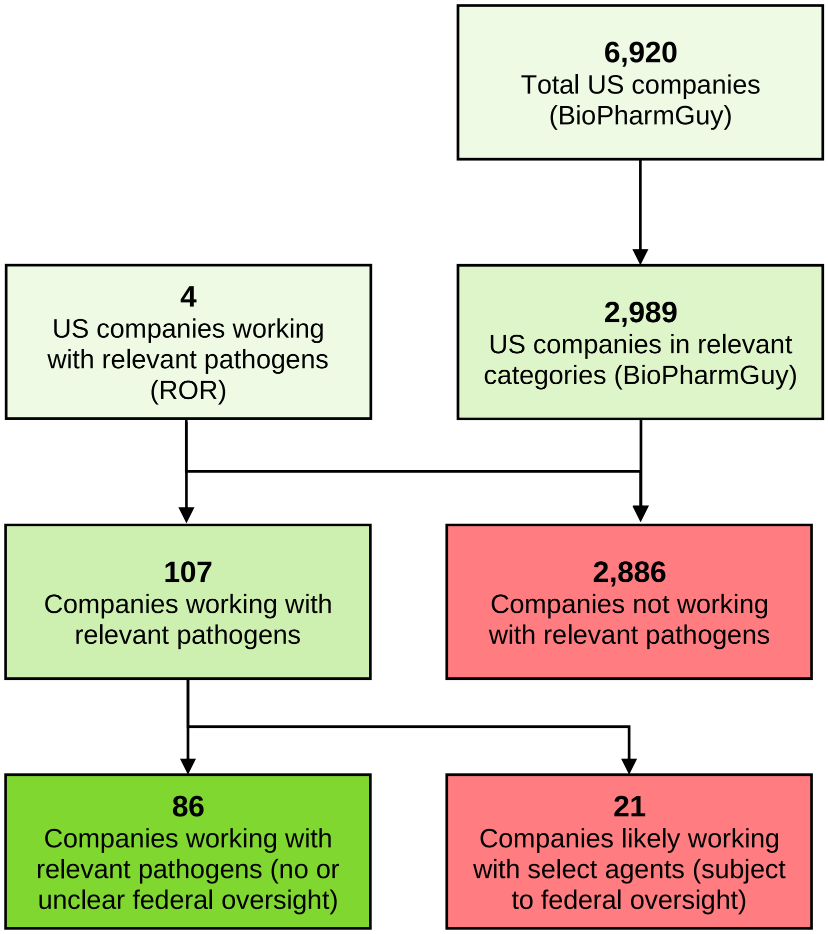

Figure 6. Flowchart of Process to Identify For-Profit Research Organizations

8. Oversight Discussions with Funders, Non-Profits, and For-Profits

8.1. Objective

A secondary research goal of this project was to characterize the internal, voluntary biosafety and biosecurity oversight practices of private organizations involved with in-scope human pathogen research. If such organizations are already voluntarily practicing strong oversight of the risks of research, there is arguably less urgency to institute requirements for external oversight.

8.2. Methods

We reached out to 21 of the funders, non-profits, and for-profits that we identified in previous tasks. To sample organizations that were more likely to represent a large fraction of private pathogen research in the US, we prioritized the largest organizations in terms of funding provided (for funders) or funding received (for for-profits and non-profits). When possible, we emailed biosafety or risk assessment professionals at each organization; otherwise, we used general contact email addresses on organizations' websites. We invited representatives from each organization to speak with us on a video call about their organization's practices for assessing and mitigating risks from laboratory accidents, deliberate misuse, and the publishing of dual-use information that could assist malicious actors. We also asked whether their organization's oversight practices varied depending on the source of funding.

8.3. Results

It was difficult to reach organizations for information, so our visibility into their practices is limited and our conclusions are very tentative. We choose to share our results here for informational value, for transparency into our process, and as a set of leads for future work.

Out of 21 contacts, we were able to hold discussions with six and obtained data over email with one more. In total, we reached two private funders, two for-profit research organizations, and three non-profit research organizations.

Table 5. Organizations that Participated in Oversight Discussions

Organization	Type
Viiv Healthcare	For-profit
ViraSource	For-profit
St. Jude Children's Hospital	Non-profit
Texas Biomedical Research Institute	Non-profit
TGen North	Non-profit
Wellcome Trust	Funder
Open Philanthropy Project	Funder

8.3.1. Funders

In general, the funders that we spoke with did not have the bandwidth to directly oversee biosafety or biosecurity risk management in the laboratories that they funded, which would have been impractical given their geographic distance from each laboratory, their lack of detailed knowledge of the technicalities of the research, and the number of laboratories that they funded.

Instead, the funders that we spoke with focused on managing biosafety and biosecurity risks indirectly through their choices of whom to fund. They focused on funding well-known and respected research performers that they knew to have a track record of high-quality research practices, and they declined to consider funding categories of research that they judged to be most concerning. In practice, the funders that we spoke with avoided funding research involving any of the seven experiments and 15 agents listed in the US government's Companion Guide for managing dual-use research of concern.[35] In addition, one funder that we spoke with maintained an in-house review process for considering potential dual-use information hazards with research projects.

8.3.2. Non-Profits and For-Profits

All of the non-profits and for-profits that we spoke with described following high standards of biosafety, as outlined by CDC guidelines. One organization described following the CDC manual "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) "to the letter."[36] Several organizations emphasized that a core element of their oversight practice involved conducting biosafety reviews whenever experimental designs changed.

Several non-profits and for-profits also emphasized the importance of a strong "safety culture" in which people are expected and encouraged to speak up about possible risks. Representatives from two organizations said that it was helpful to have very low rates of turnover among staff (more commonly found in the private sector than in academia, which has graduate students and post-docs who stay in laboratories for just a few years) to develop and maintain a strong safety culture and an institutional memory for best practices and past mistakes. Several organizations also mentioned that specializing their research on a smaller number of pathogens allowed them to develop institutional knowledge about appropriate biosafety and biosecurity practices for those pathogens.

Both non-profits and for-profits also described a number of formalized laboratory biosecurity safeguards, including badge readers, locks on freezers, limited-access areas, and buddy systems for performing lab work, which are often listed as recommended practices.[37] However, biosecurity was repeatedly framed as both lower-risk than biosafety and less in need of ongoing refinement in response to changes in experimental design.

Finally, both non-profits and for-profits had relatively little structure in place for considering or managing dual-use information hazards. As with funders, they often chose to entirely avoid any potentially sensitive agents or experimental designs when possible, using the US government's DURC companion guide as a reference. However, they largely lacked formalized practices for considering potential dual-use information hazards that could lie outside of the NIH list, such as risks related to gene drives or many RG3 pathogens.[38,39]

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[35] National Institutes of Health. (2014) Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern.

[36] Meechan PJ, Potts J. (2020) Biosafety in microbiological and biomedical laboratories.

[37] Brizee S et al. (2019) Development of a biosecurity checklist for laboratory assessment and monitoring. *Applied Biosafety.* 24 (2)**:** 83-89.

[38] Oye KA et al. (2014) Regulating gene drives. *Science.* 345 (6197)**:** 626-628.

[39] Urbina F et al. (2022) Dual use of artificial-intelligence-powered drug discovery. *Nature Machine Intelligence.* 4 (3)**:** 189-191.

8.4. Discussion

Overall, the research-performing organizations that we spoke to reported strong biosafety and biosecurity practices. Based on the study authors' experience, the practices described seemed more robust than those in laboratories that study similar pathogens in academia. Most organizations reported fewer formal processes for assessing or mitigating dual-use information hazards, and their practices were heavily anchored on the conceptions of risk outlined in the US government's risk management framework for DURC.

As noted above, our efforts to characterize organizations' practices were limited by a small sample size, and we recommend caution in generalizing to a larger sample. It is possible that the organizations that agreed to speak with us overstated the quality of their biosafety and biosecurity practices, or that only organizations with strong practices were willing to speak with us. In particular, we deliberately selected for organizations involved ample funding. It is possible that organizations with less funding also have less capability to manage biosafety and biosecurity risks, though the costs of risk management are not well-known at this time.

9. Analysis of Foreign Programs

9.1. Objective

Some countries have programs that maintain thorough records of laboratories working with biological agents. This information could be used to determine the proportion of research that falls within the private sector of those countries, and then to estimate the extent of similar research in the US. Therefore, the objectives of this task were three-fold: 1) characterize the registration requirements for various countries based on their classification of biological agents, 2) consult governmental authorities for data describing the extent of private sector research in their country, and 3) use these data to estimate the proportion of private sector research in the US.

9.2. Methods

We investigated biological agent registration requirements for non-US G-20 countries that are part of the Australia Group (an international export-control regime for materials that may contribute to chemical or biological weapons) because they have similar laws tracking pathogens as the US and they are relatively wealthy and may thus have biotechnology sectors that are similar to the US. For each country, we used Global Health Security Index scores and justification summaries to locate legislation, publications, and websites related to biological agent registration requirements.

We considered pathogens that were in scope for this project as described in Section 2.3.1.1. We also excluded pathogens if they were only subject to export regulations or voluntary regulations, because in both cases the resulting regulatory records would be unlikely to reflect the full extent of any privately-performed pathogen research occurring in that country. Once we had consolidated a list of relevant pathogens covered by regulation in relevant countries, we asked national authorities in each country to estimate the extent of research activities with biological agents on their list and the proportion of that research that was performed in the private sector. We were able to acquire information from Switzerland, Canada, and South Korea.

9.3. Results

We used available data to estimate the extent of privately performed human pathogen research in Switzerland, Canada, and South Korea. Switzerland's registry provided the most comprehensive overview of activities with biological agents. Collectively, the results were compared to make a final approximation of private research in the US.

9.3.1. Switzerland

Swiss law mandates that institutions notify the government of work with genetically modified organisms (GMOs) and all BSL-2, -3, and -4 activities.[40] Notifications are submitted to a public registry affiliated with the Federal Office of Public Health. We extracted data from the registry that included the organization, activity, and BSL associated with each notification.

A total of 3,043 notification records were extracted from the public registry. Organization names and activity descriptions were translated into English using Google Translate when applicable.

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[40] Government of Switzerland. (2003) Federal Act on Non-Human Gene Technology. 814.91.

Records with activities using GMOs only were excluded, as they fall outside of the scope of this study. Records with BSL-4 level activities were also excluded, as the biological agents involved would be considered select agents and therefore regulated in the US. The remaining 2,422 records were used to estimate the extent of private research in Switzerland.

About 71% (1,727) of activities were classified as “Research” for including experiments and analyses. About 21% of activities were classified as “Other” for describing diagnostic and quality control tests. The remaining activities (8%) were classified as “Unknown,” as the language was too vague for analysis (e.g., “Microbiology” or an organization name).

Organization names were consolidated by resolving differences in spelling, detail, or internal departments. Organizations were classified as “Private,” “Academic,” or “Government” using details from their webpages. Out of the 1,727 research activities, about 26% occurred in the private sector (Figure 7).

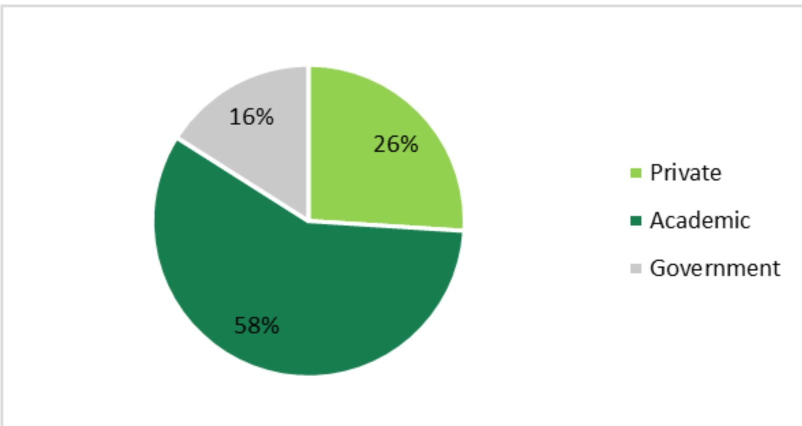

Figure 7. Swiss Registry Records of Pathogen Research Activities by Sector

9.3.2. Canada

Representatives from PHAC shared data from the Centre for Biosecurity Annual Report 2018-2019.[41] Notably, the report quantifies Pathogen and Toxin License applications and distributions by sector and risk group. Licenses are required for various activities, such as handling, producing, and transferring pathogens or toxins. One table divided the number of licenses distributed by sector. We re-categorized the sectors into “Private,” “Academic,” or “Government” to maintain consistency within our datasets. Results indicated about 70% of licenses were distributed to the private sector (Figure 8).

[41] Public Health Agency of Canada. (2020) Maximizing Impact: Biosecurity Program Annual Report 2018-2019. Prepared for Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/publications/health-risks-safety/centre-biosecurity-annual-report-2018-2019.html. Archived: https://web.archive.org/web/20230716011138/https://www.canada.ca/en/public-health/services/publications/health-risks-safety/centre-biosecurity-annual-report-2018-2019.html.

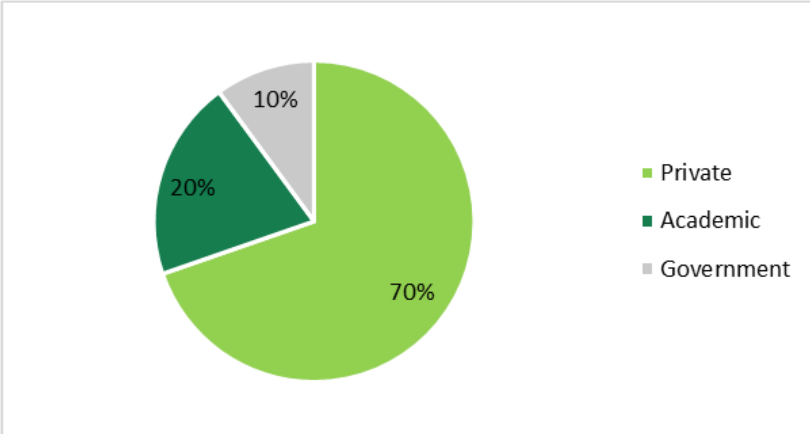

Figure 8. Canadian Pathogen and Toxin Licenses Distributed by Sector

Nearly all license activities involve RG2 and RG3 pathogens, which fall within the scope of this task. While the data do not delineate which activities the licenses are distributed for, many activities that require licensure are necessary to conduct research with pathogens. Without additional details, we estimate that the fraction of private research is equivalent to the fraction of licenses distributed to the private sector, or 70%.

9.3.3. South Korea

Our team was able to access the publication "Distribution of Pathogen Resources by the National Culture Collection for Pathogens in South Korea from 2015 to 2019" by Kim et al.[42] This paper outlines the distribution of pathogen resources in South Korea, categorized by agency, risk group classification, and purpose of distribution. Table 3 in the study divided the number of strains/cases of biological agents distributed based on the type of agency receiving them: National Institutes, Universities and Non-Profit Organizations, and For-Profit Organizations. About 40% of biological agent resources were distributed to for-profit organizations (Figure 9). This is the closest available approximation of the total fraction of pathogen research in South Korea that is private, but it is likely an underestimate because non-profits are merged with universities and therefore cannot be included in the overall total.

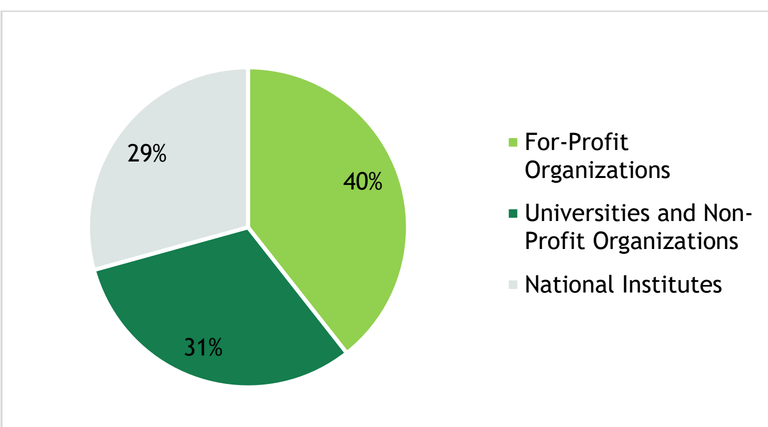

Figure 9. South Korean Pathogen Users by Sector, 2015-2019

[42] Kim SY, Bang HW, Choi YS. (2021) Distribution of pathogen resources by the national culture collection for pathogens in South Korea from 2015 to 2019. *Biopreservation and Biobanking.* 19 (6)**:** 511-524.

9.3.4. Summary of Results

Our estimation of pathogen research in the US private sector is limited by the international data we were able to acquire. The data varied in format, detail, and classifications between countries. Raw data was not readily available for us to manually curate classifications and proportions for each dataset. Despite these challenges, we were able to approximate the extent of private research conducted in Switzerland (26%) and Canada (70%). We were also able to estimate the extent of activities in the private sector of South Korea at 40%; however, this figure likely includes activities other than research and excludes non-profit organizations. Estimates for Switzerland are likely the most accurate, as we had access to data directly from their registry and were able to assign and analyze classifications in ways that aligned with the goals of this task.

10. Analysis of Research Materials

10.1. Objective

The objective of this task was to gather data on relevant pathogen research from organizations that provide resources in the bioeconomy to determine the proportion of resources sold to private research entities. We present results from three sources:

- American Type Culture Collection (ATCC), a private, non-profit, global biological resource center that provides scientists with biomaterials and resources to conduct life science research.[43]
- Addgene, a non-profit repository of DNA plasmids and cloning data that are accessible to laboratories around the world.[44]
- Twist Bioscience, a public biotechnology company based in San Francisco that manufactures synthetic DNA and DNA products for customers in a wide range of industries.[45]

10.2. ATCC – Methods and Results

We received data from ATCC consisting of order records for 54,057 orders of biomaterials from US organizations that were placed between August 31, 2016, and January 13, 2023. Each record was tagged with the name of the pathogen sold, the number of orders, and an “account group” indicating a type of customer, such as “Medical Devices” or “Veterinary Science.” Note that our analysis relies on data from orders and is therefore less likely to count organizations that use agents from existing samples rather than placing orders; however, we have no *a priori* reason to believe that these organization are more or less likely to be private.

For our analysis, we categorized account groups into five types: private, academia, government, healthcare, and research foundations. (See Table 16 in the Appendices for the groupings. “Research foundations” likely contains a mix of private and non-private organizations, making our estimate a potential undercount.) Pathogens with less than 20 sale records were aggregated into a single group named Other. We also removed five test orders internal to ATCC. Risk groups were assigned to the agents in each order using the 2016 NIH categories listed in the American Biological Safety Association (ABSA) Risk Group Database.[46]

The final dataset contained 53,594 orders for 33 different pathogens. From this dataset, the account groups categorized as private had 13,446 orders, accounting for approximately **25%** of all sales. Research foundations had the highest proportion of orders at 30%, followed by academia (26%), private (25%), government (14%), and healthcare (5%). We lacked any additional information about the “Research foundations” category, but most US research foundations conducting human pathogen research are probably affiliated with academia, which suggests that the 26% fraction from academia is an undercount and thus the 25% private-sector might be a slight overcount.

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[43] American Type Culture Collection. ATCC.org. https://www.atcc.org/. Archived: https://web.archive.org/web/20230716011533/https://www.atcc.org/. Accessed 07/15/23.

[44] Addgene. Addgene. https://www.addgene.org/. Archived: https://web.archive.org/web/20230716011658/https://www.addgene.org/. Accessed 07/15/23.

[45] Twist Bioscience. Twist Bioscience. https://www.twistbioscience.com/. Archived: https://web.archive.org/web/20230716011802/https://www.twistbioscience.com/. Accessed 07/15/23.

[46] American Biological Safety Association. Risk Group Database. https://my.absa.org/riskgroups. Archived: https://web.archive.org/web/20230716011924/https://my.absa.org/riskgroups. Accessed 07/15/23.

A full 92% of ATCC's orders were for either SARS-CoV-2 (64% of all orders) or influenza (28% of all orders). Private entities accounted for 18% and 38% of orders for each pathogen, respectively (Table 6). Identical ratios were found when examining the private fractions of Risk Group 3 and 2 pathogens more generally (18% and 38% respectively).

Table 6. Summary of ATCC Data for Frequently Studied Pathogens

Order type	% of all orders	% of SARS-CoV-2 orders	% of Influenza orders	% of all other orders
Private	25%	18%	38%	39%
Academia	27%	27%	21%	36%
Healthcare	4%	1%	11%	9%
Government	14%	18%	8%	10%
Research Foundations	30%	36%	22%	6%

10.3. Addgene – Methods and Results

We requested data from Addgene summarizing their distribution of pathogen-relevant biomaterials. Addgene provided summaries of data for their distribution of DNA plasmids within a 3-year span (January 2020 – January 2023). Because of the pandemic, their orders in this time period were dominated by SARS-CoV-2 orders, so they only provided data for SARS-CoV-2 plasmid orders. Each customer is coded in their database as private non-profit, private for-profit, or not private.

In total, 467 US organizations requested 9,196 SARS-CoV-2 plasmids in the provided time span. Of these, 91 of those organizations were classified as private (19% of all organizations) and they requested 309 plasmids (3% of all plasmids). The 91 private organizations consisted of 16 non-profits that requested 136 plasmids and 75 for-profits that requested 173 plasmids.

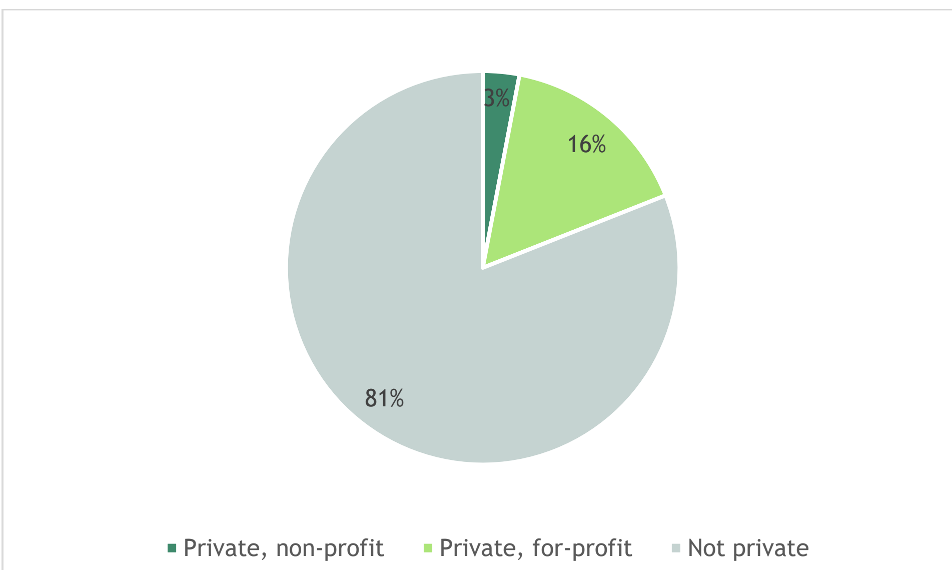

Figure 10. Addgene Customers, Jan. 2020 – Jan. 2023

10.4. Twist Bioscience – Methods and Results

We requested data from Twist summarizing the sectors of customers that ordered human-pathogen-relevant biomaterials. They were able to provide data covering their orders placed between April 2022 and March 2023.

Twist divides all ordered DNA sequences into one of three categories:

1. Sequences that are subject to a select-agent license requirement in the US. Because they are already covered by federal oversight, these sequences are outside of the scope of this report, and Twist had no such orders in the time period provided.
2. Sequences that are *not* subject to a select-agent license requirement in the US but *are* subject to a license requirement for export outside of the US under export control classification number (ECCN) 1C353.[47] These sequences must 'endow or enhance' functionality and be unique to organisms listed on the Commerce Control List (CCL). The organisms subject to ECCN 1C353 are most comparable to the pathogens designated as in scope for this report. Twist provided data for this category.
3. Sequences that are *not* subject to a licensing requirement for export outside of the US under ECCN 1C353. These are also generally outside of the scope of this report because they pertain to lower-risk organisms.

Twist reported that about 65% of its orders for non-select-agent CCL-listed pathogen sequences belonged to sectors other than government or academia (Figure 11).

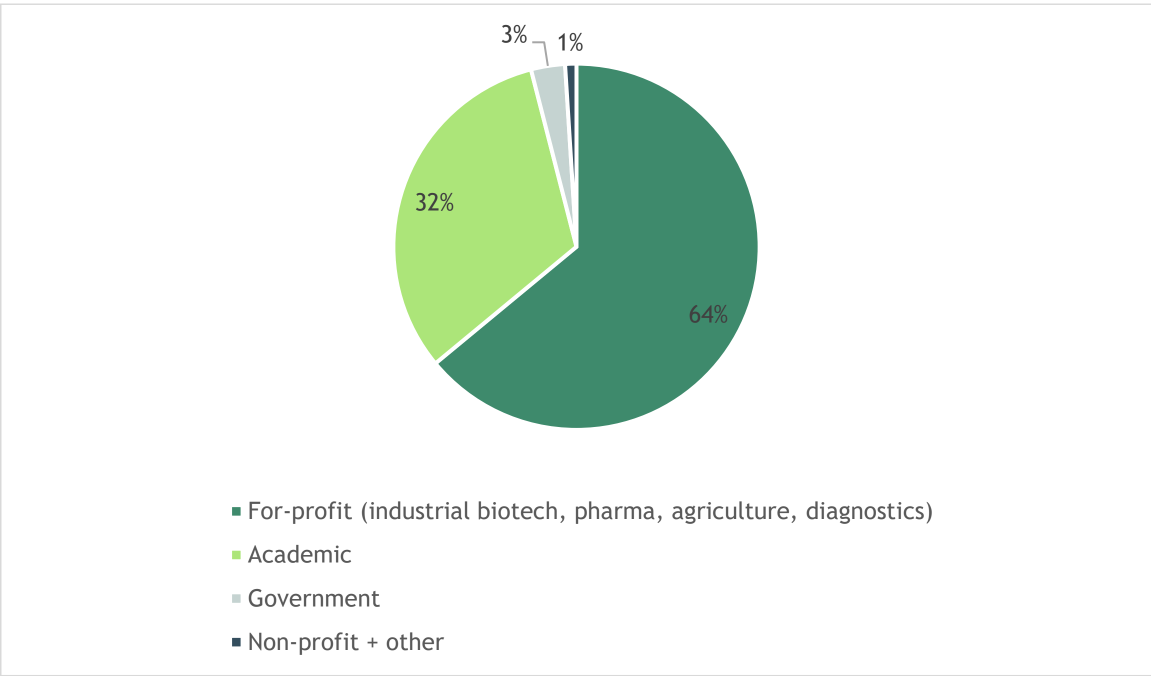

Figure 11. Twist Bioscience Customers, April 2022 - March 2023

[47] United States Government. (2020) ECCN 1C353. *Security Bola*.

11. General Discussion

11.1. Summary of Findings

Private non-profit and for-profit performers of human pathogen research in the US are subject to less oversight than government or academic research performers. Effective oversight depends in part on a clear understanding of the group to be regulated. To support informed decisions about regulation, we estimated the size, nature, and oversight capacities of the US private sector in human pathogen research by triangulating data from multiple sources. We summarize our findings below, highlighting estimates of the relative size of the private sector in **bold**.

11.1.1. Publications

Out of 42,175 studies from the past ten years involving an in-scope pathogen, only 1,499 (**3.6%**) had at least one author affiliated with a private organization. However, when we focused on a smaller set of 994 relevant references previously identified as having dual-use potential, 77 (**7.7%**) had at least one author from a private organization. This suggests that private organizations may be relatively overrepresented in potentially dual-use research. Both estimates are likely underestimates of the true size of the private sector because private organizations are far less likely to publish their research than academic labs.

11.1.1. Funding

Through internet searches of potential funders and reviews of publicly-available data from funders' websites, we identified 37 private funders that contributed to in-scope human pathogen research in the US. Of these 37 funders, only 14 were identified that plausibly contributed more than $1,000,000 per year on average, though in some cases data were not available and could only be roughly estimated.

Collectively, private funders contribute an average of about $1.2 billion annually toward in-scope human pathogen research in the US. For comparison, NIAID, the largest US government funder of infectious-disease research, contributed about $3.9 billion to research grants in 2022.[48] If we treat $3.9 billion as a rough estimate of total US government funding for human pathogen research, we find that private funding accounts for roughly **24%** of the national total. However, this estimate is uncertain because it excludes overlooked sources of both private funding (e.g., VC funding and internal profit) and government funding (e.g., National Science Foundation, Department of Defense, Biomedical Advanced Research and Development Authority).

11.1.2. Non-Profit and For-Profit Organizations

Using internet searches, publicly-available registries, and the publications and funding data described above, we identified 86 for-profit companies and 19 non-profits in the US that appeared to perform in-scope human pathogen research. Of these, 54 of the 86 for-profits (63%) and all 19 of the non-profits had accepted federal funding in the last five years, making them subject to US government's policies for managing DURC. The remaining 32 for-profits appeared to be unfunded by the US government and are thus only subject to basic OSHA workplace safety requirements.

[48] National Institutes of Health. Budget and Spending. https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/budget-and-spending. Archived: https://web.archive.org/web/20230716005123/https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/budget-and-spending. Accessed 07/15/23.

Estimating the fraction of private pathogen research based on counts of organizations is a challenge because of the difficulty of factoring in federal research. The US government is a single sprawling organization containing many nested smaller organizations with pathogen research programs that may or may not be well-documented. Estimating the scope of this research and defining relevant boundaries between organizations within the federal government is outside of the scope of this project.

However, if we ignore federally-performed research, we can compare the numbers of relevant private organizations to academic institutions as follows. In 2021, the Carnegie Classification of Institutions of Higher Education estimated that there were 302 research universities in the US – 146 R1 doctoral universities, 133 R2 doctoral universities, and 23 degree-granting "special focus research institutions" that focus on medical and health research.[49] It is plausible that all or nearly all of these research universities perform some in-scope pathogen research, given the ubiquity of life-science research in academic institutions and the wide range of research topics involving Risk Group 2 human pathogens. If we assume 105 in-scope private organizations (86 for-profits and 19 non-profits) and 302 relevant universities, then private organizations are roughly **26%** (105 / [105+302]) of the total, and the 32 for-profits that are entirely non-government funded are roughly 8% of the total. These figures are likely overestimates because they exclude government research from the denominator of each fraction.

11.1.1. Oversight Practices

To learn more about the internal biosafety and biosecurity oversight practices of private research funders and performers, we reached out to 21 of the largest funders, non-profits, and for-profits involved with human pathogen research in the US based on amounts of funding provided or received. Out of 21 contacts, we held discussions with six and exchanged emails with one more, so our findings are highly uncertain and may not generalize. More research is needed on the internal oversight and biorisk management practices of US pathogen research funders and performers.[50]

Overall, the research funders that we spoke to relied heavily on research performers to manage day-to-day biosafety and biosecurity risks. Funders managed these risks indirectly by choosing to fund performers with a strong reputation for research quality and appropriate risk management. The research performers that we spoke to reported strong biosafety and biosecurity practices and close alignment with US government documentation. Both funders and performers generally reported relatively few formal processes for assessing or mitigating dual-use information hazards, and their practices and scopes of concern were heavily anchored on the conceptions of risk outlined in the US government's risk management framework for DURC.

11.1.2. Foreign Programs

We used available data to estimate the extent of privately performed human pathogen research in non-US G-20 countries that are part of the Australia Group. We were able to secure data from three countries:

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[49] Carnegie Commission on Higher Education. Carnegie Classification of Institutions of Higher Education. https://carnegieclassifications.acenet.edu/. Archived: https://web.archive.org/web/20230716012505/https://carnegieclassifications.acenet.edu/. Accessed 07/15/23.

[50] Greene D et al. (2023b) The Biorisk Management Casebook: Insights into Contemporary Practices. Prepared for. https://doi.org/10.25740/hj505vf5601. Archived: https://web.archive.org/web/20230716013005/https://purl.stanford.edu/hj505vf5601.

- Switzerland maintains a registry that provided the most comprehensive overview of their activities with biological agents. Out of 1,727 relevant registered research activities, about **26%** occurred in the private sector.
- Representatives from the Canadian government provided summary data on organizations registered to work with in-scope pathogens. After coding organizations into relevant groups, we estimated that about **70%** of licenses were distributed to the private sector. However, this is likely an overestimate because the Canadian license data included non-research applications such as medical and agricultural work that are disproportionately performed in the private sector.
- We located a publication summarizing information about organizations registered to work with human pathogens in South Korea.[51] About **40%** of registered organizations were for-profit organizations. However, this estimate is uncertain because it excludes non-profit organizations (which were combined with universities in the original paper), and it includes non-research applications in its counts.

11.1.3. Research Materials

We received data from three organizations that provide vital research materials and support services to US performers of human pathogen research – ATCC, Addgene, and Twist Bioscience. Their customer pools and data aggregation rules varied, but we estimated the private fraction of their customers for in-scope pathogen materials as **25%** (ATCC), **19%** (Addgene), and **65%** (Twist), respectively.

The estimate for Addgene is likely to be an underestimate because it preferentially targets non-profit customers. Twist is likely to be an overestimate because it counts numbers of sequence orders rather than sequence customers and counts of orders can be skewed upwards by a small number of customers ordering many sequences.

11.2. Synthesis of data

Based on the estimates summarized above, **we estimate that about one quarter of in-scope human pathogen research performed in the United States occurs in the private sector.**

- As illustrated in Figure 12 below, four out of the ten estimates collected for this report cluster tightly around 24-26%.
- All estimates below 24% were judged to be likely underestimates, all those above 26% were likely overestimates, and all but one of those at 24-26% were judged to be neither under- nor overestimates.
- We believe that the strongest estimates are from ATCC (25%), because of its substantial coverage of the US life science research enterprise, and the Swiss government (26%), because of its detailed nationwide records.
- Our estimates are roughly consistent with recent surveys that estimated that about 20-22% of biosafety officers are working in the private sector.[52]

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[51] Kim SY, Bang HW, Choi YS. (2021) Distribution of pathogen resources by the national culture collection for pathogens in South Korea from 2015 to 2019. *Biopreservation and Biobanking.* 19 (6)**:** 511-524.

[52] Gillum D et al. (2022) Experiences during the COVID-19 pandemic: a survey of biosafety professionals. *Applied Biosafety.* 27 (3)**:** 127-143.

- The low-end outliers from publication data (3.6% and 7.7%) are likely significant underestimates because academic organizations are much more likely to publish than non-academic private organizations.
- The high-end outliers from the Canadian government (70%) and Twist (65%) are likely significant overestimates because the Canadian government includes non-research uses of human pathogens (which are likely mostly in private industry) and because Twist both markets heavily to the private sector and tracks the numbers of sequences ordered (which are likely to be skewed by small numbers of private actors making large orders).

Figure 12. Summary of estimates of the relative size of the private sector in US human pathogen research. Upward arrows indicate likely overestimates; downward arrows indicate likely underestimates; bidirectional arrows indicate potential over- or under-estimates.

11.3. Policy Implications

Thoughtful oversight of the private sector is needed. The private sector probably does not perform most of the human pathogen research in the US, but it performs a significant fraction, accounting for over $1 billion in annual funding, and it potentially performs an outsized fraction of research with dual-use potential because private authors were relatively over-represented in our sample of potential dual-use publications (7.7%) compared to human pathogen research publications in general (3.6%).

Of the 105 total non-profit and for-profit US performers of human pathogen research that we identified, only 32 for-profits had not accepted federal funds in the past five years. These organizations (30% of all those we identified) are currently the least well-covered by federal oversight.

The US private sector representatives that we spoke with described strong internal laboratory biosafety and biosecurity practices, but it is unclear whether other less well-funded private-sector organizations maintain similar practices. However, to the extent that the private sector already voluntarily practices biosafety and biosecurity, external government oversight may not be a substantial added burden. More research is needed to understand the extent to which specific policy requirements would impose additional burdens on smaller organizations.

Whether US private-sector laboratories have stronger biosafety and biosecurity practices on average than academic laboratories is unclear. Academic laboratories have been criticized for a lack of "safety culture" and lax attitudes toward biorisk management among researchers and regulatory staff.[53,54,55] In addition, compared to private labs, academic laboratories and research centers are likely to engage in a wider range of research topics using a more diverse range of pathogens, and they likely experience greater turnover as students and researchers move through the academic pipeline. These factors may also hamper the accumulation of norms and expertise that constitute a safety culture. In addition, though our discussants did not explicitly mention it, private research organizations may have stronger biosecurity practices than academic labs if they invest more effort in monitoring how employees spend their time and defending against corporate espionage. As the NSABB and others have noted, norms and safety culture continue to be an important complement to formal oversight.[56,57,58]

In addition to direct laboratory biosafety and biosecurity risks, life science research can also indirectly create "information hazards" by releasing dual-use information that could enable others to cause harm. Most of the private sector representatives that we spoke with stated that they minimized information hazards by entirely avoiding work with any of 15 agents or seven experiment types that are named in the federal DURC policy.[59] Our oversight conversations and a 2017 stakeholder engagement meeting by the NIH both found that research organizations anchor strongly on these lists as a de facto definition of DURC, and they choose not to consider risks that lie outside of the lists.[60] This strategy does meet the letter of the DURC policy, but it arguably does not entirely meet the original, more expansive definition of DURC.[61] Life scientists and policy scholars have noted that there are many areas of research that do not involve the 15 agents or seven experiment types but are arguably still DURC by the original definition, such as work with gene drives or many RG3 pathogens.[62] The list of experiments and agents that qualify for DURC review should be regularly updated, as was originally

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[53] Greene D, Palmer MJ, Relman DA. (2023a) Motivating Proactive Biorisk Management. *Health security.* 21 (1)**:** 46-60.

[54] Race MS, Hammond E. (2008) An evaluation of the role and effectiveness of institutional biosafety committees in providing oversight and security at biocontainment laboratories. *Biosecurity and bioterrorism: biodefense strategy, practice, and science.* 6 (1)**:** 19-35.

[55] Schröder I et al. (2016) Laboratory safety attitudes and practices: A comparison of academic, government, and industry researchers. *Journal of Chemical Health & Safety.* 23 (1)**:** 12-23.

[56] National Science Advisory Board for Biosecurity. (2023) Proposed Biosecurity Oversight Framework for the Future of Science. Prepared for. https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf. Archived: https://web.archive.org/web/20230716003955/https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

[57] Greene D, Palmer MJ, Relman DA. (2023a) Motivating Proactive Biorisk Management. *Health security.* 21 (1)**:** 46-60.

[58] Perkins D et al. (2019) The culture of biosafety, biosecurity, and responsible conduct in the life sciences: a comprehensive literature review. *Applied Biosafety.* 24 (1)**:** 34-45.

[59] National Institutes of Health. (2014) Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern.

[60] Evans SW et al. (2021) Stakeholder Engagement Workshop on the Implementation of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: workshop report. *Available at SSRN 3955051.*

[61] "Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security" - National Institutes of Health. (2014) Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern.

[62] Koblentz G. The Evolving Global Biosecurity Landscape. https://armscontrolcenter.org/wp-content/uploads/2022/04/Koblentz-Evolving-Global-Biosecurity-Landscape.pdf. Archived: https://web.archive.org/web/20230716004402/https://armscontrolcenter.org/wp-content/uploads/2022/04/Koblentz-Evolving-Global-Biosecurity-Landscape.pdf. Last Updated 03/22/22. Accessed 07/15/23.

recommended by the NSABB in its original 2007 report that influenced the creation of the DURC policy.[63]

11.4. Limitations and Future Work

Each of the data sources in this project has its own specific limitations that have been characterized in more detail in previous sections of this report, but broadly:

- Estimates of the size of the private sector based on publications likely underestimate its size because the private sector is less incentivized to publish its work than is academia.
- Estimates based on funding streams and simple counts of organizations are uncertain primarily because they fail to include government funding and research. In addition, some private research organizations likely contract out to academic subcontractors that are subject to oversight.
- Estimates based on the records of foreign countries (South Korea, Switzerland, and Canada) depend on both the similarity of those countries to the United States and the accuracy and relevance of their collected data.
- Finally, estimates based on the records of research-material providers (ATCC, Addgene, and Twist) also depend on the nature of their customer data as well as their coverage of the sector and biases in their target markets.

The limitations of each data source are not obviously strongly related to one another, leading us to believe that as a group, our estimates contain noise but not systematic upward or downward bias. And as noted in Figure 12, the groupings of over- and under-estimates suggest a plausible middle range of potential values for the size of the private sector centered roughly around 25%.

Future work could use additional data sources for more independent estimates. For example, patent data may reveal institutions that register patents involved with relevant human pathogens. One challenge with this approach is that patent “trolls” or “hoarders” sometimes seek to pre-emptively establish patents that claim research product ideas bearing little or no relation to the idea originally patented. Another possible data source could be from states or regions such as Frederick, MD and Cambridge, MA that track BSL-3 labs within their borders. However, care must be taken to ensure that the states and regions are representative of the country as a whole.

Finally, future work could draw finer-grained distinctions between different levels of government oversight. Our analyses of non-profit and for-profit organizations estimated whether they worked with any select agents and/or had received federal funding in the last five years. Organizations that did neither are the least subject to federal biorisk management oversight. Other organizations exist in a gray area governed primarily by the P3CO framework and DURC policy. Future research could characterize the identified US non-profits and for-profits in more depth in order to determine the relative importance of extending oversight coverage to new organizations vs. strengthening existing coverage.

[63] National Science Advisory Board for Biosecurity. (2023) Proposed Biosecurity Oversight Framework for the Future of Science. Prepared for. https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf. Archived: https://web.archive.org/web/20230716003955/https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

12. Appendix A. Supplementary Information for

Bibliometric Analysis

Table 7. Relevant Pathogen List, Categorized Within Viral Genera and Bacteria

Agent Classification	Included Agents
BACTERIA	*Bartonella*; *Brucella canis*; *Mycobacterium bovis*; *M. tuberculosis*; *Orientia tsutsugamushi*; *Pasteurella multocida* type B "buffalo" and other virulent strains; *Rickettsia akari*; *R. australis*; *R. canada*; *R. conorii*; *R. rickettsii*; *R; siberica*; *R. typhi* (*R. mooseri*)
ALPHAVIRUSES	Barmah Forest virus; Chikungunya virus; Everglades virus; Getah virus; Mayaro virus; O'nyong-nyong virus; Ross River virus; Semliki Forest virus; Sindbis virus; Western equine encephalitis virus
BANDAVIRUSES	Bhanja virus; Heartland virus; SFTS virus (Dabie bandavirus)
CORONAVIRUSES	MERS coronavirus; SARS-CoV-2
DELTARETROVIRUSES	Human T-lymphotropic virus
FLAVIVIRUSES	Dengue virus; Japanese encephalitis virus; Murray Valley encephalitis virus; Powassan virus; St. Louis encephalitis virus; West Nile virus; Yellow fever virus
INFLUENZAVIRUSES	Influenza virus (non-select agent strains)
LENTIVIRUSES	Human immunodeficiency virus (HIV); Simian immunodeficiency virus (SIV)
LYMPHOCRYPTOVIRUSES	Herpes B virus
LYSSAVIRUSES	Australian bat lyssavirus; Duvenhage virus; European bat lyssavirus; Mokola virus; Rabies virus
MAMMARENAVIRUSES	Flexal mammarenavirus; Lymphocytic choriomeningitis virus; Pichinde virus; Whitewater Arroyo virus
MORBILLIVIRUSES	Measles virus
ORTHOBORNAVIRUSES	Borna disease virus
ORTHOBUNYAVIRUSES	Bangui virus; Bunyamwera virus; Bwamba virus; Cache Valley virus; California encephalitis virus; Caraparu virus; Catu virus; Gan Gan virus; Guaroa virus; Itaya virus; Jamestown Canyon virus; La Crosse virus; Ngari virus; Oropouche virus; Shuni virus; Snowshoe hare virus; Tacaiuma virus; Tataguine virus; Trubanaman virus; Wanowrie virus; Wyeomyia virus
ORTHOHANTAVIRUSES	Andes virus; Bayou virus; Black Creek Canal virus; Dobrava virus; Hantaan virus; Juquitiba virus; Laguna Negra virus; Puumala virus; Seoul virus; Sin Nombre virus
ORTHOPOXVIRUSES	Cowpox virus
RUBIVIRUSES	Rubella virus
RUBULAVIRUSES	Mumps virus
SEADORNAVIRUSES	Banna virus
THOGOTOVIRUSES	Bourbon virus; Dhori virus; Thogoto virus
VARICELLOVIRUSES	Suid herpesvirus 1; Varicella-zoster virus (human herpesvirus 3)
VESICULOVIRUSES	Chandipura virus; Piry virus; Vesicular stomatitis virus

Table 8. Final Strings Used to Search Scopus for Studies Conducting Research with Pathogens of Interest

Search String ID	Search String	Date Conducted	Number of Results
MAMMARENAVIRUSES_All	TITLE-ABS("flexal mammarenavirus" OR "lymphocytic choriomeningitis virus" OR "Pichinde virus" OR "Whitewater Arroyo virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	465
CORONAVIRUSES_MERS	TITLE-ABS("MERS coronavirus" OR "MERS-CoV") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	759
CORONAVIRUSES_SARS-CoV-2	TITLE-ABS("SARS-CoV-2") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	09/09/2022	15,036
FLAVIVIRUSES_Dengue	TITLE-ABS("Dengue virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	2,141
FLAVIVIRUSES_Others	TITLE-ABS("Japanese encephalitis virus" OR "Murray Valley encephalitis virus" OR "Powassan virus" OR "St. Louis encephalitis virus" OR "West Nile virus" OR "Yellow fever virus" OR "Aroa virus" OR "Banzi virus" OR "Kokobera virus" OR "Louping ill virus" OR "Ntaya virus" OR "Rio Bravo virus" OR "Usutu virus" OR "Wesselsbron virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	1,987
FLAVIVIRUSES_Zika	TITLE-ABS("Zika virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	2,651
ORTHOHANTAVIRUSES_All	TITLE-ABS(hantavirus OR "Andes virus" OR "Bayou virus" OR "Black Creek Canal virus" OR "Dobrava virus" OR "Dobrava-Belgrade virus" OR "Hantaan virus" OR "Juquitiba virus" OR "Laguna Negra virus" OR "Puumala virus" OR "Seoul virus" OR "Blue River virus" OR "Monongahela virus" OR "New York virus" OR "New York orthohantavirus" OR "Sin Nombre virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	359
LYMPHOCRYPTOVIRUSES_All	TITLE-ABS("herpes B virus" OR "cercopithecine herpesvirus 1" OR "macacine alphaherpesvirus 1" OR "macacine herpesvirus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	29
VARICELLOVIRUSES_All	TITLE-ABS("suid herpesvirus 1" OR "varicella-zoster virus" OR "human herpesvirus 3") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	832

Search String ID	Search String	Date Conducted	Number of Results
Rubiviruses_All	TITLE-ABS("rubella virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	119
Influenzaviruses_All	TITLE-ABS("influenza virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	5,097
Thogotoviruses_All	TITLE-ABS("Bourbon virus" OR "Dhori virus" OR "Thogoto virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	21
Morbilliviruses_All	TITLE-ABS("measles virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	392
Rubulaviruses_All	TITLE-ABS("mumps virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	89
Orthobunyaviruses_All	TITLE-ABS(("Bunyamwera virus" OR "Bwamba virus" OR "Cache Valley virus" OR "California encephalitis virus" OR "Caraparu virus" OR "Catu virus" OR "Gan Gan virus" OR "Guaroa virus" OR "Itaya virus" OR "Jamestown Canyon virus" OR "La Crosse virus" OR "Ngari virus" OR "Oropouche virus" OR "Shuni virus" OR "Snowshoe hare virus" OR "Tacaiuma virus" OR "Tataguine virus" OR "Wyeomyia virus") OR ("Bangui virus" OR "Trubanaman virus" OR "Wanowrie virus")) AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	156
Bandaviruses_All	TITLE-ABS("Bhanja virus" OR "Heartland virus" OR "severe fever with thrombocytopenia syndrome virus" OR "SFTS virus" OR "Dabie bandavirus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	106
Orthopoxviruses_All	TITLE-ABS("cowpox virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	45
Deltaretroviruses_All	TITLE-ABS("human T-lymphotropic virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	129
Lentiviruses_HIV	TITLE-ABS("human immunodeficiency virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	10,231
Lentiviruses_Others	TITLE-ABS("simian immunodeficiency virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	979

Search String ID	Search String	Date Conducted	Number of Results
Lyssaviruses_All	TITLE-ABS(lyssavirus OR "Australian bat lyssavirus" OR "Duvenhage virus" OR "European bat lyssavirus" OR "Mokola virus" OR rabies) AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	1,256
Vesiculoviruses_All	TITLE-ABS(vesiculovirus OR "Chandipura virus" OR "Piry virus" OR "vesicular stomatitis virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	873
Seadornaviruses_All	TITLE-ABS("Banna virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	1
Alphaviruses_All	TITLE-ABS("Barmah Forest virus" OR "Chikungunya virus" OR "Everglades virus" OR "Getah virus" OR "Mayaro virus" OR "O'nyong-nyong virus" OR "Ross River virus" OR "Semliki Forest virus" OR "Sindbis virus" OR "Western equine encephalitis virus") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	1,159
RG3Bacteria_Mbovis	TITLE-ABS("Mycobacterium bovis") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	606
RG3Bacteria_Mtuberculosis	TITLE-ABS("Mycobacterium tuberculosis") AND PUBYEAR > 2011 AND PUBYEAR < 2015 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	5,728
RG3Bacteria_Others	TITLE-ABS("Bartonella" OR "Brucella canis" OR "Orientia tsutsugamushi" OR "Pasteurella multocida" OR "Rickettsia akari" OR "Rickettsia australis" OR "Rickettsia canada" OR "Rickettsia conorii" OR "Rickettsia rickettsii" OR "Rickettsia siberica" OR "Rickettsia typhi" OR "Rickettsia mooseri") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	1,229
BSL3	ALL("biologic safety level 3" OR "biological safety level 3" OR "biosafety level 3" OR "BSL-3") AND PUBYEAR > 2011 AND (LIMIT-TO(LANGUAGE,"English")) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(AFFILCOUNTRY,"United States"))	10/04/2022	334
		TOTAL RESULTS	**52,809**

Table 9. Funder Affiliations for Publications Matching Pathogen List with 1+ Private Author

Pathogen Queries	Has Pvt		Only Pvt		Has Both		Only NonPvt		EIDs
	%	n	%	n	%	n	%	n	n
Summary Totals									
All queries*	3.8%	44	0.3%	3	3.6%	41	96.2%	1,108	1,152
All pathogen queries**	3.8%	44	0.3%	3	3.6%	41	96.2%	1,103	1,147
Pathogen queries with ≥10 EIDs	3.9%	44	0.3%	3	3.6%	41	96.1%	1,091	1,135
Pathogen queries with <10 EIDs***	0.0%	0	0.0%	0	0.0%	0	100.0%	18	18
By Individual Pathogen Query									
Mammarenaviruses	7.4%	2	0.0%	0	7.4%	2	92.6%	25	27
Coronaviruses (MERS)	6.7%	1	0.0%	0	6.7%	1	93.3%	14	15
Coronaviruses (SARS-CoV-2)	5.4%	10	0.5%	1	4.8%	9	94.7%	177	187
Flaviviruses (Zika)	5.2%	4	0.0%	0	5.2%	4	94.8%	73	77
Alphaviruses	5.0%	1	5.0%	1	0.0%	0	95.0%	19	20
Risk Group 3 Bacteria (M. tuberculosis)	4.6%	7	0.0%	0	4.6%	7	95.4%	146	153
Vesiculoviruses	4.2%	1	0.0%	0	4.2%	1	95.8%	23	24
Influenzaviruses	4.0%	16	0.3%	1	3.8%	15	96.0%	383	399
Lyssaviruses	2.8%	1	0.0%	0	2.8%	1	97.2%	35	36
Lentiviruses (Others)	2.1%	1	0.0%	0	2.1%	1	97.9%	46	47
Lentiviruses (HIV)	1.5%	2	0.0%	0	1.5%	2	98.5%	133	135
Flaviviruses (Dengue)	0.0%	0	0.0%	0	0.0%	0	100.0%	50	50
Flaviviruses (Others)	0.0%	0	0.0%	0	0.0%	0	100.0%	20	20
Risk Group 3 Bacteria (M. bovis)	0.0%	0	0.0%	0	0.0%	0	100.0%	12	12
Varicelloviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	12	12
Risk Group 3 Bacteria (Others)	0.0%	0	0.0%	0	0.0%	0	100.0%	6	6
Morbilliviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	3	3
Deltaretroviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	2	2
Rubiviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	2	2
Rubulaviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	2	2
Orthobunyaviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	1	1
Lymphocryptoviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	1	1
Orthopoxviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	1	1
Orthohantaviruses	0.0%	0	0.0%	0	0.0%	0	100.0%	1	1
BSL3 Query									
BSL3**	0.0%	0	0.0%	0	0.0%	0	100.0%	10	10

*EIDs can be categorized under multiple pathogen queries.
**The "BSL3" query was not included in the pathogen queries totals.
***Rows colored in dark grey denote pathogen queries with <10 EIDs.

Appendix B. Supplementary Information for Dual-Use Literature Analysis

Table 10. Private Organizations with 1+ Author in One Reference Identified as Having Dual-Use Potential

Organization	Frequency
J. Craig Venter Institute	7
St. Jude Children's Research Hospital	7
List Biological Laboratories, Inc.	6
Battelle Memorial Institute	5
Integrated DNA Technologies	4
Translational Genomics Research Institute	4
EcoHealth Alliance	3
Hardy Diagnostics	2
La Jolla Institute for Allergy and Immunology	2
ActoGeniX N.V.	1
AdVnt Biotechnologies	1
Bioautomation	1
Biopeptide Co.	1
BioPort Corporation	1
Bioqual	1
CSBio	1
CSL Behring	1
DNASTAR	1
DynPort Vaccine Company	1
eBioscience	1
EMD Millicore	1
Genelux Corporation	1

Genewiz	1
Genzyme Corporation	1
Geo-Centers, Inc.	1
HealthPartners Research Foundation	1
Howard Hughes Medical Institute	1
Human Genome Sciences	1
IHRC, Inc.	1
Institute for Biological Energy Alternatives	1
Institute for Systems Biology	1
Integrated Genomics (Igenbio)	1
Marshfield Clinic Research Foundation	1
MediQuick Urgent Care, Inc.	1
Metabiota	1
Midwest Research Institute	1
New England BioLabs Inc.	1
Oklahoma Medical Research Foundation	1
PATH (Program for Appropriate Technology in Health)	1
Public Health Foundation Enterprise	1
Roche NimbleGen	1
Salk Institute for Biological Studies	1
Sigma-Aldrich	1
Synthetic Genomics	1
VaxGen, Inc.	1
Vector Laboratories	1
VenatoRx Pharmaceuticals	1
Versiti Blood Research Institute	1

ViroDefense	1
ViroPharma	1
Wyeth Biopharma	1
Zalgen Labs	1

Appendix C. Supplementary Information for Analysis of Private Funders

Table 11. Internet Search Strings Used to Identify Private Funders of In-Scope Human Pathogen Research

Search string
“non-profit medical research organization”
“private funding organization”
“philanthropic organization”
“medical research foundation”
“charitable foundation”
“philanthropic medical research organization”
“charitable organization”
“independent charitable foundation”

Table 12. Major Private US Pathogen Research Funders

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
American Lung Association	Bacteria	$450,000	<$450,000	Not investigated (annual private donations likely <$1mm)	https://www.lung.org/research/awards-and-grants-opportunities	Fraction of private recipients unknown
American Society For Microbiology	Broad pathogen research	$60,000	<$60,000	Not investigated (annual private donations likely <$1mm)	https://asm.org/Fellowships/ASM-Conference-Grant	Fraction of private recipients unknown
American Thoracic Society	Bacteria	$150,000	$0	Not investigated (annual private donations likely <$1mm)	https://research.thoracic.org/impact/research-program-recipients/	Based on examples, no private recipients

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
AmFAR: The American Foundation for AIDS Research	Viruses	$2,000,000	$522,662	Not investigated (annual private donations likely <$1mm)	https://www.amfar.org/research/grants/	Estimate for private donations based on 2022 grants. All private 2022 grants went to Wistar Institute.
AMR Action Fund	Malaria	$27,000,000	$27,000,000	BioVersys, Venatorx, Adaptive Phage Therapeutics	https://www.crunchbase.com/organization/amr-action-fund/recent_investments	AMR Action Fund reports its individual investments publicly on Crunchbase.
Antibiotic Research UK	Bacteria	$237,000	$0	Not investigated (annual private donations likely <$1mm)	https://www.antibioticresearch.org.uk/antibiotic-research-uk-awards-grants-to-fund-research-worth-200000/	Based on examples, no private recipients
Bay Area Lyme Foundation	Bacteria	$300,000	$25,000	Not investigated (annual private donations likely <$1mm)	https://www.bayarealyme.org/our-research/emerging-leader-award/	Only identifiable private funding example is $100k in 2019
Bill And Melinda Gates Foundation	Broad medical research	$149,649,026	$100,000,000	Pfizer, Calibr, Merck	https://www.gatesfoundation.org/about/committed-grants	Roughly estimated by subsetting publicly-available Gates grant data to "Global Health" grants to US recipients from 2021-2022, grouping by recipient, and visually identifying largest recipients that are also private research performers.
Bloomberg Philanthropies	Broad medical research	<$1,000,000	$0	Not investigated (annual private donations likely <$1mm)	https://www.bloomberg.org/public-health/covid-19-response/investing-in-potential-covid-19-treatments/	Based on examples, no private recipients

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
Burroughs Wellcome Fund	Broad medical research	$250,000	$0	Not investigated (annual private donations likely <$1mm)	https://www.bwfund.org/funding-opportunities/infectious-diseases/investigators-in-the-pathogenesis-of-infectious-disease/grant-recipients/	Based on examples, no private recipients
Caudwell LymeCo Charity	Bacteria	$37,000	$0	Not investigated (annual private donations likely <$1mm)	https://caudwelllyme.com/research/applying-for-research-funding	Based on examples, no private recipients
Clayton Foundation Of Research	Broad medical research	unknown	$0	Not investigated (annual private donations likely <$1mm)	https://www.claytonbiotech.com/about-us/research-institutions	Based on examples, no private recipients
Coalition for Epidemic Preparedness Innovations	Vaccines	$600,000,000	$450,000,000	Novavax, Inovio, Public Health Vaccines, Emergent Biosolutions	https://cepi.net/wp-content/uploads/2022/04/CEPI_2021-Annual-Progress-Report-1.pdf	Estimates are approximations from CEPI's 2021 annual progress report. CEPI vaccine development funding grew about 6x from 2019 to 2020, overwhelmingly to contribute to COVID-19 vaccines. About 3/4 of CEPI vaccine development partners are US-based private organizations.
CRDFglobal	Bacteria	unknown	$0	Not investigated (annual private donations likely <$1mm)	https://www.crdfglobal.org/what-we-do/global-health/	Based on examples, no private recipients
Creutzfeldt-Jakob Disease Foundation	Prions	$1,000,000	$0	Not investigated (annual private donations likely <$1mm)	https://cjdfoundation.org/grant-recipients	Based on examples, no private recipients

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
Drugs For Neglected Diseases Initiative	Broad pathogen research	$55,949,556	$36,926,707	unknown	https://dndi.org/wp-content/uploads/2022/07/DNDi-RD-Portfolio-June-2022.pdf	A 2021 DNDI report estimates €66 million in expenditures, with 79% to "R&D and access". 61% of listed partner organizations are private, so a rough estimate of 2021 private funding is €66mm * 79% * 61% = €34412400 or $36926707. All financial conversions performed 3/13/23.
FIND: Foundation for Innovative New Diagnostics	Broad pathogen research	$10,000,000	$1,000,000	unknown	https://annual-report-21.my.canva.site/	FIND's total annual grants for 2021 were $114mm. The fraction of grants that are US research-focused is not shared but likely >10%. The fraction of research grants to private performers is also not shared, but some identified recipients are private.
Foundation To Prevent Antibiotic Resistance	Bacteria	$300,000	$0	Not investigated (annual private donations likely <$1mm)	https://parfoundation.org/wp-content/uploads/2021/11/PAR-Foundation-Impact-Report-2021.pdf	Based on examples, no private recipients
Fungal Infection Trust	Fungi	$37,000	<$10,000	Not investigated (annual private donations likely <$1mm)	https://fungalinfectiontrust.org/research-grants/grants-awarded/	Fraction of private recipients unknown
Gilead Foundation	Viruses	$1,080,000	$0	Not investigated (annual private donations likely <$1mm)	https://researchscholars.gilead.com/en/hiv_portal/award-recipients	Based on examples, no private recipients
Healthcare Infection Society	Broad pathogen research	$120,000	$0	Not investigated (annual private donations likely <$1mm)	https://www.his.org.uk/funding-awards/funded-research/	Based on examples, no private recipients

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
Howard Hughes Medical Institute	Broad medical research	$300,000,000	$0	Not investigated (annual private donations likely <$1mm)	https://www.hhmi.org/news/hhmi-invests-300-million-33-new-investigators	Based on examples, no private recipients
International AIDS Society	Viruses	unknown	$0	Not investigated (annual private donations likely <$1mm)	https://www.iasociety.org/grants	Funding does not appear to be directed to US recipients
International Society For Infectious Diseases	Broad pathogen research	$56,000	<$56,000	Not investigated (annual private donations likely <$1mm)	https://isid.org/research/isid-research-grants/#:~:text=ISID's%20research%20grants%20are%20one,diseases%20researchers%20from%2046%20countries	Funding does not appear to be directed to US recipients
Livlyme Foundation	Bacteria	$50,000	$0	Not investigated (annual private donations likely <$1mm)	https://livlymefoundation.org/research-2/	Based on examples, no private recipients
Lyme Disease Association	Bacteria	<$1,000,000	<$1,000,000	Not investigated (annual private donations likely <$1mm)	https://lymediseaseassociation.org/grants/research/lda-awarded-research-grants/#List	Few public grant examples, mostly academic
March Of Dimes	Broad medical research	unknown	<$1,000,000	Not investigated (annual private donations likely <$1mm)	https://www.marchofdimes.org/our-work/research/grants-awards	Most or all funding recipients are academic
Medicines For Malaria Venture	Malaria	$54,000,000	$18,000,000	Novartis, GSK, Merck, Calibr	https://www.mmv.org/sites/default/files/uploads/docs/publications/MMV_Glance_2022_ENG_20221104.pdf	64% of MMV's stated annual total contributions is dedicated to research - $54mm. 17/50 drugs in their pipeline (34%) are being developed by private US organizations. $54mm * 34% = $18mm.

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
Meningitis Now	Viruses	unknown	$0.00	Not investigated (annual private donations likely <$1mm)	https://www.meningitisnow.org/meningitis-explained/research/our-completed-research-projects/	Funding does not appear to be directed to US recipients
Meningitis Research Foundation	Viruses	unknown	$0.00	Not investigated (annual private donations likely <$1mm)	https://www.meningitis.org/research-projects	Funding does not appear to be directed to US recipients
Pediatric Infectious Disease Society	Broad pathogen research	$1,000,000	$50,000	Not investigated (annual private donations likely <$1mm)	https://pidsfoundation.org/awards/past-recipients/	Few public grant examples, mostly academic
Royal Society Of Tropical Medicine And Hygiene	Viruses	$435,000.00	$0.00	Not investigated (annual private donations likely <$1mm)	https://www.rstmh.org/grants/grant-awardees-2022	Funding does not appear to be directed to US recipients
Society For Academic Emergency Medicine	Broad pathogen research	$200,000.00	$0.00	Not investigated (annual private donations likely <$1mm)	https://www.saem.org/about-saem/academies-interest-groups-affiliates2/saem-foundation/impact-of-a-donation/saemf-grantees	Based on examples, no private recipients
Steven & Alexandra Cohen Foundation	Lyme	$10,000,000	$1,000,000	Institute for Systems Biology	https://www.steveandalex.org/ticks-suck/	Roughly estimated from grants and amounts listed on main page. ISB is the only private recipient organization listed.
TB Alliance	Tuberculosis	$10,000,000	$1,000,000	Viatris, Bill And Melinda Gates Medical Research Institute	https://www.tballiance.org/sites/default/files/assets/TBAlliance_GATB_2021_fst-1231_EV.pdf	TB Alliance's total annual grants for 2021 were $46mm. The fraction of grants that are US research-focused is not shared but likely >10%. The fraction of research grants to private performers is also not shared, but some identified recipients are private.

Funder	Focus area	Approx. avg. annual US pathogen research funding	Approx. avg. annual private US pathogen research funding	Major private recipients	Source	Notes
Thrasher Research Fund	Broad pathogen research	$4,375,000	$150,000	Not investigated (annual private donations likely <$1mm)	https://www.thrasherresearch.org/content/thrasher/bc/thrasher/Downloads/2018-19_Thrasher%20Biennial%20Report.pdf	Ballpark from annual report; funding private organizations appears rare
Wellcome Trust	Broad medical research	$500,000.00	$500,000.00	Not investigated (annual private donations likely <$1mm)	https://wellcome.org/grant-funding/funded-people-and-projects	Appear to be few US recipients and small subset is private

Appendix D. Supplementary Information for Analysis of Non-Profit Research Organizations

Table 13. Search Strings Used to Identify Non-Profit Research Organizations

Search string
(Infectious Disease Research OR Biomedical Research) AND (Non-profit OR NPO OR Private)
(Infectious Disease Research OR Biomedical Research) AND (Non-profit OR NPO OR Private) AND (Funders OR Grants)

Table 14. US Non-Profit Human Pathogen Research Organizations

Name	Primary role	Academic affiliation?	Likely works with select agents?	Received federal funding 2019-2023?
Fred Hutch Cancer Center	Research institute	University of Washington	No	Yes
Lundquist Institute	Research institute	UCLA	No	Yes
Nemours Children's Hospital	Hospital	University of Central Florida	No	No
Phoenix Children's Research Hospital	Hospital	University of Arizona	No	No
Sanford Burnham Prebys	Research institute	Confers degrees	No	Yes
Beaumont Health Hospital	Hospital	Oakland School of Medicine	No	No
Houston Methodist Hospital	Hospital	Cornell University and Texas A&M University	No	No
Boston Children's Hospital	Hospital	Harvard University	No	No
Whitehead Institute	Research institute	MIT	No	Yes
Gladstone Institute	Research institute	University of California	No	Yes
Brigham and Women's Hospital	Hospital	Harvard Medical School	No	No
Center for Global Infection Disease Research (Seattle Children's Hospital)	Research institute	University of Washington	No	Yes
CZ Biohub	Research institute	Stanford and UCSF	No	No

Name	Primary role	Academic affiliation?	Likely works with select agents?	Received federal funding 2019-2023?
Center for Discovery and Innovation (Hackensack Meridian Health)	Research institute	Hackensack Meridian School of Medicine	No	No
Cleveland Clinic (Lerner Research Institute)	Research institute	Cleveland Clinic Lerner College of Medicine, Case Western Reserve University, Heritage College, and Kent State University	No	Yes
Feinstein Institute for Medical Research	Research institute	Hofstra/Northwell and Elmezzi Graduate School of Molecular Medicine	No	No
St. Jude Children's Research Hospital	Research institute	No	Yes	Yes
Texas Biomedical Research Institute	Research institute	No	Yes	Yes
American Type Culture Collection (ATCC)	Contract research or research support	No	Yes	Yes
SRI International	Government contractor	No	Yes	Yes
Leidos Biomedical Research	Research institute	No	Yes	Yes
Southern Research	Research institute	No	Yes	Yes
Battelle Memorial Institute	Government contractor	No	Yes	Yes
Salk Institute for Biological Studies	Research institute	No	No	Yes
J. Craig Venter Institute	Research institute	No	No	Yes
La Jolla Institute for Immunology	Research institute	No	No	Yes
Vitalant Research Institute	Research institute	No	No	Yes
Trudeau Institute	Research institute	No	No	Yes
The Jackson Laboratory	Research institute	No	No	Yes

Name	Primary role	Academic affiliation?	Likely works with select agents?	Received federal funding 2019-2023?
Lovelace Biomedical	Contract research or research support	No	No	Yes
Allina Health	Research institute	No	No	Yes
Oklahoma Medical Research Foundation	Research institute	No	No	Yes
Access to Advanced Health Institute	Research institute	No	No	Yes
IITRI	Research institute	No	No	Yes
Lankenau Institute for Medical Research	Research institute	No	No	Yes
Baruch S. Blumberg Institute	Research institute	No	No	Yes
Biomedical Research Institute of Southern California	Research institute	No	No	Yes
Wistar Institute	Research institute	No	No	Yes
Translational Genomics Research Institute (TGen)	Research institute	No	No	Yes
MRIGlobal	Government contractor	No	No	Yes
Noblis	Government contractor	No	No	Yes

Appendix E. Supplementary Information for Analysis of For-Profit Research Organizations

Table 15. US For-Profit Human Pathogen Research Organizations

Business Name	Description/Relevant Research	Likely works with select agents?	Received federal funding 2019-2023?
Advanced BioScience Laboratories	Vaccines and therapeutics incl. Ebola; NIAID funding	Yes	Yes
Aldatu Biosciences	Drug resistance testing for HIV; diagnostics for Lassa virus, CCHF virus, Ebola and Marburg viruses; all research is NIAID-funded	Yes	Yes
Arisan Therapeutics	Antiviral programs for arenaviruses and Ebola virus; federal funding	Yes	Yes
Biofactura	Smallpox virus and Marburg virus therapeutics; federal funding	Yes	Yes
Biologics Resources	Conjugate anthrax vaccine; NIH funding	Yes	Yes
BlueWillow Biologics	Vaccine for SARS-CoV-2 (and NIH-funded vaccines for anthrax and H5N1 avian influenza virus)	Yes	Yes
Calder Biosciences	Universal flu vaccine; NIAID and NIA funding	Yes	Yes
Emergent BioSolutions	Smallpox vaccine and anthrax antitoxin	Yes	Yes
Inovio Pharmaceuticals	Vaccines for MERS, SARS-CoV-2, and select agents (Ebola virus and Lassa virus)	Yes	Yes
Integrated BioTherapeutics	Vaccines and therapeutics for Ebola, Marburg, and Nipah viruses	Yes	Yes
Mapp Biopharmaceutical	Antivirals for hantavirus and various select agents (Ebola and Marburg viruses, Hendra and Nipah viruses, Junin and Machupo viruses)	Yes	Yes
Maxwell Biosciences	Developing universal antiviral, testing w Ebola and others; coordination with NIAID	Yes	Yes
Medigen	Vaccines for CHIKV, Dengue virus, influenza virus, Japanese encephalitis virus, Yellow fever virus, Zika virus, and a select agent (Lassa virus)	Yes	Yes
Planet Biotechnology	Therapeutics for MERS and anthrax; federal funding	Yes	Yes
RetroVirox	Offers antiviral assays for highly select agents incl. Lassa virus and avian influenza	Yes	Yes

Business Name	Description/Relevant Research	Likely works with select agents?	Received federal funding 2019-2023?
Therapeutics Systems Research Laboratories	Antimicrobial drug development; NIAID funding	Yes	Yes
Siga	Smallpox virus therapeutics	Yes	Yes
Zalgen Laboratories	Virus research, diagnostics, and therapeutics including Lassa virus and Ebola	Yes	Yes
GeoVax	Vaccines for SARS-CoV-2, pan-coronavirus, Zika virus, and select agents (Ebola virus and Lassa virus)	Yes	No
NanoViricides	Antivirals for Dengue virus, HIV, influenza virus, rabies virus, varicella-zoster virus, and select agents (Ebola and Marburg viruses)	Yes	No
Uvax Bio	Vaccines for Dengue virus, HIV, influenza virus, SARS-CoV-2, Zika virus, tuberculosis, and select agents (Ebola and Marburg viruses, Lassa virus)	Yes	No
Aegis Life	Vaccines and therapeutics for HIV, influenza virus, SARS-CoV-2, and pan-coronavirus	No	No
Aerium Therapeutics	Therapeutics for SARS-CoV-2	No	No
Affinivax	Vaccine for SARS-CoV-2	No	No
Aligos Therapeutics	Antiviral for SARS-CoV-2	No	No
Altesa Biosciences	Various antivirals	No	No
Ansun BioPharma	Antivirals for influenza virus	No	No
Aridis Pharmaceuticals	Therapeutics for SARS-CoV-2	No	Yes
AstraZeneca	Various vaccines and therapeutics	No	Yes
Atea Pharmaceuticals	Antivirals for Dengue virus and SARS-CoV-2	No	No
BioNTech	Various vaccines, including for SARS-CoV-2	No	No
Blue Lake Biotechnology	Vaccine for SARS-CoV-2	No	Yes
Blue Water Vaccines	Vaccine for influenza virus	No	No
Bristol Myers Squibb	Therapeutics for SARS-CoV-2	No	Yes
Centivax	Vaccine for influenza virus	No	Yes
Cidara Therapeutics	Antivirals for influenza virus and SARS-CoV-2	No	No
Clear Creek Bio	Antiviral for SARS-CoV-2	No	Yes

Business Name	Description/Relevant Research	Likely works with select agents?	Received federal funding 2019-2023?
Cocrystal Pharma	Therapeutics for influenza virus and SARS-CoV-2	No	No
Codagenix	Vaccines for Dengue virus, influenza virus, SARS-CoV-2, and Yellow fever virus	No	Yes
Crestone	Antimicrobials for tuberculosis	No	Yes
Curevo Vaccine	Vaccine for varicella-zoster virus	No	Yes
CyanVac	Vaccine for SARS-CoV-2	No	Yes
CytoDyn	Therapeutics for HIV	No	No
Daiichi Sankyo	Vaccine for SARS-CoV-2	No	Yes
Enanta Pharmaceuticals	Antiviral for SARS-CoV-2	No	No
EnGen Bio	Vaccine for influenza virus	No	Yes
Evrys Bio	Antivirals for influenza virus and SARS-CoV-2	No	Yes
Exavir Therapeutics	Therapeutics for HIV	No	No
Fimbrion Therapeutics	Tuberculosis antibiotic	No	Yes
FluGen	Vaccine for influenza virus	No	Yes
Fosun Pharma	Vaccine for SARS-CoV-2	No	Yes
Genentech	Various antivirals	No	Yes
Gilead	Vaccines and therapeutics for HIV and SARS-CoV-2	No	Yes
GSK	Various vaccines and therapeutics	No	Yes
Hsiri Therapeutics	Antibiotic development	No	Yes
IBT Bioservices	In vitro antiviral testing and infection models	No	No
Icosavax	Vaccines and therapeutics for influenza virus and SARS-CoV-2	No	No
Innovation Pharmaceuticals	Therapeutics for SARS-CoV-2	No	No
Invivyd	Therapeutics for influenza virus and SARS-CoV-2	No	No
InvVax	Vaccine for influenza virus	No	Yes
Iterum Therapeutics	Antibiotic development	No	Yes
Janssen Pharmaceuticals	Various vaccines and therapeutics	No	Yes
JMI Laboratories	Antimicrobial therapeutics	No	No
L2 Diagnostics	Vaccines for Powassan virus and Zika virus	No	Yes
Longhorn Vaccines	Inactivation media for influenza virus and SARS-CoV-2	No	Yes
Marpē Therapeutics	Antivirals for Dengue virus, influenza viruses, and Zika virus	No	No

Business Name	Description/Relevant Research	Likely works with select agents?	Received federal funding 2019-2023?
Maxim Biomedical	Diagnostics for HIV and SARS-CoV-2	No	Yes
MediciNova	Therapeutics for SARS-CoV-2	No	Yes
Meissa Vaccines	Antivirals for SARS-CoV-2	No	Yes
MerciaPharma	Vaccine for influenza virus	No	No
Merck	Various vaccines and therapeutics	No	Yes
Microbix Biosystems	Antigen production	No	No
MicuRx Pharmaceuticals	Antiviral for SARS-CoV-2	No	No
Najit Technologies	Vaccines for CHIKV, influenza virus, West Nile virus, Yellow fever virus, and Zika virus	No	Yes
Novartis	Therapeutics for Dengue virus and SARS-CoV-2	No	Yes
Novateinbio	Recombinant viruses, including influenza virus	No	No
PAI Life Sciences	Therapeutic for tuberculosis	No	Yes
Pardes Biosciences	Therapeutics for SARS-CoV-2	No	No
PDS Biotechnology	Vaccines for influenza virus, SARS-CoV-2, and tuberculosis	No	Yes
Pfizer	Various vaccines and therapeutics	No	Yes
PineTree Therapeutics	Broad antiviral	No	Yes
Prosetta Biosciences	Various antivirals	No	Yes
Pulmotect	Broad antiviral, studied against SARS-CoV-2	No	Yes
Qpex Biopharma	Antimicrobial therapeutics	No	Yes
Regeneron	Therapeutics for SARS-CoV-2	No	Yes
Ridgeback Biotherapeutics	Antiviral for SARS-CoV-2 (developed under collaboration with Merck)	No	Yes
Rigel Pharmaceuticals	Therapeutics for SARS-CoV-2	No	Yes
Romark Laboratories	Broad antiviral	No	Yes
RVAC Medicines	Vaccine for SARS-CoV-2	No	No
Sanofi	Various vaccines	No	Yes
Sequella	Antimicrobial therapeutics	No	Yes
Sigmovir Biosystems	Influenza research in cotton rat model of human disease	No	Yes
Sixty Degrees Pharma	Therapeutics for Dengue virus and SARS-CoV-2	No	Yes

Business Name	Description/Relevant Research	Likely works with select agents?	Received federal funding 2019-2023?
Tetherex Pharmaceuticals	Vaccine for SARS-CoV-2	No	No
Therapeutics Systems Research Laboratories	Antimicrobial drug development	No	No
Trellis Bioscience	Therapeutic for influenza virus	No	Yes
Valneva	Vaccines for Japanese encephalitis virus and SARS-CoV-2	No	Yes
Vaxart	Vaccine for SARS-CoV-2	No	Yes
Vaxxinity	Vaccine for SARS-CoV-2	No	Yes
VBI Vaccines	Vaccine for SARS-CoV-2, pan-coronavirus, and Zika virus	No	Yes
Vibalogics (now Recibiopharm)	CDMO specializing in "live viruses and viral vectors"	No	No
ViiV Healthcare	Therapeutics for HIV	No	Yes
Vir Biotechnology	Therapeutics for HIV (collaboration with Gates Foundation), influenza virus, SARS-CoV-2 (collaboration with GlaxoSmithKline), and tuberculosis	No	Yes
ViraSource	Propagates virus stocks of all BSL-2 viruses	No	No
Viriom	Antivirals for HIV, influenza virus, and SARS-CoV-2	No	No
Virios Therapeutics	Therapeutics for SARS-CoV-2	No	No
Vivaldi Biosciences	Vaccine for influenza virus	No	Yes

Appendix F. Supplementary Information for Analysis of Research Materials

Table 16. ATCC Account Group Names and Types

Order type	Account Groups
Private	Agriculture; Agriculture/Processed Foods; Bioinformatics; Bioproduction; Biotechnology/Life Sciences; CDMO or CMO; Chemical or Environmental; Contract Lab; Contract Research Organization; Food & Beverage; Genomic Profiling or Testing; Human Therapeutics R&D (Pharma/Biopharma); Industrial; IVD or Assay Development; Manufacturing; Medical Devices; Official Distributor; Other; Pharmaceutical; Reagents & Tools Supplier
Academia	University/Education; Academia or Education; Academia or Education (E-Proc Only)
Healthcare	Hospitals/Clinical; Diagnostics Lab; Clinical Labs; Veterinary Science
Government	Government; GovCon; US Government; US Government (E-Proc Only)
Research Foundation	Research Foundation

Appendix G. Presentation Attendees

We are grateful for feedback from the following attendees of an in-person presentation of this project on May 31, 2023:

- Gregory Koblentz, George Mason University
- Rebecca Moritz, Colorado State University
- Matthew Sharkey, US Administration for Strategic Preparedness and Response
- Dave Shepherd, US Department of Homeland Security
- Filippa Lentzos, Kings College London
- Alan Slobodin, US House of Representatives
- Harry Samuels, US House of Representatives
- Matt Walsh, Johns Hopkins University
- Josh Wentzel, Texas A&M University