

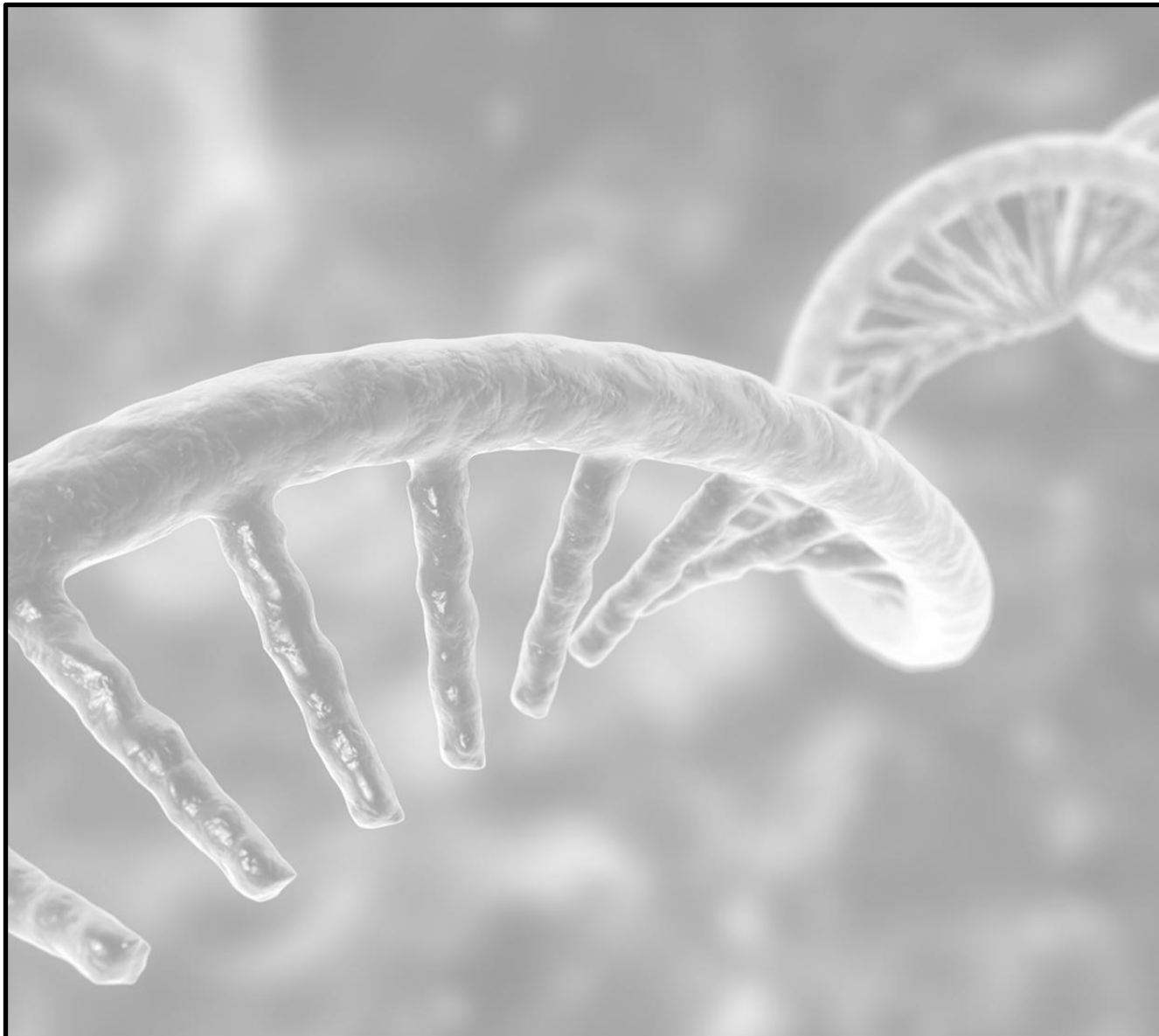
# THE MRNA INNOVATION ECOSYSTEM (U.S.)

2025 ASSESSMENT OF ECONOMIC IMPACT,  
THERAPEUTIC POTENTIAL, AND POLICY IMPLICATIONS

DATA COLLECTED MARCH – APRIL 2025



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# The mRNA Innovation Ecosystem (U.S.): 2025 Assessment of Economic Impact, Therapeutic Potential & Policy Implications

May 2025

mRNA technology is at an important developmental stage. The research demonstrates unequivocally that mRNA technology represents a transformative platform with substantial healthcare and economic implications. With appropriate policy support, mRNA can strengthen American biotechnology leadership, generate high-value employment and manufacturing, enhance national security preparedness, and deliver innovative therapeutic approaches for patients with limited treatment alternatives. Without strategic support, innovation activities will likely migrate internationally, potentially redefining the United States' position from innovation leader to technology recipient.

Current policy decisions may significantly influence both mRNA technology development and America's position in the global biomedical innovation ecosystem in coming years. **U.S. Government policies and funding cuts to mRNA research represent a critical threat** to America's biomedical leadership, as they would cause U.S. research and manufacturing jobs to move to Europe and Asia, delay therapeutic advances in cancer, rare disease and other diseases by years, lose billions in potential healthcare savings, forfeit U.S. biomedical leadership to Europe and Asia and put U.S. National Security in the hands of other countries—transforming a budgetary decision into an inflection point that could permanently alter both America's economic competitiveness and its autonomy in accessing future life-saving mRNA therapies in biotech innovation.

This comprehensive market analysis, derived from structured interviews with **106 senior mRNA industry professionals**, highlights both the exceptional potential of mRNA technologies and the consequences associated with potential funding interruptions. Due to the scientific potential and robust U.S. workforce that are at risk because of recent actions, The Alliance for mRNA Medicines undertook this study to better assess and quantify those impacts. Below are the key insights highlighted in the executive summary:

- **Transformational Benefits of mRNA over the Next 5-10 Years** including Cancer & Rare Disease Therapies
- **Artificial Intelligence's Importance** for Unlocking mRNA Medicines
- mRNA is **Cost-Effective and Could Lower Pricing** for Prescription Drugs
- **Chronic Disease** May Be Revolutionized by mRNA
- Economics of **mRNA Workforce**, Research Budgets & the **Role of Public Funding**
- **Policy-Related Disruptions**: Current Impacts and Projected Consequences
- **Global Competitiveness**: Vulnerability Assessment
- **Policy Considerations** and Strategic Imperatives
- **Breakthrough Innovations** Expanding Therapeutic Applications

## Transformational Benefits of mRNA over the Next 5-10 Years

- **Personalized Cancer Immunotherapies**: The most promising near-term benefit with late-stage trials for melanoma, colorectal, pancreatic, and triple-negative breast cancers

- **Rare Genetic Disease Treatments:** Protein replacement and gene-editing approaches for underserved conditions such as cystic fibrosis, muscular dystrophy, and various metabolic and rare diseases
- **Manufacturing Innovation:** Transforming biopharmaceutical manufacturing by simplifying traditional complex biologics production, enabling small-scale personalized interventions and creating viable economics for ultra-rare disease therapies
- **Expanded Longevity and Quality of Life:** Showing potential for one-time treatments to replace lifelong management of chronic disease, more targeted approaches with fewer side effects and using advanced delivery systems to expand the range of treatable conditions including to neurological applications and other conditions
- **Infectious Disease Prevention and Pandemic Preparedness:** mRNA technology is advancing infectious disease management by reducing development timelines from years to months. Applications extend beyond respiratory viruses to include vaccines for HIV, malaria, and tuberculosis

*"Upcoming late-Phase 3 global clinical trial on the new antigen vaccine for melanoma. They're already recruiting over one thousand subjects."*

*"I've seen one mRNA molecule...when treated [in conjunction with a PD-1 inhibitor] for a certain type of cancer, where the **relapse rate was reduced by almost 60%**."*

*"Examples of populations to be positively impacted by life-saving and life-enhancing treatments currently in development: (a) 18% of patients in the U.S. with cystic fibrosis (CF) either are not eligible or do not qualify for currently approved CF treatments...(b) There are approximately 4,400 patients with ornithine transcarbamylase deficiency disease (OTCD) [for which] current treatments are grossly inadequate"*

### Nearly All Industry Leaders (95%) Emphasized Artificial Intelligence's Importance for Unlocking mRNA Medicines

As the U.S. accelerates investments in AI across sectors, it is seen as **'critical' that mRNA innovation advances in parallel with Artificial Intelligence**. These technologies are deeply complementary; AI can radically accelerate mRNA drug design, optimization, and personalization. Experts note that investing in both AI and mRNA together over the next 5–10 years will be key to unlocking their full therapeutic potential and maintaining global leadership

*"AI significantly would enhance the development of mRNA technology by improving design, optimizing processes, personalizing treatment, and accelerating clinical trials. **The integration of AI and mRNA technology has great potential to bring more effective and safer therapies** to patients more quickly and efficiently."*

### mRNA is Cost-Effective and Could Lower Pricing for Prescription Drugs

Most respondents (88%) believe mRNA technologies have the potential to reduce costs, lower pricing and/or increase access, with 49% naming manufacturing efficiency in their responses:

1. **Manufacturing Processing Efficiency (49%):** Transformation from cell-based to cell-free enzymatic synthesis enables smaller facilities, lower capital requirements, and reduced labor costs
2. **Dose Reduction (18%):** mRNA's inherent potency enables dramatically lower dosages compared to traditional biologics
3. **Precision Medicine Economics (18%):** Targeted treatments reduce wasted resources and overall healthcare costs

4. **Platform Flexibility (17%):** mRNA platform technology enables rapid adaptation to new targets, accelerating timelines & reducing R&D costs
5. **Market Dynamics and Competition (10%):** Increased competition among mRNA developers over time will drive cost reduction and potentially lowered pricing

*"I believe mRNA could reduce the cost in therapies and prescription drugs just because of the sheer volume of doses you can produce per batch. If you see the actual dosage of an mRNA vaccine or therapy, it's way, way, way lower. It's probably a few micrograms when compared to grams when it comes to monoclonal antibodies... You can have much smaller facilities, fully single use, very well controlled."*

*"If you increase the quality of your mRNA, you may be able to get the same therapeutic effect at a lower dose. That's also the big selling point of self-amplifying RNA. If you can just administer a dose that is ten times lower and get the same therapeutic effect, obviously your cost of goods is going to be lower, and your therapy is going to be much more cost-effective."*

### Chronic Disease Management May Be Revolutionized by mRNA

**mRNA innovation is fundamentally shifting healthcare paradigms from chronic management to potentially curative, personalized, and rapidly deployable therapies**, thereby expanding treatment accessibility and significantly enhancing patient quality of life. Research in mRNA medicine encompasses various areas of chronic disease including very promising clinical trial results treating cancers and rare diseases, which includes serious childhood diseases, as well as emerging studies into treatments for neurological conditions and other diseases.

*"Many prescription drugs are designed to treat symptoms of a disease rather than directly address the underlying causes. mRNA-based medicines provide the opportunity to directly engage at the source of disease, which allows **for curative treatments**...that ultimately should be **more cost-effective than chronic administration of conventional drugs.**"*

### Economics of mRNA Workforce, Research Budgets and the Role of Public Funding

The sector represents an important economic component with organizations reporting an average of 336 mRNA-focused employees and **66% of mRNA jobs based in the United States**. Annual budgets for mRNA-related research and development exhibit considerable variability (<\$1 million to \$250 million; average: \$43.6 million; median: \$15 million), reflecting an ecosystem encompassing early-stage ventures (with 25% of respondents having budgets less than \$4 million) through established pharmaceutical corporations (with the top 22% of respondents reporting budgets exceeding \$50 million).

The public-private funding relationship demonstrates a complementary partnership essential to the sector's sustainability. Approximately 25% of organizations receive direct federal funding, while 44% report indirect impact through partnerships and supply chains, indicating **at least 69% of mRNA organizations are affected by federal funding**.

Of those direct recipients, **only 24% of mRNA research budgets come from federal funding** grants (which averages out to less than 7% of research budgets across all mRNA organizations surveyed) **but those grants are estimated to have supported over 60% of preclinical mRNA therapeutic and vaccine development** – fueling discovery, jobs and breakthroughs. This represents a small government investment that creates a critical catalyst for higher-risk innovation and is necessary to encourage private investment.

*"Funding from the government really sets the tone for how the investors feel about investing in the private for-profit organizations"*

### Policy-Related Disruptions: Current Impacts and Potential Consequences

Nearly half of the organizations interviewed (48%) report **already experiencing direct mRNA-related impacts from current policy uncertainty and funding cuts**, causing real-world consequences. Respondents reported multiple economic consequences impacting their organization including an additional 9% who reported only indirect impacts:

- **Reduced Scope of Projects (54%)**: Delayed developmental timelines, cutback to mRNA R&D, postponed trials and studies, and program terminations
- **Budget Reductions (46%)**: Budget reductions and freezes to ongoing projects
- **Delayed Capital Investments (46%)**: Delayed funds for major assets (such as equipment, technology and facilities) hampering long-term goals and productivity
- **Partnership Terminations (46%)**: Terminated collaborations, with some U.S.-based partnerships shifting, especially to Europe or Asia
- **Job Losses or Hiring Freezes (30%)**: Implementation of layoffs, hiring freezes, and talent reallocation affecting specialized personnel
- **Relocation of Projects, Division or Entire Business (20%)**: Reallocating resources away from mRNA or moving operations to countries outside of the U.S.

*"We had a collaboration with a strategic partner and lost NIH funding recently. Our partner canceled the partnership, and all the project activities came to a stop. We have already invested a lot of money on this project (people, equipment, capital investment)."*

*"Our company has been forced to look overseas for manufacturing, development, and approval in order to de-risk our efforts."*

**If federal funding for mRNA research significantly diminishes, potential consequences could be severe and compounded on top of current impacts.** Industry leaders anticipate multiple potential consequences including: delaying planned initiatives (53%), need to reduce scope of existing programs (48%), need to seek alternative funding sources (48%), expecting to reduce workforce (41%), terminating specific programs (40%), considering pivoting away from mRNA technologies (30%) and finally, relocating operations to other countries (30%).

*"Restrictions in regard to funding could actually be detrimental to a small organization like ours where quite frankly it's the difference between keeping lights on and lights going off inside the organization."*

Organizations report an average of **45% of mRNA-related positions potentially at risk**, with 21% of organizations indicating 100% of their mRNA positions would be threatened under adverse policy scenarios.

### Global Competitiveness: Vulnerability Assessment

While 79% of respondents indicate the United States currently maintains leadership in mRNA research and development (45% "significantly ahead," 34% "slightly ahead"), this position demonstrates increasing vulnerability. According to 81%, anti-mRNA government policies would "likely" cause top innovation and talent to leave the U.S. for other countries, even though 93% believe that mRNA is critical to America's biotech leadership on the global stage.



If the U.S. loses its leadership position in mRNA technology, respondents identified a range of interconnected negative consequences:

- **Economic Impacts:** Lost revenue from licensing and exports, diminished job creation in high-value R&D and manufacturing and reduced investment in U.S. biotech sector
- **Healthcare Consequences:** Delayed access to treatments for U.S. patients, higher costs for imported mRNA therapies and dependence on foreign suppliers for technology
- **National Security Vulnerabilities:** Compromised pandemic preparedness and biological threat response capabilities
- **Scientific Ecosystem Erosion:** "Reverse brain drain" affecting current researchers and future talent development
- **Strategic Disadvantages:** Reduced global influence in setting standards for emerging biotechnologies, shift in global biotech toward competitor nations and potential leverage by other countries during health crises

*"The U.S. would lose billions of potential corporate profits and tax revenues, many thousands of high-paying scientific jobs, and be vulnerable to the decisions of foreign governments in order to access these critical new mRNA therapies"*

*"There is a reason that the United States is the research and research training destination for the world... There is no question that **mRNA medicines are the new path forward** in drug development, **and if the U.S. does not embrace this path, the U.S. will lose an entire generation (or more) of intellectual capital**"*

*"U.S. citizens will need to travel outside the country to receive life-saving/altering therapeutics... Other geographies will take the lead with respect to the technical know-how for the development and manufacture of this new class of medicines."*

*"Pandemic preparedness, which is one of the major applications of the mRNA technology, currently is not just a healthcare issue, but it's a national defense issue. So, we need to make sure **in the U.S. that we have the technology to be able to deal with outbreaks as they happen.**"*

## Policy Considerations and Strategic Imperatives

Industry leaders were asked to describe policy frameworks that would help advance mRNA in the U.S. Top answers include:

- **Regulatory Modernization:** Streamline regulatory pathways such as clearer FDA guidelines, expedited review processes and standardized manufacturing protocols
- **Long-Term Investment Commitment:** Sustained funding aligned with extended development timelines rather than short-term political considerations
- **Science-Driven Policy Formulation:** Countering misconceptions with comprehensive technological understanding
- **Domestic Manufacturing Capacity:** Develop onshore manufacturing capabilities, domestic supply chains, and initiatives to stimulate investments
- **Talent Development and Collaboration:** Invest in STEM and specialized training and strengthen public-private partnerships and academic-industry collaborations
- **Therapeutic Versatility Beyond Vaccines:** Acknowledging mRNA's extensive applications beyond vaccine development

*"It's in its very early stages as a therapeutic modality. The potential for human health is enormous, but abandoning mRNA now would be like abandoning protein-based drugs or small molecule-based drugs. It's a whole potential universe of possibilities that would be foreclosed on."*

## Breakthrough Innovations Expanding Therapeutic Applications

Transformative innovations are rapidly redefining mRNA's therapeutic potential, with 61% of stakeholders mentioning the advance of precision medicine and patient-specific therapies:

1. **Precision Medicine Advancement (61%)**: Evolution to precisely tailored interventions, particularly in oncology with treatments encoding patient-specific neoantigens
2. **Production Process Enhancement (26%)**: Closed-system manufacturing, streamlined purification processes, and point-of-care manufacturing of individualized treatments
3. **Tissue-Targeting Breakthroughs (24%)**: New therapeutic applications are possible using enhanced lipid nanoparticle formulations, targeting delivery to previously inaccessible tissues
4. **Molecular Structure Optimization (21%)**: Self-amplifying mRNA achieving equivalent efficacy at approximately one-fifth of standard concentration, significantly enhancing cost-effectiveness and manufacturing efficiency

*"Cancer vaccines using mRNA are truly individualized medicine, specific to the particular time when a tumor is sampled."*

*"The other aspect that is evolving very fast is the delivery. This is mostly done with LNPs, and in the past, it was always very easy to target the liver, but extrahepatic delivery has always been quite difficult. However, in the past few years, a lot of progress has been made in this regard."*



The Alliance for mRNA Medicines (AMM) is the leading global organization dedicated to advancing and advocating for mRNA and next-generation encoding RNA therapeutics and vaccines for the benefit of patients, public health, and society. Our mission is to propel the future of mRNA medicine, improve patients' lives, and advance scientific knowledge by convening and empowering mRNA industry leaders, innovators, scientists, and other key stakeholders. Learn more at <https://mrnamedicines.org>

***This research was conducted in partnership with*** 

UserCue is the market leader for primary research automation for healthcare and life sciences organizations, conducting comprehensive studies with hundreds of key opinion leaders and industry experts—all completed within one week. Specializing in life science and healthcare market assessments, UserCue delivers integrated quantitative and qualitative insights through end-to-end research execution for startups and Fortune 500 enterprises.

## About the Study

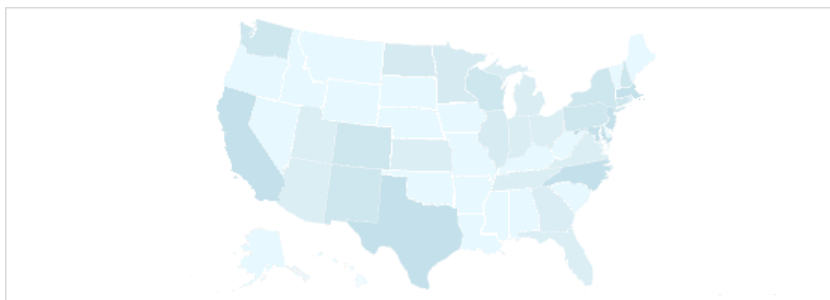
**Project Background:** The Alliance for mRNA Medicine (AMM) is assessing the potential impact of federal funding cuts for mRNA research, which, beyond COVID-19 vaccines, holds broad implications for healthcare innovation, economic development, and national security.

**Research Objectives:**

- Assess the economic impact of mRNA R&D, including employment, investment, and U.S. global competitiveness.
- Examine the role of federal funding in advancing innovation and the impact of anti-mRNA government policies.
- Identify real-world applications of mRNA technology beyond COVID-19 and assess patient populations impacted by development delays.

Key Metrics	Data
Sample Size	106 senior professionals across mRNA field
Organization Types	Biopharmaceutical/Biotech (51%), Pharmaceutical (15%), CDMO (12%), Life Science Tools & Tech (11%), Academic Research Institutions and Other (11%)
Geographic Distribution	U.S. HQ (71%), Germany (8%), UK (6%), Switzerland (5%), Canada (4%), APAC (3%), Other EU (3%). All international organizations report U.S. presence
Organization Size	Small (<100 employees): 28%      Medium (100-999 employees): 25% Large (1,000-9,999 employees): 24%      Enterprise (10,000+ employees): 23%
Respondent Profiles	<ul style="list-style-type: none"> <li>• Director (25%), C-Suite Executive (20%), Vice President/VP (20%), Senior Director (14%), Scientist (7%), EVP/SVP (6%), Manager (6%), Other (2%)</li> <li>• 87% with 10+ years of experience</li> <li>• 84% directly engaged in mRNA decision-making</li> </ul>
Primary Therapeutic Focus Areas	Oncology (70%), Immunotherapies (56%), Gene Therapies (53%), Rare Genetic Diseases (49%). Multiple area selections were allowed
Indicator	Key Findings
mRNA Employment	<ul style="list-style-type: none"> <li>• Average: 328 employees per organization focused on mRNA</li> <li>• Range: 2 (small firms) to 6,000 (large biopharma)</li> <li>• 66% of mRNA jobs are U.S.-based (average)</li> </ul>
Annual R&D Budgets	<ul style="list-style-type: none"> <li>• Range: &lt;\$1M-\$250M</li> <li>• Median: \$15M; Average: \$43.6M</li> <li>• 25% below \$4M; top 22% exceeds \$50M</li> </ul>
Current Activities	<ul style="list-style-type: none"> <li>• Therapeutic Development (67%)</li> <li>• Manufacturing &amp; Production (38%)</li> <li>• Platform Technology &amp; Delivery (33%)</li> <li>• Enabling Services (22%)</li> </ul>

**Geography of mRNA experience:** According to the industry leaders surveyed, the top states where mRNA employees are based includes California, Massachusetts, Maryland, New Jersey, Texas and North Carolina, although employment spans across the U.S. with 29 states mentioned. *Heat map below shows states mentioned with mRNA-related jobs by highest to lowest concentrations.*





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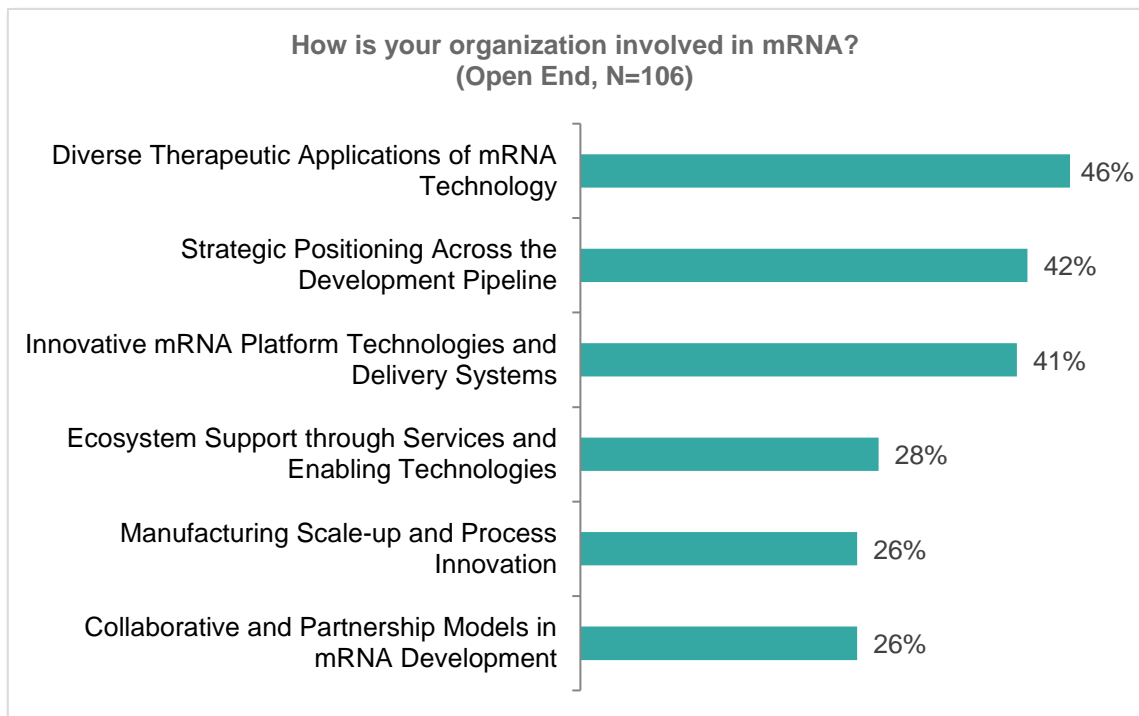
## National Assessment of mRNA

### Section 1: Organizational Involvement in mRNA

#### 1.1 Organizations Engage in a Wide Range of mRNA Business Arenas

Question: How is your organization involved in mRNA? (Open End, N=106, % = percentage who mentioned each theme) Top themes listed below, ordered greatest to least mentions.

Organizations are simultaneously exploring diverse therapeutic areas, novel targets, optimizing pipelines, scaling platforms, and leveraging partnerships—to de-risk development and accelerate the translation of mRNA innovations into real-world therapies.



#### Involvement Across Diverse Conditions

Organizations are leveraging mRNA technology across a spectrum of areas:

- **Oncology** (solid tumors like melanoma, pancreatic, hepatocellular, lung cancer, as well as hematological cancers)
- **Rare genetic diseases** (OTC deficiency, cystic fibrosis, Dravet syndrome)
- **Infectious diseases** (influenza, RSV, tuberculosis)

Post-COVID success has significantly expanded infectious disease applications. Platform-based approaches dominate, allowing adaptation across multiple disease categories.

*"My company is involved in epigenomic engineering, and we use mRNA-encoded therapeutics for the technology... our lead asset is in hepatocellular carcinoma. It's in phase II, and we have another asset in small cell lung cancer."*

*"My organization is developing therapeutics for two rare disease conditions, ornithine transcarboxylase deficiency and cystic fibrosis. We developed an mRNA COVID-19 vaccine and are working on clinical development for influenza."*

## Strategic Pipeline Positioning

Organizations position strategically with distinct strategies at each development stage.

- **Early-stage** groups maintain broad exploratory programs across diverse applications.
- **Mid-stage** organizations narrow therapeutic focus as they enter clinical development, balancing innovation with regulatory pathways.
- **Late-stage** entities often adopt more conservative therapeutic approaches while focusing on commercialization preparation.

Many maintain portfolios spanning multiple stages—advanced vaccine programs alongside early-stage gene editing initiatives.

*"Currently, most of these projects are in the early stage of development, and by early, I mean they're still preclinical and mostly in the development phase where we are still testing it out in small or large animal model systems."*

## Innovation Across Platform Technologies & Delivery Systems

Innovation spans three dimensions:

- **Delivery vehicles** (advanced LNPs, polymeric carriers, exosomes, dendrimers)
- **RNA engineering** (self-amplifying RNA, circular RNA, modified mRNA)
- **Integrated platforms** combining multiple technologies

Delivery technologies focus on cellular uptake, reduced immunogenicity, enhanced stability, and tissue-specific targeting—particularly for challenging environments like CNS or lung tissue. Self-amplifying RNA enables enhanced protein expression from smaller doses. Proprietary delivery technologies determine viable therapeutic applications.

*"We're currently developing a whole set of technologies in the field of RNA... that cover the RNA design capabilities and algorithm... and in the field of encapsulation we have developed novel lipid nanoparticles for RNA formulation, and this goes together with the formulation system that we are working on together with a US-based formulation equipment company."*

## Expanded Ecosystem Support

Organizations enable the ecosystem through:

- CDMOs offering specialized production services
- Suppliers of critical reagents (enzymes, lipids, raw materials)
- Equipment providers and technology platform licensors.

Business models vary from fee-for-service to technology licensing and strategic partnerships. Many emphasize quality, scalability, and regulatory compliance.

This ecosystem has expanded dramatically post-COVID, democratizing access to specialized capabilities previously prohibitively expensive for individual developers.

*"My organization is a CDMO that is only focusing on the mRNA modality. What we do is we have preclinical, early stage, and commercial development and manufacturing capability. Our idea is to be able to support academia, biotech, and large pharmaceutical companies throughout the entire life cycle of an mRNA-based therapy."*

### Scaling-Up Manufacturing

Organizations are investing in capabilities spanning:

- Small-batch personalized therapies up to industrial-scale production
- Continuous flow manufacturing, microfluidic systems, and novel purification approaches
- Sophisticated quality control systems with GMP compliance.

Several highlighted investments in raw material production and supply chain resilience addressing vulnerabilities exposed during COVID vaccine scaling, ensuring domestic manufacturing capacity for critical components.

*"My company is a next-generation RNA therapeutics contract research, development, and manufacturing organization (CRDMO) company focusing on personalized medicine. Current bioreactor-based RNA manufacturing processes are not appropriate for individualized therapeutics. They have solved the industry challenges by providing a unique end-to-end platform, including RNA design, nanoparticle delivery, and revolutionary GMP biochip-based precision manufacturing."*

### Collaborative Partnerships

Organizations increasingly form strategic alliances to complement capabilities, access specialized technologies, and accelerate development timelines across the rapidly evolving mRNA landscape.

*"The [RNA Center] was conceived as a collaboration with [biotechnology company], and we use [their] reagents and proprietary IVT SOPs; however, we also perform research on features of RNA that may result in improved mRNA stability and/or protein translation."*



## Section 2: Therapeutic Potential & Innovation

### 2.1 mRNA's Recent Breakthroughs: Personalized Therapies Lead Innovation

Question: What do you consider to be the most significant innovations in mRNA that have occurred in the past 1-2 years? (Open End, N=106)

These breakthroughs collectively mark mRNA's evolution from a pandemic vaccine platform into a versatile therapeutic engine—powering personalized cancer vaccines, on-site manufacturing, targeted delivery beyond the liver, and next-gen RNA architectures.

#### Expansion into Personalized Therapeutics and Novel Applications

mRNA technology has rapidly expanded beyond vaccines into diverse therapeutic areas:

- Personalized cancer treatments with patient-specific neoantigens
- Targeted approaches for previously untreatable conditions
- Protein replacement therapy for rare genetic diseases

This represents a fundamental shift from pandemic-driven vaccine development to precisely tailored medicine.

*"The most significant innovation in mRNA post-COVID is really a cancer vaccine where cancer antigens are encoded in mRNA, injecting the patient's body to elicit an immune response against the tumor itself... the cancer vaccine is a truly individualized medicine and can even be specific to a particular time when the tumor is sampled."*

#### Manufacturing and Scale-Up Innovations

Significant advancements in mRNA production processes include:

- Continuous flow manufacturing systems replacing traditional batch methods
- Streamlined purification processes and enhanced quality control
- Decentralized manufacturing approaches enabling on-site production of personalized treatments

*"There have been several concepts developed as mRNA vaccine-in-a-box kind of a concept, where fully automated mRNA vaccine manufacturing could be done in a small box, and then this could be easily shipped and transported across the world. You can end up manufacturing these individual vaccines or personalized vaccines at the patient's site."*

#### Advanced Delivery Systems

Breakthrough innovations in delivery mechanisms, dramatically expanding potential applications, include:

- Enhanced lipid nanoparticle (LNP) formulations
- Precise delivery to previously inaccessible tissues (lungs, brain, kidneys)
- Cell-specific and subcellular compartment targeting

*"The other aspect that is evolving very fast is the delivery. This is mostly done with LNPs, and in the past, it was always very easy to target the liver, but extrahepatic delivery has always been quite difficult. However, in the past few years, a lot of progress has been made in this regard, so specific organs or even specific tissues can now be targeted."*



## Novel mRNA Structures

Fundamental innovations in mRNA molecular structure include:

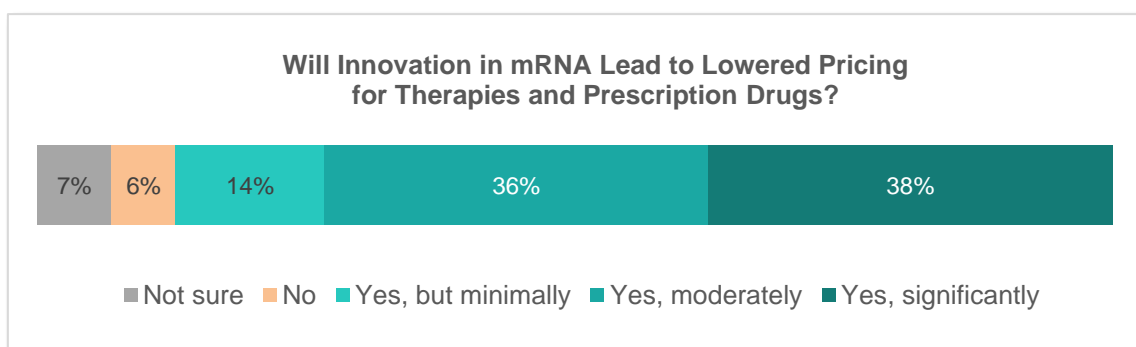
- Self-amplifying mRNA (saRNA) capable of replicating within cells
- Significantly reduced dosing requirements (as little as one-fifth the concentration)
- Enhanced stability and therapeutic performance

*"In terms of self-amplifying mRNA, the impact on health care, patients, and medicine would be that we could get bigger manufacturing capability and a lot lower cost. For example, a self-amplified mRNA vaccine is ten micrograms per dose compared to a regular mRNA, which is fifty micrograms to a hundred micrograms per dose."*

## 2.2 Experts Believe mRNA Innovation Will Lower Therapy & Drug Pricing

Question: Do you think innovation in mRNA would lead to lowered pricing for therapies and prescription drugs? (Single Select, N=106, % = percentage who mentioned each theme)

This optimism underscores that cost containment is seen as a central payoff of the mRNA revolution—driven by platform standardization, streamlined manufacturing, and reduced development timelines.



## 2.3 In Addition to Pricing, mRNA Also Has The Potential To Enable Lower Costs and Increase Access

Question: Why/How would innovation in mRNA lead to lowered pricing for therapies and prescription drugs? (Open End, n=79, those who indicated innovation in mRNA would significantly or moderately lead to lowered pricing for therapies and prescription drugs, % = percentage who mentioned each theme)

mRNA innovation has the potential to redefine healthcare economics by not only streamlining production and optimizing dosages but also shifting the treatment paradigm from ongoing symptom management to one-time curative therapies, ultimately driving significant long-term cost reductions across the entire healthcare system. Additionally, mRNA's unique manufacturing characteristics—including smaller facility footprints, cell-free synthesis, and rapid production cycles—position it as an ideal candidate for expanding domestic biomanufacturing capabilities.

### Manufacturing Processing Efficiency (49%)

The primary pathway to lower pricing through mRNA innovation centers on fundamental manufacturing advantages:

- Cell-free enzymatic synthesis eliminating complex cell culture systems
- Dramatically reduced facility requirements and simplified purification
- Shortened production timelines and reduced specialized labor needs
- Smaller manufacturing footprints and fewer complex systems

These processes, along with mRNA microdosing capabilities, directly reduce both capital and operational costs and create a cascade of manufacturing efficiencies throughout the production chain.

*"I believe mRNA could reduce the cost in therapies and prescription drugs, just because of the sheer volume of doses you can produce per batch. If you see the actual dosage of an mRNA vaccine or therapy, it's way, way, way lower. It's probably a few micrograms when compared to grams when it comes to monoclonal antibodies. So, your overall requirement goes down drastically. You can have much smaller facilities, fully single use, very well controlled."*

### **Dose Reduction (18%)**

Another cost reduction driver centers on mRNA's ability to achieve therapeutic effects with substantially lower doses:

- Self-amplifying mRNA reducing concentrations by an order of magnitude (50-100 µg to 5-10 µg per dose)
- Immediate material savings where raw materials constitute up to 80% of manufacturing costs
- Enhanced potency enabling lower dosing throughout manufacturing

*"If you increase the quality of your mRNA, you may be able to get the same therapeutic effect at a lower dose. That's also the big selling point of self-amplifying RNA. If you can just administer a dose that is ten times lower and get the same therapeutic effect, obviously your cost of goods is going to be lower and your therapy is going to be much more cost-effective."*

### **Precision Medicine Economics (18%)**

mRNA-based approaches offer potential for fundamental treatment changes:

- Addressing genetic causes directly rather than managing symptoms
- Enabling curative rather than chronic management approaches
- Reducing lifetime treatment costs through fewer administrations
- Decreasing need for secondary medications and hospitalizations

*"Many prescription drugs are designed to treat symptoms of a disease rather than directly address the underlying causes. mRNA-based medicines provide the opportunity to directly engage at the source of disease, which allows for curative treatments in a small number (perhaps only 1) of administrations that ultimately should be more cost-effective than chronic administration of conventional drugs."*

### **Platform Flexibility (17%)**

The platform nature of mRNA technology creates significant development advantages:

- **Modularity** enabling rapid iteration and easier customization
- **Compressed development timelines** compared to traditional therapeutics
- **Reduced R&D expenses** and minimized costly clinical failures
- **Accelerated time-to-market** for new therapies

*"In contrast to other therapies and drugs, mRNA medicines are an extremely facile modality to work with. This is due to several factors. One is the ease with which one can look at different mRNA molecules by simple modulation of the DNA template from which it is derived. Another is the rapid scalability of production and the already implemented manufacturing mechanisms that were put in place during the COVID pandemic."*

## Market Dynamics and Competition (10%)

Market dynamics and competition play critical roles in driving therapy pricing reductions:

- **Multiple companies** entering the maturing mRNA field creates competitive pressure
- **Natural price reductions** as markets mature and manufacturing standardizes
- Historical patterns of initially expensive technologies becoming **more affordable over time**

*"Competition drives innovation which would ultimately lead to cheaper production cost, and for companies who want to scale that will be significantly cheaper. When your cost of goods sold is significantly reduced then prices for such products will be significantly reduced and hopefully patients would not have to pay so much."*

## 2.4 Continuing Transformational Benefits of mRNA over the Next 5-10 Years

Question: What specific lifesaving or life-enhancing benefits do you expect to see from mRNA medicines in the next 5-10 years? (Open End, N=106, % = percentage who mentioned each theme)

mRNA innovation is fundamentally shifting healthcare paradigms from chronic management to potentially curative, personalized, and rapidly deployable therapies, thereby expanding treatment accessibility and significantly enhancing patient quality of life.

## Personalized Cancer Immunotherapies (48%)

mRNA technologies are revolutionizing cancer treatment through:

- **Highly personalized** approaches training immune systems to recognize individual patients' cancer cells
- **Neoantigen vaccines** tailored to specific tumor profiles for aggressive cancers
- **Promising clinical trials** showing up to 60% reduction in relapse rates when combined with immunotherapies alone
- Potential shift from expensive ex vivo cell therapies to **more accessible in vivo approaches**

"One of the most exciting developments in mRNA therapeutics is the development of personalized mRNA cancer vaccines. There's early evidence that such personalized mRNA cancer vaccines are more effective than other therapies against deadly cancers such as pancreatic cancer and triple-negative breast cancer."

"I've seen one mRNA molecule...when treated [in conjunction with a PD-1 inhibitor] for a certain type of cancer, where the **relapse rate was reduced by almost 60%**. I'm sure this is just like one of the examples and there are several out there in the market or several upcoming examples. Definitely, it's going to be a significant game changer in the next five to ten years."

### Rare Genetic Disease Treatments (39%)

mRNA medicines address previously untreatable genetic diseases through:

- Direct **protein replacement** and **gene editing** approaches
- Treatments for patients that are **ineligible for current therapies**
- Shift toward **one-time or short-course treatments** rather than lifelong management
- **Clinical success** in conditions like transthyretin amyloidosis advancing to Phase 3 trials

"Examples of populations to be positively impacted by life-saving and life-enhancing treatments currently in development: (a) 18% of patients in the U.S. with cystic fibrosis (CF) either are not eligible or do not qualify for currently approved CF treatments...(b) There are approximately 4,400 patients with ornithine transcarbamylase deficiency disease (OTCD) [for which] current treatments are grossly inadequate"

"One company, for example, has demonstrated a safe and potent clinical reduction of validated target genes for transthyretin amyloidosis as well as plasma kallikrein for hereditary angioedema. These clinical successes, for validated disease-causing genes, have progressed to ongoing pivotal phase 3 trials and are expected to compete with approved commercial therapies..."

### Infectious Disease Prevention and Pandemic Preparedness (25%)

Building on COVID-19 vaccine success, mRNA technology advances infectious disease management by:

- **Reducing development timelines** from years to months
- **Extending applications** to HIV, malaria, and tuberculosis
- **Enabling rapid adaptation** to emerging viral strains
- Allowing for **combination vaccines** and **simplified manufacturing**

"mRNA platforms have already demonstrated their ability to rapidly develop vaccines—as seen with the COVID-19 mRNA vaccines that were designed, tested, and deployed within a year. In the future, this speed could mean faster containment of outbreaks such as novel influenza strains or emerging zoonotic viruses."

### Expanded Longevity and Quality of Life (15%)

mRNA medicines promise broader life-enhancing benefits through:

- **Lifespan extension** and **improved quality of life**

- **Reduced reliance** on harsh treatments like chemotherapy
- **More targeted approaches** with fewer side effects
- Addressing **root molecular causes** rather than symptoms
- Restore cellular functions and slow disease progression (e.g. in inherited metabolic, neurodegenerative diseases, etc.)

*"Elongation of Life: For patients with inherited metabolic disorders, rare enzyme deficiencies, or neurodegenerative diseases, mRNA therapeutics have the potential to restore essential cellular functions, slow disease progression, and extend lifespan by addressing the root molecular cause of illness—not just its symptoms."*

### Manufacturing Innovations (14%)

mRNA technology transforms biopharmaceutical manufacturing by:

- **Simplifying** traditional complex biologics production
- **Enabling rapid development cycles** and small-scale personalized production
- **Creating viable economics** for ultra-rare disease therapies
- Leveraging the body's protein-producing machinery

*"Due to the reduced timelines, I believe this technology has the ability to provide more personalized medicines to patients. There is a possibility that samples could be taken...and then processed through some development phase where they could potentially make a targeted medicine for that specific patient in a matter of weeks."*

## 2.5 Nearly All (95%) Emphasized Artificial Intelligence's Importance for Unlocking mRNA Medicines

Question: What advancements will be necessary to move mRNA medicines forward over the next 5-10 years? (Open End, N=106, % = percentage who mentioned)

The future of mRNA medicines depends on integrating AI-driven design, scalable manufacturing, and targeted delivery, supported by strong regulatory frameworks and molecular engineering. As U.S. AI investment accelerates, advancing mRNA innovation in parallel is seen as critical to unlocking therapeutic potential and sustaining biotech leadership.

### Artificial Intelligence Integration (95%)

Nearly all participants emphasized AI's importance for unlocking mRNA medicines:

- Applications span sequence optimization, immunogenicity prediction, delivery system design, and clinical trial enhancement
- Particular promise for personalized medicine applications like neoantigen identification
- Incremental growth expected as high-quality datasets expand
- Complementary technologies that together can maintain U.S. biotech leadership

*"AI significantly would enhance the development of mRNA technology by improving design, optimizing processes, personalizing treatment, and accelerating clinical trials. The integration of AI and mRNA technology has great potential to bring more effective and safer therapies to patients more quickly and efficiently."*

## Manufacturing Innovation

Manufacturing limitations are a critical barrier to broader mRNA adoption:

- High production costs driven by specialized reagents
- Need for scalable methods supporting both mass production (vaccines) and personalized small-batch manufacturing (cancer therapies, rare diseases)
- Few companies capable of full commercial-scale production integrating plasmid/cell-free DNA synthesis, mRNA manufacturing, and LNP formulation
- Complex challenges in maintaining quality control across varied production scales

*"Precision manufacturing for N of 1 therapeutics that can be scaled out to serve hundreds of thousands of patients per year, in a cost-efficient manner."*

## Enhanced Delivery Systems

Current delivery systems face key limitations:

- Inadequate targeting beyond the liver (e.g. lung, muscle, brain, immune cells, etc.); need for organ- and cell-specific delivery
- Need to improve endosomal escape efficiency
- Need to reduce delivery vehicle immunogenicity
- Development of new carriers beyond traditional lipid nanoparticles (LNPs)

*"The most important advancement is going to be in delivery. The lipid nanoparticle, as it exists, is an adequate delivery system, but it is not optimal. It doesn't target well, it doesn't penetrate the cell that well, and if you want to move to diseases where you're not stimulating an immune response, but maybe trying to replace an enzyme using mRNA, you're going to need a better delivery system."*

## Supportive Ecosystem: Regulatory, Funding, and Public Engagement

Beyond technical innovations, experts identify the need for:

- Modernized regulatory frameworks suited to mRNA
- Sustained funding to continue innovation momentum post-COVID
- Stronger public education to counter misinformation
- Close collaboration between industry and regulatory authorities

*"We will need to publicly observe several success stories of mRNA therapies. Public perception, more than anything else, will enable future medical breakthroughs. If the public doesn't approve, mRNA will be bogged down, similar to stem cell research."*

## mRNA Molecular Engineering

Enhancing intrinsic mRNA properties focuses on:

- Improving stability through sequence optimization and 5' cap/poly(A) tail modifications to extend duration of action



- Reducing immunogenicity to minimize inflammatory side effects, especially for non-vaccine therapies
- Increasing potency to enable lower dosing and enhance therapeutic efficiency
- Exploring alternative structures like circular RNA for greater stability and functional flexibility

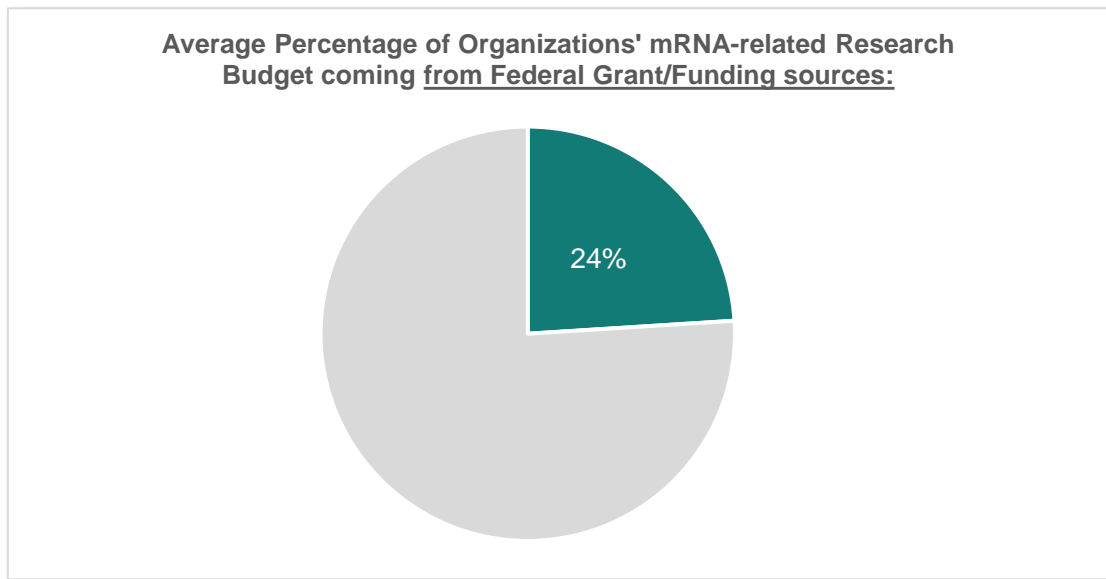
*"The primary enhancement needed now is in the production of high-quality mRNA drug substance, and in determining the canonical rules for translating a designer protein sequence into an mRNA (possibly in combination with a guide RNA) that is maximally effective and safe for human use, given the complexity and variability of the human immune system response across individuals."*



## Section 3: NIH Funding Impact

### 3.1 Percentage of mRNA-related Budget from NIH or Other Federal Funding

Question: What percentage of your organization's mRNA-related budget comes from NIH or other federal grant/funding sources, including HHS (BARDA, ARPA-H), NSF, DoD, VA, CDC, etc.? (Open End Numeric, n=26, those who have directly received NIH or other federal funding for mRNA-related research or projects).

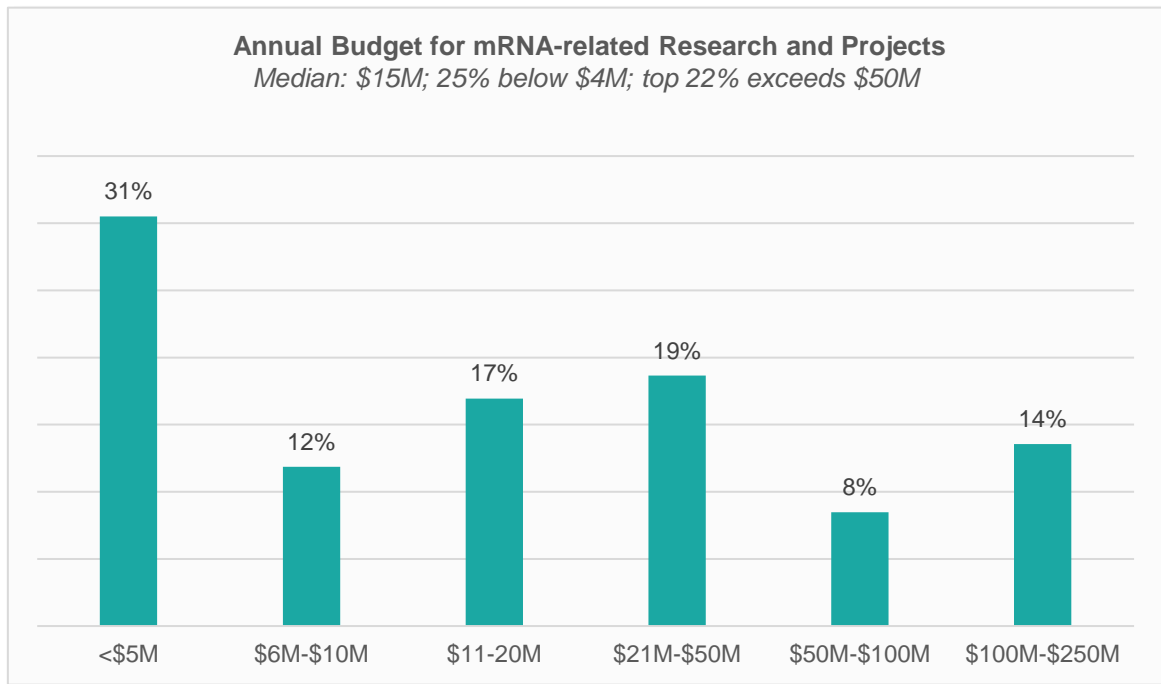


Additional mRNA budget sources for organizations that are receiving federal grants include:

- **Investment and traditional financing** (e.g. equity, debt, etc.) – **54%** of mRNA budget on average
- State or local grant/funding sources – 9% of mRNA budget on average
- Other sources – 14% of mRNA budget on average

### 3.2 Annual Budget for mRNA-related Research and Projects

Question: What is your organization's approximate annual budget for mRNA-related research or projects? Please provide your answer in total \$USD. (Open End Numeric, n=76, those who know their organization's approximate annual budget for mRNA-related research or projects)



### 3.3 Federal Funding Also Indirectly Impacts Organizations

Question: Please explain how your organization is indirectly impacted by federal funding for mRNA research or projects. Consider impacts through partnerships, supply chain, talent pipeline, collaborative research, or other relationships. (Open End, n=48, those who do not receive NIH funding, but their organization is indirectly impacted by federal funding, % = percentage who mentioned each theme)

These interconnected dependencies create a complex ecosystem where funding decisions ripple through multiple relationships, affecting even organizations without direct federal support. This underscores the urgent need for organizations to adopt more resilient R&D models and diversified partnership frameworks to sustain continuous mRNA innovation.

#### Academic/Research Partnership Disruption (44%)

Federal funding to academic institutions underpins the innovation pipeline:

- Universities generate critical discoveries and technologies that drive commercial development
- Funding cuts disrupt the flow of early-stage breakthroughs essential for industry growth
- Reductions create vulnerabilities across the ecosystem, even for companies not directly funded

*"While we do not receive funds directly from federal institutions like the NIH and maybe NSF and all that I think it's important to highlight the fact most of basic science takes place in our universities and they are sponsored by federal funding... our technology is coming from [an organization] which receives a lot of funding from NIH so if that funding were cut then chances are that [it would impact innovation]."*

## Collaborative Network and Client Disruption (44%)

Funding losses create operational and financial ripple effects across the ecosystem:

- **Cancelled agreements** as collaborators and partners lose funding
- **Delayed projects** and reduced demand for research and service providers
- **Revenue losses** impacting organizations multiple steps removed from direct recipients

*"We see a huge impact of federal budget cuts. Multiple partners or collaborators canceled the agreements with us."*

## Innovation Pipeline Vulnerability (27%)

Federal funding sustains critical early-stage innovation:

- Supports **proof-of-concept work** and translation of basic scientific discoveries
- Enables **high-risk exploratory research** vulnerable to private sector underinvestment
- Funds **rare disease research** and **foundational studies** without immediate commercial returns
- Maintains **essential building blocks** for future medical and technological breakthroughs

*"Well if you look at the amount of mRNA companies that are in early preclinical, sub 65% percent of the mRNA companies are currently in preclinical they haven't even gotten through to phase one or started their CMC... many of these companies are funded by federal organizations and they are just not getting the grants or funding that they need to do the good science to get them to the point where they have proof of concept."*

## Talent Pipeline and Workforce Development (25%)

Federal funding shapes the future scientific workforce:

- Organizations rely on scientists trained through federally funded academic programs
- Funding disruptions threaten long-term workforce development and talent pipelines
- Specialized expertise in emerging fields is particularly at risk
- Potential for talent shortages or migration to other industries or countries

*"Our strategy has been to hire the brightest and the best from research organizations in the US, so we do see that there's going to be an impact on highly qualified young people coming out that we can hire into our organization, particularly if there's a scale back in the research that is carried out in academia."*

## Market Dynamics and Investment Climate (15%)

Federal funding shapes private investment dynamics:

- Uncertainty or cuts trigger investor hesitancy and reduced confidence
- Limits organizations' ability to raise capital and secure partnerships

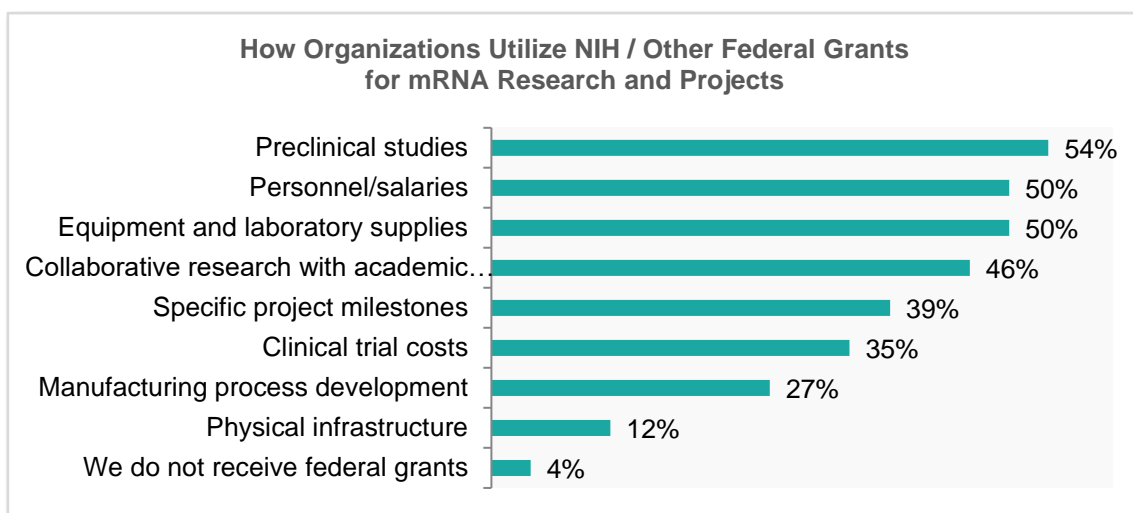
- Creates a complex interdependence between public funding and private investment flows
- Impacts financial stability across the broader innovation ecosystem

*"Venture capital funds are currently not doing anything; they're holding on to their money because there is no certainty that what is said today will still be true tomorrow."*

### 3.4 How Organizations Utilize NIH and Other Federal Funding

Question: How does your organization utilize NIH or other federal grants for mRNA research and projects? Select all that apply. (Multi Select, n=26, those who receive NIH or other federal funding, % = percentage who mentioned each theme)

Federal grant funding for mRNA research primarily supports foundational science, with a gap in later-stage development support. Small biotechnology companies—often the drivers of the most innovative preclinical therapies—depend heavily on these funds. Experts note that continued funding cuts therefore place some of the most promising early-stage pipelines at direct risk, potentially eliminating breakthrough therapies before they can reach patients.



### 3.5 Federal Funding Necessary for Key mRNA Breakthroughs

Question: What specific achievements or advances has your organization accomplished using NIH or other federal funding for mRNA research or projects? (Open End, n=26, those who receive NIH or other federal funding)

Federal funding for mRNA research has catalyzed transformative achievements across the entire development spectrum, with organizations successfully leveraging these resources to overcome critical bottlenecks in manufacturing scale-up, while simultaneously expanding mRNA applications beyond vaccines into oncology and other therapeutic areas, demonstrating how strategic public investment has accelerated the translation of laboratory concepts into real-world clinical impact.

#### Manufacturing Scale-Up

Federal funding has been crucial for scaling mRNA technologies:

- Addressed critical bottlenecks in moving from lab-scale to industrial production
- Enabled investments in automation systems, facility expansion, and process optimization
- Strengthened domestic manufacturing capacity for resilience and rapid response
- BARDA funding played a key role in pandemic preparedness efforts

"We have used federal funding to build out our automation capabilities to develop high throughput cloning and mRNA production for screening of new constructs."

### Clinical Translation of mRNA Therapies

Federal funding has accelerated mRNA clinical advancement:

- Enabled progression from preclinical testing to Phase 1 trials
- Supported advancement into later-stage clinical development
- Expanded therapeutic focus beyond COVID-19 vaccines
- Advanced applications in oncology (e.g., pancreatic, triple-negative breast cancer) and infectious diseases (e.g., H5N1 influenza)

"We have developed a personalized cancer vaccine program against triple negative breast cancer that will be initiated this year, and that was supported in part by NIH funding."

### Preclinical Validation and Optimization

Federal funding has enabled critical de-risking for mRNA development:

- Mechanistic validation and refinement of mRNA approaches
- Translation of laboratory findings into in-vivo models
- Optimization of dosing strategies and formulation stability
- Support for foundational studies often too exploratory for commercial investment

"This collaboration—enabled in part by the heightened federal interest in RNA technologies following the pandemic—helped demonstrate that mRNA platforms could generate strong, antigen-specific T-cell responses. Early preclinical studies provided proof-of-concept data that laid the groundwork for subsequent clinical trials targeting immuno-oncology indications."

### Strategic Research Collaborations

Federal funding has fueled critical multi-stakeholder collaborations:

- Strategic alliances linking academia, industry, and government agencies
- Partnerships with major pharmaceutical companies
- Public-private funding models and knowledge exchange initiatives
- Collaborative research networks accelerating mRNA innovation

"We developed our platform with a public/private funding partnership. We have been very focused on developing made-in-America products."

### Innovative Platform Technologies

Federal funding has enabled key technological breakthroughs in mRNA:

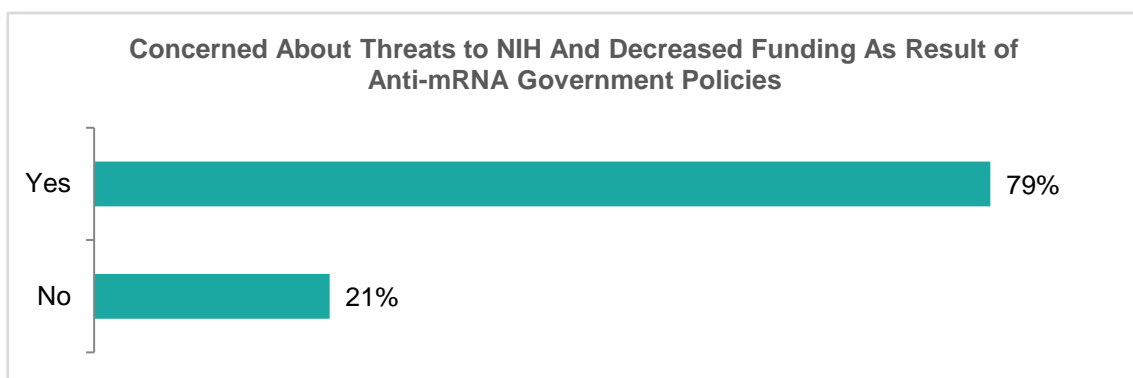


- Development of novel delivery systems like optimized lipid nanoparticles
- Enhancement of molecular components such as improved RNA polymerases
- Creation of new platform variants, including circular RNA
- Expanded functionality, efficacy, and versatility across diverse therapeutic applications

*"Discovery and characterization of single subunit RNA polymerases that exhibit improved qualities, such as purity, cap incorporation, integrity, and lower dsRNA compared to the industry standard of T7."*

### 3.6 Most Express Concern Over NIH Funding Threats from Anti-mRNA Government Policies

Question: Are you worried about threats to the NIH as it relates to decreased funding as a result of anti-mRNA government policies? (Single Select, N=106)



### 3.7 Perspectives on Other Potential Anti-mRNA Government Policies

Question: What about other potential anti-mRNA government policies, including threats to other funding/grant sources, cutting other internal federal agencies (such as the FDA, BARDA, ARPA-H, CDC, and CMS) or state/ federal mRNA bans? (Open End, N=106, % = percentage who mentioned each theme)

Anti-mRNA policies create a potentially self-reinforcing cycle where scientific innovation, industry stability, and global competitiveness deteriorate simultaneously—ultimately transforming the United States from a pandemic solution provider to a dependent nation reliant on foreign biomedical advances.

#### Disruption of the mRNA Research and Development Pipeline (67%)

Anti-mRNA policies would trigger cascading research bottlenecks:

- Impede clinical translation and commercialization of new therapies
- Disproportionately impact early-stage research and breakthrough applications
- Create regulatory approval bottlenecks, even for funded projects
- Lead to halted trials, abandoned research, and prolonged development timelines

*"This would stall preclinical and early clinical development, particularly for oncologic, neurodegenerative, and pediatric rare disease applications, many of which depend entirely on federal seed funding."*

*"Clinical trials will be halted if these policies are put in place, which compromises countless years of research and funding, not to mention the people involved in the trial who would be left without recourse."*

### **Economic and Workforce Destabilization (26%)**

Anti-mRNA policies threaten organizational viability:

- Disproportionately impact smaller biotech companies reliant on federal support
- Drive talent exodus as researchers leave amid funding uncertainty
- Undermine market confidence, making continued investment harder to justify
- Disrupt critical collaborative networks linking academia, industry, and government

*"Reduced funding will distract talent from coming to the U.S. Current experts will leave their posts. It is already happening."*

*"Biotech and big pharma cannot be innovative if they are not influenced by academic research. It will be interesting to avoid this cut-off, let's say, academic research."*

### **Undermining of Scientific Integrity (24%)**

Anti-mRNA policies often stem from non-scientific motivations:

- Undermine scientific integrity and erode public trust
- Arise from misinformation or inadequate scientific understanding
- Reinforce negative perceptions and reduce public acceptance
- Create barriers to adoption even for effective therapies

*"It simply creates a bad name for all mRNA work, regardless of the field, from a public opinion point of view. People working in the field know how much work went into the science behind mRNA platform modalities."*

### **Delayed Patient Access and Compromised Health Outcomes (15%)**

Anti-mRNA policies would harm patients directly:

- Severely impact vulnerable populations with limited treatment options
- Affect patients with rare diseases, cancer, and immune-compromised conditions
- Undermine pandemic preparedness and rapid response capabilities
- Delay or block access to potentially life-saving therapies

*"The current situation is untenable. The cuts to funding will be disastrous for every disease state, especially orphan diseases. Our organization is terrified by these cuts, and as a parent of two children with cystic fibrosis, I fear that research will stall and new therapies won't come to fruition. It is devastating."*

### **Diminished U.S. Global Leadership (13%)**

Anti-mRNA policies would erode U.S. leadership in biotech:

- Trigger a global shift in research, investment, and talent to more supportive regions

- Push researchers, companies, and capital abroad
- Enable countries like China to gain technological and economic advantage
- Increase U.S. dependence on foreign sources during future health crises

*"As we see cuts to FDA, BARDA, and other agencies or federal organizations, we are likely to be moving our investment away from the U.S. and focusing in on other jurisdictions that are easier to deal with. So, we would likely be carrying out more partnerships within Europe, for example, and also with Asia."*

### 3.8 Increased mRNA Support Would Drive mRNA Collaboration and Manufacturing

Question: Let's think about a scenario where instead of cuts and anti-mRNA government policies, there is increased support, both in terms of funding and personnel, from the FDA and other regulatory agencies on mRNA-related matters. Could you tell me what specifically such a change could do to better support your organization? (Open End, N=106, % = percentage who mentioned each theme)

Increased support for mRNA research would unlock breakthrough medical innovations by creating an integrated ecosystem where high-risk scientific exploration, streamlined regulatory pathways, cross-sector collaboration, and domestic manufacturing capabilities collectively address critical healthcare challenges while strengthening national competitiveness.

#### Enhanced Research Capabilities and Innovation (44%)

Additional funding could expand mRNA research scope and depth:

- Hire more scientists and scale experimental efforts
- Pursue higher-risk, potentially transformative projects
- Advance mRNA properties like stability, delivery, and potency
- Expand applications into more challenging therapeutic areas

*"If there is an increase in mRNA funding and personnel, I think there's a lot left to achieve. The organizations can start working on the next generation mRNAs, and yeah, we can target several life-threatening and other clinical indications which do not have a cure as of today."*

#### Accelerated Regulatory Processes (40%)

Increased regulatory support would accelerate mRNA development:

- Provide critical clarity on mRNA-specific regulatory guidelines
- Address uncertainty that hampers development timelines and increases risk
- Establish specialized frameworks for novel mRNA applications
- Streamline agency interactions and restore COVID-era regulatory efficiencies

*"One of the difficulties that the mRNA field has been struggling with since its inception and most of all after COVID is a lack of regulatory guidelines...as long as there is no regulatory clarity on what is and what is not acceptable, we don't know how to develop our processes."*

#### Strengthened Cross-Sector Collaboration (25%)

Government support would strengthen the mRNA innovation ecosystem:

- Stimulate collaborations between academia, industry, and regulatory agencies
- Build knowledge exchange networks and shared research infrastructure
- Foster collaborative R&D linking fundamental science to applications
- Facilitate talent movement across sectors and communities of practice

*"Basically, if there are more funding toward the mRNA-related matters, then there are more papers going out from universities. Universities are able to run more preclinical research. This creates more spin-off companies, biotech companies that would rather go into phase one materials and then this phase one would be provided to CDMOs and the CDMO activity would thrive."*

### **Economic Competitiveness (21%)**

Organizations emphasized broader economic and strategic benefits:

- Strengthened national competitiveness in the global mRNA landscape
- Job creation, biotech sector growth, and development of centers of excellence
- Stable investment environment attracting private capital
- Established reimbursement frameworks and protection of intellectual property rights

*"IP protection and capital investments into infrastructure are critical to secure a U.S. position of protection scientifically and economically. Preventing the intellectual brain drain from the U.S. to other regions is important for U.S. economic stability, production, protection, and strength."*

### **Enhanced Manufacturing Capacity (14%)**

Increased support would strengthen mRNA manufacturing infrastructure:

- Build domestic manufacturing capabilities to ensure supply chain resilience
- Reduce production costs and improve manufacturing quality
- Provide access to manufacturing resources for smaller organizations
- Address bottlenecks in translating research into clinical-grade materials and products

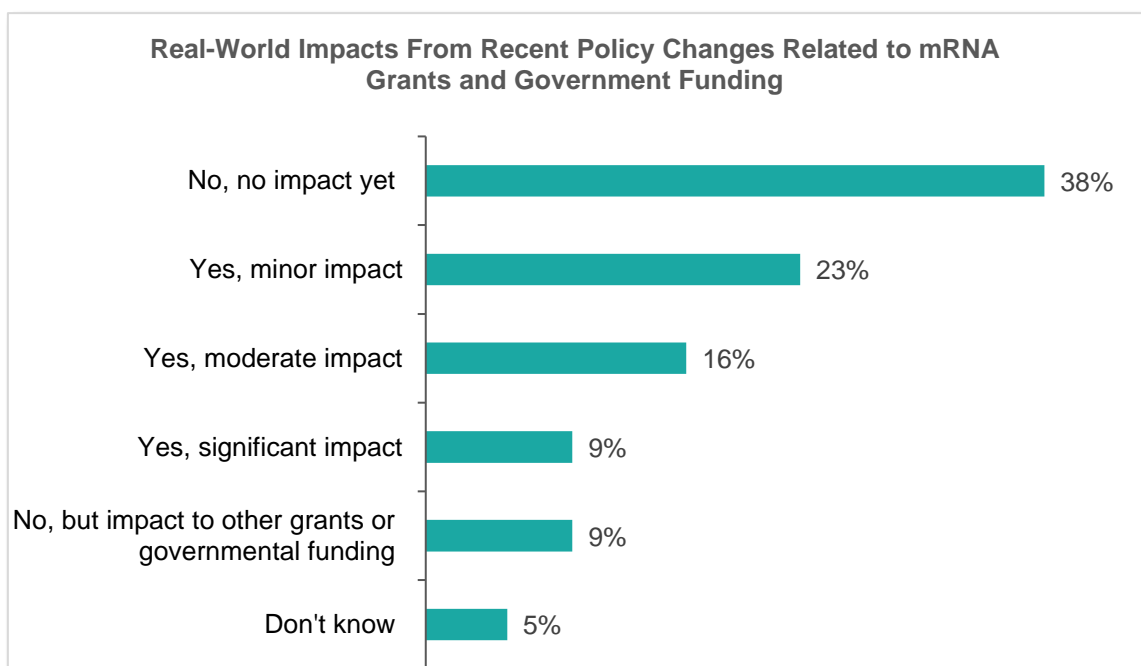
*"If ARPA-H or BARDA funded regional GMP mRNA facilities or core infrastructure grants: Academic and nonprofit labs like ours could access shared manufacturing capacity for IND-grade LNPs and RNA synthesis, reducing our dependence on costly outsourcing."*

## Section 4: Real World Impact

### 4.1 Nearly Half (48%) Have Experienced Direct Real-World Impact from mRNA Funding Policy Shifts

Question: Has your organization already experienced any real-world impact from recent policy changes related to mRNA grants and governmental funding? (Single Select, N=106)

The mRNA field is experiencing a bifurcated impact from recent policy changes, with 48% of organizations feeling direct mRNA effects (ranging from minor to significant) while another 9% have been affected by funding cuts but only indirectly to mRNA and 38% remain largely insulated, suggesting an uneven distribution of funding policy consequences that likely reflects organizational differences in funding dependency, geographic location, and strategic positioning within the mRNA ecosystem.



### 4.2 Range of Economic Consequences from Recent Policy Changes

Question: What economic consequences has your organization experienced from these changes? Select all that apply. (Multi Select, N=61, If chose one of the three "Yes..." responses or the "No, but impact to other grants or governmental funding" from question in 4.1)



### 4.3 Specific Impacts Already Experienced Due To Recent Policy Changes

Question: Please describe the specific impacts your organization has experienced due to recent policy changes related to mRNA grants or governmental funding AND/OR other grants or governmental funding. (Open End, N=61, If chose one of the three "Yes..." responses or the "No, but impact to other grants or governmental funding" from question in 4.1)

Funding policy changes are not just creating temporary operational challenges but are reshaping the global therapeutic innovation landscape as organizations shift research priorities away from high-risk mRNA projects and physically relocate intellectual capital from the U.S. to Europe and Asia.

#### Research Operation Disruptions

Policy changes have forced organizations to adjust development activities:

- Delayed timelines, reduced project scope, and program terminations
- Postponed clinical trials and curtailed research studies
- Inefficient resource allocation due to funding uncertainty
- Cascading impacts compromising long-term research goals

*"We had a collaboration with a strategic partner and lost NIH funding recently. Our partner canceled the partnership, and all the project activities came to a stop. We have already invested a lot of money on this project (people, equipment, capital investment)."*

#### Budget and Funding Constraints

Organizations are experiencing direct financial impacts:

- Immediate funding cuts and uncertainty around future grants
- Severity ranging from manageable reductions to existential threats
- Budget freezes and reduced R&D investment



- Sunk costs from halted projects and sustainability concerns

*"When the availability of grant funding is restricted, the probability of getting that funding is minimal or not possible at all, and that impacts our R&D expenses. Then, we have to reassess and reduce our R&D spending."*

## Collaborative Relationship Realignments

Policy changes are disrupting collaborative relationships:

- Terminated or paused partnerships, especially with academic institutions
- Geographic shifts of collaborations to Europe and Asia
- Funding constraints and policy uncertainty driving international moves
- Disruption of research synergies and innovation ecosystems

*"A lot of our partnerships were in the U.S., and those are right now on pause. We cannot proceed further with them. We have to think about how we can move our long-term U.S. collaborations to other countries in Europe or Asia, and we're currently working on establishing a budget to transfer all those projects."*

## Scientific Workforce Contractions

Organizations are making significant workforce adjustments:

- Layoffs, hiring freezes, and compensation restructuring
- Talent reallocation and geographic workforce shifts
- Impacts extending beyond job losses to specialized talent retention
- Substantial staff reductions in research-intensive departments

*"We are actually facing a hiring freeze right now, and we are not hiring anyone from the U.S. We are making strategies to reduce headcount there because if there is no future work happening, then paying those salaries and investing in those facilities doesn't make any sense."*

*"I think one of the key experiences in terms of the recent policy changes is that there have been a lot of decreases in pay, no merit increases, the bonuses have been drastically cut, the jobs have been frozen, and the people who were redundant have gone through workforce reduction. Also, the most important thing is that there has been no travel."*

## Strategic Reprioritization

Organizations are implementing major strategic shifts:

- Reprioritizing therapeutic indications based on funding realities
- Redirecting resources toward alternative modalities
- Relocating operations to more supportive geographic regions
- Reassessing research portfolios, often at the expense of higher-risk innovation

*"We had to reallocate resources away from mRNA towards CAR-T and NK cells due to challenges in funding."*

## 4.4 Other Organizations Across Scientific Innovation Adversely Affected

Question: Do you know of any other organizations across industries that have been adversely affected due to recent policy changes related to mRNA grants or governmental funding AND/OR other grants or governmental funding. (Open End, N=106)

Policy changes targeting mRNA funding expose a fundamental vulnerability in scientific innovation ecosystems—where disruption at one-point triggers cascading failures across interconnected organizations in academia, industry, and international collaboration, potentially causing structural damage to research capacity and global competitive positioning.

### Industry Operational Restructuring

Biotech and pharmaceutical companies are making major operational adjustments:

- **Workforce reductions**, program cancellations, and strategic reprioritization
- **Downsizing** reported even among established players
- **CDMOs facing layoffs** and facility closures
- Many organizations are **narrowing research focus** and reallocating resources beyond mRNA

*"Yeah, I've had—given the negative sentiments in the mRNA space—I've seen companies downsize. [Several large mRNA companies have downsized or are considering it], and RNA cell and gene companies are just—it's just hard to raise money in this environment because investors are not bullish in this space, and it makes it harder to raise money and companies are just filing for bankruptcy or laying off people."*

### Academic Research Funding Crisis

Academic institutions are facing profound operational challenges:

- **Spending restrictions**, hiring freezes, and program terminations
- **Reduced capacity** in PhD programs and early-career research opportunities
- **Major research centers impacted**
- **Intergenerational effects** risking long-term damage to the scientific talent pipeline

*"Our academic collaborators have mentioned that they have concerns about having to cut programs and reduce the size of incoming grad school classes. An entire generation of potential scientists could be hampered by NIH cuts and general government hesitancy to fund basic research."*

*"I've heard potential plans to lay off from multiple non-profit organizations."*

### R&D Ecosystem Disruption

Funding changes are creating ripple effects across the R&D ecosystem:

- Severed academic-industry partnerships as companies withdraw from early-stage collaborations
- Strained international research collaborations, especially with cost-competitive regions like China

- Negative impacts on supporting industries, including raw material and reagent suppliers
- CROs supporting early clinical development facing significant operational challenges

*"The entire scientific ecosystem has been affected, from reagent manufacturers to companies producing disposables, consumables, etc."*

*"Restrictions to governmental funding of research conducted in partnership with cost-competitive Chinese organizations has reduced the number of competitive service providers and increased overall drug development costs."*

### **Shifting International Dynamics**

Policy changes are reshaping the international research landscape:

- Foreign-trained specialists are planning to leave the U.S., creating clinical trial staffing shortages
- Companies are pausing or relocating U.S. manufacturing investments due to political uncertainty
- Organizations are forming international partnerships, particularly in Europe and Asia
- European pharma companies, especially in Germany, report major disruptions tied to U.S. policy shifts

*"We have heard about some of the hospitals that we work with who are conducting clinical trials have seen that the physicians who come from foreign places are making plans to leave the U.S. This is going to put some of our trials and some of our hospitals under a lot of pressure because there's not an easily available lot of staff to cover for some of the vacancies that this is creating."*

## Section 5: Potential Funding Disruptions and Anti-mRNA Government Policies

### 5.1 Over Half (53%) Expect Delayed Initiatives if mRNA Federal Funding Reduced

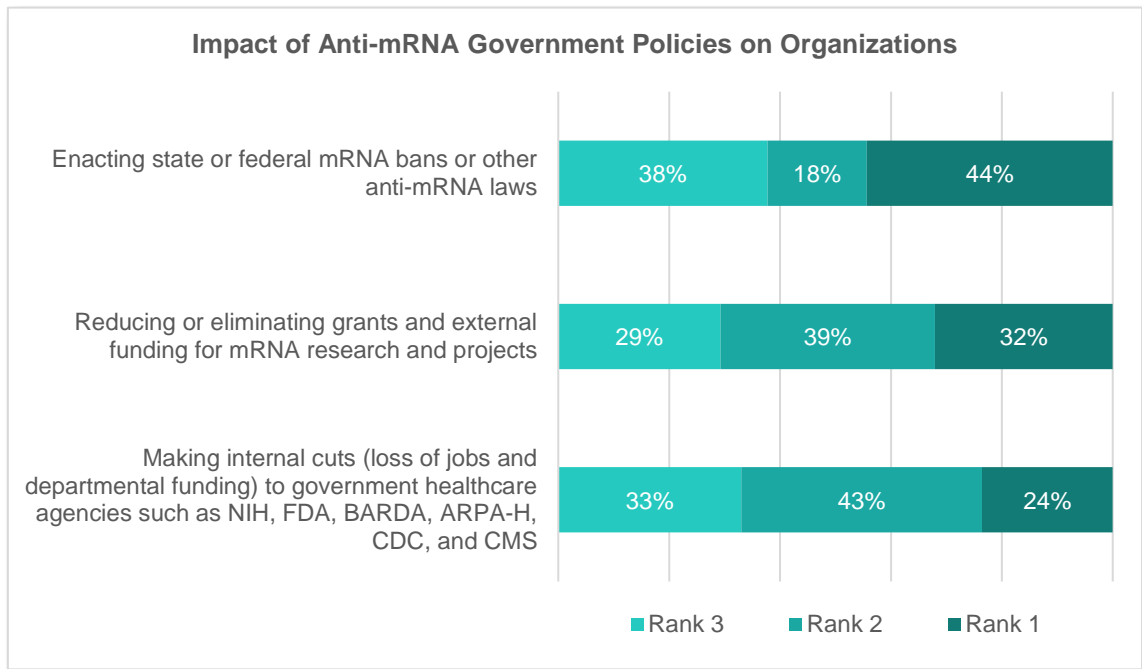
Question: Looking into the future, what specific consequences would your organization face if federal funding for mRNA research and projects were significantly reduced from where it is today (beyond what you may have already experienced)? (Multi Select, N=106)



### 5.2 State or Federal mRNA Bans Would Have the Greatest Impact on Organizations

Question: Please rank how the following anti-mRNA government policies would affect your organization, in order of their greatest potential impact with 1 being the highest. (Ranking, N=106)

This suggests that direct legislative prohibition presents a more immediate existential threat to organizations than gradual funding reductions.



**Follow-Up Question:** Why do you believe [Rank #1] has the greatest potential impact on your organization?

**Reasons ‘Enacting Federal or State Bans’ Ranked as #1 Potential Impact:**

Enacting state or federal mRNA bans is seen as the most impactful threat to 44% of participants because it would dismantle the entire research, investment, manufacturing, and commercialization ecosystem—halting innovation, collapsing market viability, and endangering public health.

**Comprehensive Disruption of Market, Operations, and Research Ecosystem**

The dominant theme highlights the multi-faceted impact of legal restrictions that would eliminate market incentives, remove the U.S. as a viable market, halt manufacturing and research, disrupt supply chains, and potentially force relocation of operations abroad.

*"That would restrict the kind of medicines that could be made by pharmaceutical companies, and if those medicines could not be made or sold, companies would have no incentive to design them."*

*"If mRNA bans are enacted, our customers will immediately stop work on mRNA-based programs, halting both consumable and capital sales instantly."*

**Deterrence of Investment and Collapse of Economic Viability**

Experts emphasize that bans would make investments "too risky", triggering immediate withdrawal of private capital and effectively "killing the whole field" by making commercialization impossible.

*"If there is a reduced market for the vaccines in the U.S., nobody will fund these products with VC money."*

### **Immediate Halt to Research and Development Activities**

Participants stress that bans would immediately stop projects "in their tracks," completely halting rather than merely slowing research progress and forcing relocation of operations.

*"Innovative research and development activities would have to stop for USA-based companies, regardless of whether they are funded by private or government sources."*

*"If there were laws and bans around this, we would not be able to make material or drugs in the U.S. with these technologies."*

### **Obstruction of Medical Progress and Public Health Protection**

Responses highlight that mRNA bans would block critical medical advances, increase mortality from preventable diseases, and eliminate potential curative treatments for currently incurable conditions.

*"It can lead to halted medical advancements; for example, a ban could slow or stop the progress in these areas, leading to significant public health risks."*

### **Reasons 'Reducing or Eliminating Grants and External Funding' Ranked as #1 Potential Impact:**

Reducing or eliminating grants and external funding would significantly slow mRNA innovation, disrupt early-stage research, and destabilize the scientific workforce, though some believe alternative funding could partially mitigate the impact.

### **Slowed Innovation and Disrupted Research Progression**

The predominant theme emphasizes that reducing or eliminating grants and external funding would severely impede innovation and research progression in mRNA technology. Many describe funding as "critical" to supporting current R&D and advancing projects to clinical development. Respondents highlight that mRNA technology is still in its early stages, with numerous technical challenges requiring significant innovation efforts that depend heavily on external funding.

*"Because the research level is where everything starts – if we reduce that, we're not testing as many drug candidates, which means fewer successes and fewer large-scale manufacturing jobs later."*

*"Reducing or eliminating grants for mRNA research would have a huge impact by slowing down innovation and progress in vaccine and therapy development, delaying clinical trials and access to life-saving treatments."*

### **Economic Disruption and Workforce Destabilization**

Experts describe a "trickle-down effect" where reduced academic funding leads to diminished innovation, fewer trained researchers and clinicians, and ultimately a smaller workforce in the industry.

"The impact is already evident with partners pulling away from projects, indicating a disruption in our supply chain and collaborative efforts."

### Alternative Funding Strategies as Mitigation

Some experts suggest that the impact of reducing grants and external funding might be mitigated through alternative funding approaches. One participant noted that organizations "cannot depend completely on grants" and must "rely on alternative funding," indicating a need for funding diversification. Another stated that their "internal projects are funded by other sources," suggesting limited vulnerability to external funding cuts.

*"Because the mRNA innovation is promising and industry leaders see it as life-changing, firms will bet on it."*

### Reasons 'Making Internal Cuts to Government Healthcare Agencies' Ranked as #1 Potential Impact:

Internal cuts to government healthcare agencies are seen as highly impactful to 24% because they would delay regulatory approvals, disrupt early research funding, and weaken the operational infrastructure that supports mRNA innovation and commercialization.

### Regulatory Delays and Approval Bottlenecks

The primary concern focuses on how agency cuts would impair regulatory review processes, creating significant delays in application approvals and clinical trial initiations. Multiple respondents specifically mention delayed IND (Investigational New Drug) reviews and slower clearance of medical devices and therapeutics. Several experts also highlight the cascading effect where delayed regulatory processes impact other companies' applications and ultimately affect patients.

"There won't be enough personnel in the agencies, leading to backlogs in approvals for medical devices, therapeutics, and ultimately delaying access to cures."

### Disruption of Research Funding and Operational Infrastructure

Experts emphasize that government agencies serve as critical funders and de-riskers of early mRNA research, with one participant describing them as "the first VC" in the innovation pipeline. Multiple respondents highlight that internal cuts would directly affect funding flows, institutional support, and collaborative capabilities. Several note that reduced government funding can negatively influence private investor sentiment.

*"Many of our biotech clients rely on government funding for sourcing and developing their RNA innovation."*



## 5.3 Organizations Reiterate Financial Pressures and Regulatory Hurdles As Additional Threats

Question: Are there any other potential factors that you believe could have the greatest impact on your organization?  
(Open End, N=106)

The mRNA sector stands at a critical inflection point where interconnected challenges across financial stability, regulatory clarity, public confidence, global competitiveness, and supply chain resilience create a systemic vulnerability landscape that threatens organizational viability and requires coordinated solutions to successfully transition from pandemic-driven growth to sustainable commercial development.

### Financial Sustainability and Funding Ecosystem

Financial sustainability is a critical concern for mRNA organizations:

- Direct funding cuts and broader economic pressures threaten stability
- Vulnerability varies; some rely on internal R&D funding, others depend on external capital
- Existential risk for organizations heavily reliant on venture or public funding
- Healthcare reimbursement policies, especially Medicare/Medicaid, are key to market viability

*"Yes, a refusal by Medicare to reimburse gene editing medicines would be devastating to the field."*

*"If the financial markets continue to stay soft and I'm not able to raise the money to build out the mRNA manufacturing capabilities for personalized medicines in the Boston area, my company will not be a viable entity."*

### Regulatory Barriers and Political Interference

Organizations express deep concern about political and regulatory threats:

- Politically motivated anti-mRNA policies undermining research continuity
- Potential government bans that could block access to FDA-approved therapies
- Regulatory hurdles slowing clinical development and approval timelines
- Both catastrophic risks from outright bans and cumulative damage from regulatory burdens

*"State or federal bans could: Prevent physicians from offering FDA-authorized or approved mRNA therapies, Block hospitals from participating in clinical trials or expanded access programs, remove patient autonomy in seeking advanced treatments, even in terminal cases..."*

### Public Trust and Market Perception

Public sentiment and market confidence are critical to mRNA's future:

- Negative public perception ripples through investor sentiment and funding flows
- Impacts market acceptance, regulatory decisions, and organizational viability
- Creates multi-layered barriers that hinder technology adoption

*"If there is significant public sentiment against mRNA medicines, it is hard to make a business case for it."*

## Global Competition

International competition presents major challenges for mRNA organizations:

- Vulnerability to unfair practices like foreign market dumping
- Intellectual property theft concerns, especially involving Chinese entities
- Foreign competitors leveraging financial strength to gain market advantages

*"Keeping the Chinese from dumping reagents and consumables on the U.S. market and using their strength and dollars to steal IP and drive anticompetitive behavior in the biotech industry."*

## Supply Chain Resilience

Robust supply chains and domestic manufacturing are strategic priorities:

- Immediate operational challenges from material shortages
- Rising costs of overseas-sourced materials
- Long-term need to build resilient domestic production infrastructure

*"Supply chain shortages and domestic manufacturing capability."*

## 5.4 Anti-mRNA Policies Could Cause Major Operational Disruption

Question: How would your organization specifically be affected if anti-mRNA government policies are established, including funding/grant disruptions, cutting internal federal agencies and state or federal mRNA bans (beyond what you have already experienced)? (Open End, N=106, % = percentage who mentioned each theme)

Anti-mRNA policies represent an existential watershed for an emerging biomedical ecosystem, threatening not just individual therapies but an entire innovation infrastructure—driving specialized organizations toward extinction, forcing critical research offshore, and fundamentally restructuring the global competitive landscape in advanced therapeutics in ways that would be difficult to reverse once momentum is lost.

### Operational Disruption (41%)

Organizations anticipate major disruptions across operations and research:

- Complete operational halts or scaled-back activities with selective program freezes
- Workforce impacts from targeted cuts to major scientific staff layoffs
- Research disruptions, especially for projects at critical transition points
- Delays in FDA review processes compounding development pipeline challenges

*"If NIH, DoD, or BARDA funding were cut or reallocated due to anti-mRNA sentiment, we would be forced to terminate preclinical and IND-enabling studies, Lose momentum on projects nearing first-in-human readiness, Be unable to support postdocs and research staff currently funded by these grants."*

## Financial Vulnerability (19%)

Anti-mRNA policies create multifaceted financial challenges:

- Direct constraints from government funding cuts
- Indirect erosion of investor confidence through negative policy signals
- Increased difficulty securing private equity, venture capital, and industry partnerships
- Disproportionate impact on high-risk innovation typically reliant on government de-risking

*"As stated, federal funding cuts would reduce high-risk innovation research breakthroughs since private investors are risk averse. Also, an outright ban on mRNA drugs would stop the entire industry."*

## Strategic Portfolio Realignment (17%)

Organizations are implementing deliberate strategic adaptations:

- Reprioritizing portfolios and reallocating resources away from mRNA projects
- Redirecting efforts toward alternative modalities like protein-based therapies, synthetic delivery systems, and gene-editing platforms
- Depth of realignment varies based on each organization's mRNA specialization

*"I think my organization, as a CDMO, would also start thinking about how it can divert the existing technology manpower and then the resources which are available internally to do something else other than mRNA because there are such strong anti-mRNA government policies."*

## Existential Business Model Threats for mRNA-Centric Organizations (17%)

For mRNA-focused organizations, anti-mRNA policies pose an existential threat:

- No viable path forward under restrictive policies
- "Catastrophic" impacts described, with an all-or-nothing outlook
- Some state plainly their organizations "would not exist" if mRNA were banned

*"Catastrophic impact, as we are an mRNA medicines company with proprietary mRNA and mRNA delivery system platforms."*

## Geographic Displacement (16%)

Organizations anticipate strategic geographic shifts driven by policy pressures:

- "Push" factors include escaping restrictive U.S. policies
- "Pull" factors include more supportive regulatory and funding environments abroad
- Shifts range from complete research relocations to targeted moves in manufacturing and clinical trials
- Alternative bases mentioned include Europe, Canada, and Asia

*"Need to manufacture and run clinical trials outside the US. Avoidance of FDA filing, focusing on EMEA or other regions to evaluate RNA medicines."*

## 5.5 Anti-mRNA Policies Threaten Rare Disease and Cancer Patients Most

Question: If anti-mRNA government policies, including funding/grant disruptions, cutting internal federal agencies and state or federal mRNA bans forced your organization to slow or halt research and projects, describe any specific patient populations or communities that would be adversely impacted. (Open End, N=106, % = percentage who mentioned each theme)

Anti-mRNA policies could significantly impede medical innovation progress that disproportionately harms the most vulnerable patient populations—including rare disease communities, cancer patients with limited alternatives, and underserved demographic groups—while simultaneously dismantling critical pandemic infrastructure, effectively sacrificing both current lives and future generations' access to potentially transformative treatments.

### Vulnerable Rare Disease Communities (46%)

Rare disease patients would face disproportionate harm:

- Already limited treatment alternatives and historical underservice by conventional pharma
- mRNA offers potentially transformative therapies for these populations
- Children with rare diseases are particularly vulnerable to delayed interventions
- Delays could result in life-long consequences or premature death

*"Rare disease patients would be hit the hardest because they are traditionally underserved by large for-profit pharmaceutical companies."*

### Impact on Cancer Patients Across Treatment Stages (45%)

Disruptions would severely impact cancer patients:

- Affect patients with advanced or difficult-to-treat cancers (melanoma, pancreatic, Triple Negative Breast Cancer)
- Interrupt treatment for patients already enrolled in clinical trials
- Eliminate opportunities for personalized cancer vaccine development
- Disproportionately harm patients with few alternative treatment options

*"Triple-negative breast cancer disproportionately affects younger women and women of color, especially African American and Hispanic populations. It is highly aggressive and lacks targeted therapies."*

*"As the data comes in that personalized RNA cancer vaccines actually are effective, all the preliminary data does suggest that these mRNA cancer vaccines will be effective for cancers that are now difficult to treat, such as pancreatic cancer."*

### Infectious Disease Prevention and Pandemic Preparedness (32%)

A slowdown in mRNA research would undermine public health and pandemic preparedness:

- Hamper everyday infectious disease management
- Weaken large-scale public health and outbreak response capabilities
- Leave populations vulnerable to future pandemics
- Undercut rapid-response efforts where mRNA's speed is critical

*"The loss of mRNA as a tool for fighting infectious disease will likely ensure that we will not be able to rapidly respond to the next pandemic, which could be even more devastating than COVID."*

### Impacts on Vulnerable Demographic Groups (16%)

Disruptions would disproportionately harm vulnerable demographic groups:

- Pediatric patients and elderly individuals facing age-based vulnerabilities
- Immunocompromised populations heavily reliant on mRNA advances
- Rural, inner-city, and lower-income communities affected by socioeconomic disparities
- Overlapping challenges amplify consequences for marginalized groups

*"Children, elderly, and the immunocompromised are likely to be the most adversely impacted. Lower-income communities around the world are also in jeopardy."*

### Specialized Therapeutic Areas with Unique mRNA Applications (14%)

Specialized conditions would lose access to potential mRNA breakthroughs:

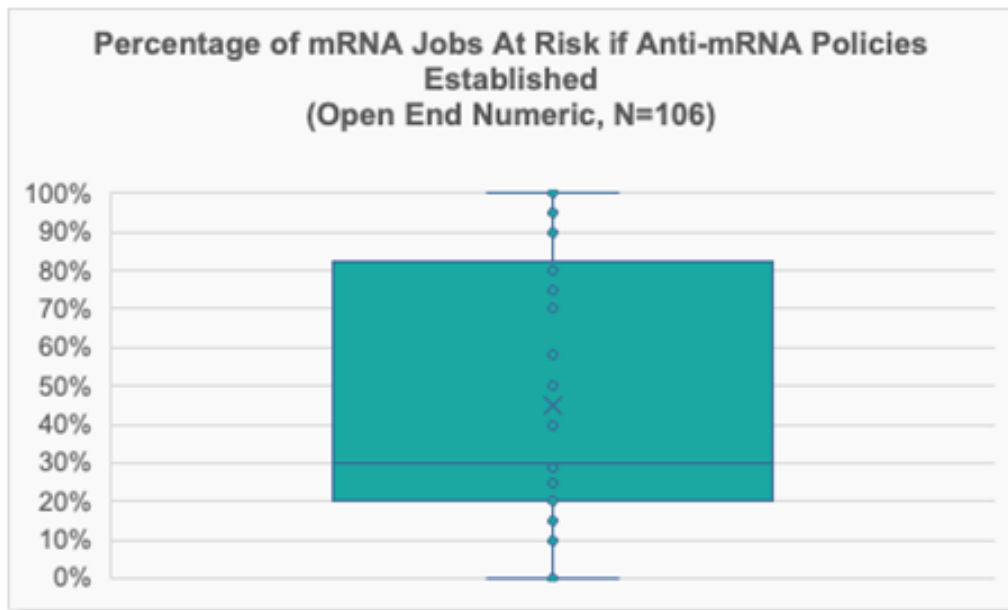
- Neurodegenerative diseases or disorders
- Autoimmune diseases
- Specific organ system diseases uniquely suited to mRNA solutions
- Conditions with few or ineffective conventional treatment options

*"I think there may be particular impacts on those with neurodegenerative disease. In the area of oncology, the impact may be more delayed but will be significant."*

## 5.6 Organizations Predict 45% Of Jobs Would Be At-Risk Under Anti-mRNA Government Policies

Question: If anti-mRNA government policies are established (including funding/grant disruptions, cutting internal federal agencies and state or federal mRNA bans) approximately what percentage of mRNA-related jobs at your organization might be at risk? (Open End Numeric, N=106)

Up to 45% of mRNA-related jobs are potentially at risk, with 21% of respondents indicating **all** such roles at their organization could be eliminated under hostile policy conditions



## 5.7 Anti-mRNA Policies Would Create a Broad Disruption of Research Innovation

Question: How would enacting anti-mRNA government policies, including funding/grant disruptions, cutting internal federal agencies and state or federal mRNA bans affect the broader development of treatments for cancer, rare diseases, and other therapeutic areas? (Open End, N=106, % = percentage who mentioned each theme)

Anti-mRNA policies would create a devastating cascade of medical innovation regression that disproportionately harms the most vulnerable patient populations—including rare disease communities, cancer patients with limited alternatives, and underserved demographic groups—while simultaneously dismantling critical pandemic infrastructure, effectively sacrificing both current lives and future generations' access to potentially transformative treatments.

### Broad Disruption of Research Innovation (57%)

Anti-mRNA policies would severely disrupt the treatment development continuum:

- Cause significant delays of 5–15 years in therapeutic advancement
- Create technical barriers to lead validation and development
- Result in canceled clinical trials and widespread research stagnation
- Disproportionately hinder breakthroughs for previously untreatable conditions

*"[Anti-mRNA policies would] set back people like ten fifteen years to develop new methods or new therapies... mRNA research is one of the most significant research [areas] being used for treatment of diseases such as cancer rare disease and therapeutic areas."*

### Health Outcome Impacts (26%)

Anti-mRNA policies would have severe human consequences:

- Restrict access to potentially life-saving mRNA therapies, leading to preventable deaths among patients with no effective alternatives
- Severely impact patients with aggressive cancers such as pancreatic cancer and glioblastoma
- Halt therapeutic development for rare genetic diseases lacking viable treatments
- Block innovation for conditions where conventional approaches have consistently failed

*"Illnesses such as pancreatic cancer and glioblastoma, which have historically been a non-negotiable death sentence, have witnessed significant positive treatments using mRNA-based therapies. Patients who suffer from these conditions would lose the potential for literally life-saving medicine."*

### Rare Diseases are the Most Vulnerable to mRNA Disruptions (17%)

Various disease categories would be unequally impacted by mRNA disruptions:

- Rare diseases and orphan oncology indications are most vulnerable
- Aggressive cancers, especially solid tumors, highly depend on mRNA advances
- Loss of specialized mRNA capabilities, including unique delivery mechanisms
- Distinctive immunological applications where alternatives cannot match mRNA's efficacy

*"I know of no other therapeutic, especially when delivered locally, such as into the spinal fluid, that can have such a major impact on the development of or the progression of rare diseases."*

### Industry Structural Impacts (14%)

Operational and structural consequences of anti-mRNA policies would include:

- Bankruptcies, particularly among smaller, mRNA-focused companies with limited financial buffers
- Layoffs of highly specialized scientists critical to early-stage innovation
- Forced strategic realignments, including abandoning mRNA pipelines for alternative technologies
- Clear stratification by organization size, with startups and smaller biotech's far more vulnerable than large pharmaceutical firms

*"Our mother company would basically be bankrupt because it only works on the mRNA modality, and by the same occasion, the daughter company also would be collapsed."*

*"Given how nascent the field is, a federal ban would likely lead most smaller organizations that focus here to die on the vine. Larger pharma's with investments in this area will likely cease to work on it."*

### U.S. Competitive Position and Research Migration (9%)

Anti-mRNA policies would erode U.S. global leadership in biotechnology:

- Undermine U.S. leadership in biomedical and biotechnology innovation



- Trigger immediate research relocation to more supportive international environments
- Drive longer-term structural shifts as operations and talent permanently move abroad
- Risk creating a future where American patients lack access to treatments developed overseas

*"These therapies will move to Europe and other regions in the world and not be available to the US."*

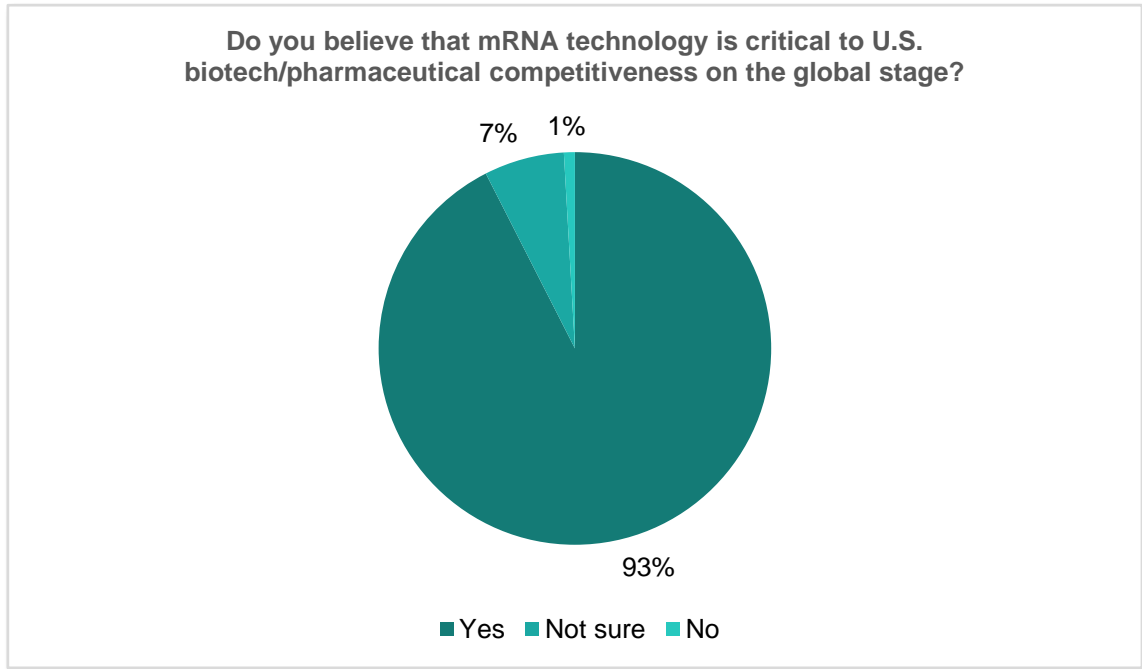
*"It would have a devastating impact on the development of novel therapeutics and would crush the U.S.'s dominance in biotech"*

*"It would cause some delay until we have moved to another country."*

## Section 6: Global Competitiveness

### 6.1 mRNA Plays a Critical Role in U.S. Biotech Competitiveness

Question: Do you believe that mRNA technology is critical to U.S. biotech/pharmaceutical competitiveness on the global stage? (Single Select, N=106)



## 6.2 Reasons mRNA Technology Is Critical to U.S. Competitiveness

Question: Why do you believe mRNA technology [is/is not] critical to U.S. competitiveness? (Open End, N=106)

mRNA technology represents a strategic cornerstone of U.S. competitiveness, combining scientific leadership, economic advantages, and national security imperatives in a global innovation race where American hesitation risks not only ceding technological dominance to determined international competitors like China, but also transforming the U.S. from a bioinnovation leader into a dependent follower in what many experts describe as the defining healthcare platform of the 21st century.

### Global Innovation Race

Multiple countries are rapidly advancing mRNA leadership:

- Focused investment and supportive regulatory environments, particularly in China
- Strategic advances by European nations and other Asian countries
- U.S. hesitation risks losing competitive advantage in a technology it pioneered
- Competition now extends to scientific leadership and setting future global healthcare standards

*"The U.S. pioneered mRNA and now the world is poised to take it from us. China's investment in mRNA since 2020 has been massive, and they could overtake the U.S. if we let them."*

### Transformative Healthcare Platform

mRNA represents a paradigm shift in therapeutic development:

- Unprecedented adaptability across diverse conditions
- "Biological software" properties enabling programmability and rapid design
- Precision targeting of disease mechanisms at the molecular level
- Ability to rapidly create new therapies by altering genetic code once delivery systems are established

*"mRNA technology is like biological software because it has such broad indications. Our inability to compete in this area will be devastating for our competition worldwide and also for the health of U.S. citizens."*

### Economic Impact and Talent Ecosystem

Leadership in mRNA creates a virtuous economic and innovation cycle:

- Job creation, tax revenue, and global sales reinforce U.S. competitiveness
- Economic benefits extend beyond mRNA into the broader innovation economy
- Diminished support risks capital flight and "brain drain" of top scientific talent
- Scientists may relocate to countries with more supportive research environments

*"It's too obvious, you know. If you lose competitiveness in mRNA technology, you just drive the investment away, and also you drive away those talents; they turn elsewhere."*

## Scientific Leadership at Risk

The United States' preeminent position in mRNA technology is at risk:

- Built through decades of sustained investment, research, and innovation
- Represents global leadership in a transformative therapeutic platform

Many participants expressed concern that this leadership position is precarious and could rapidly erode without continued support.

*"There is a reason that the United States is the research and research training destination for the world. Not only does this country have young men and women with the gusto, curiosity, and ambition necessary to devote their lives to scientific research, we also attract some of the brightest minds from all of the developed countries of the world. There is no question that mRNA medicines are the new path forward in drug development, and if the U.S. does not embrace this path, the U.S. will lose an entire generation (or more) of intellectual capital."*

## National Security and Pandemic Preparedness

mRNA technology is critical to U.S. national security by:

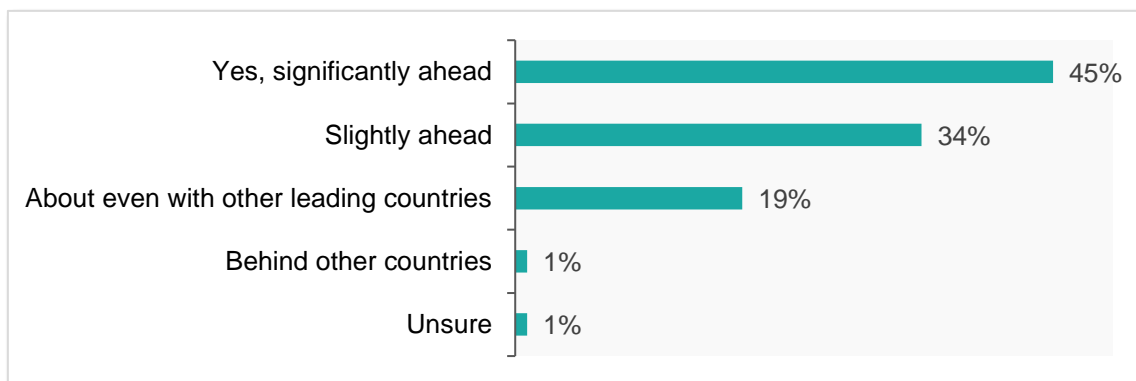
- Enabling rapid response to public health emergencies
- Demonstrating critical capabilities during the COVID-19 pandemic
- Allowing quick modifications to address virtually any infectious disease
- Providing crucial capabilities for addressing biological threats

Without robust domestic mRNA capabilities, respondents warn the U.S. would become increasingly vulnerable to future health crises and dependent on foreign entities for critical medical countermeasures.

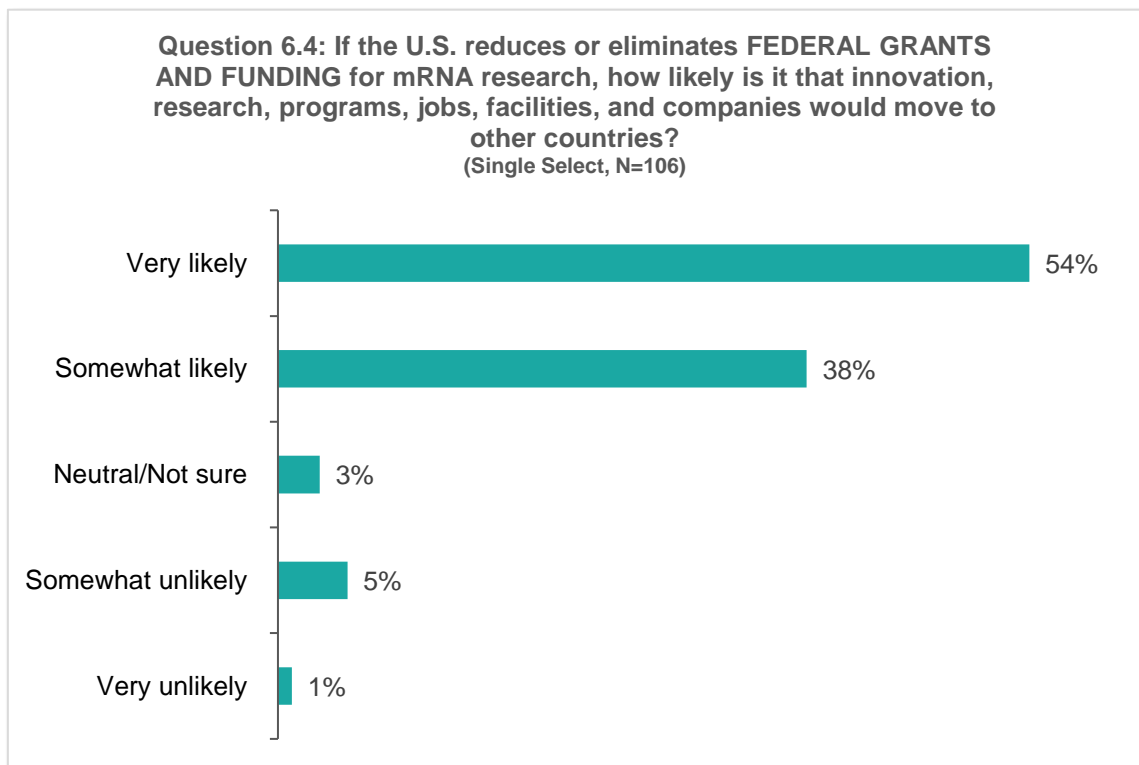
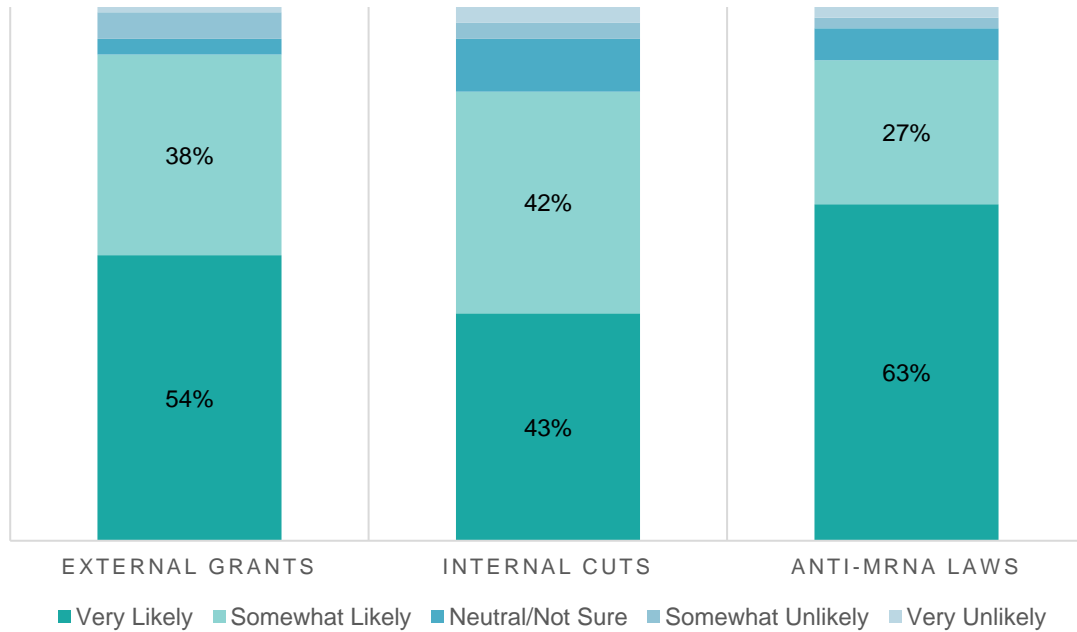
*"mRNA technology is critical because it allows a fast approach to pandemic preparedness. It has the potential to help us with cancer immunotherapy, and it is also able to help with non-rare diseases."*

## 6.3 Most Believe U.S. Leads in mRNA Research & Development

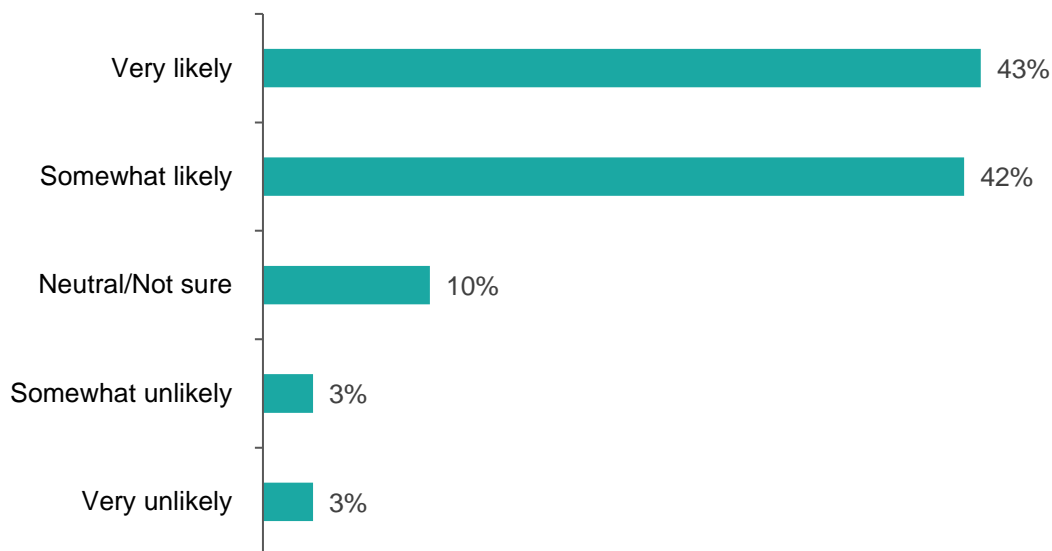
Question: Do you believe the U.S. currently leads the world in mRNA research and development? (Single Select, N=106)



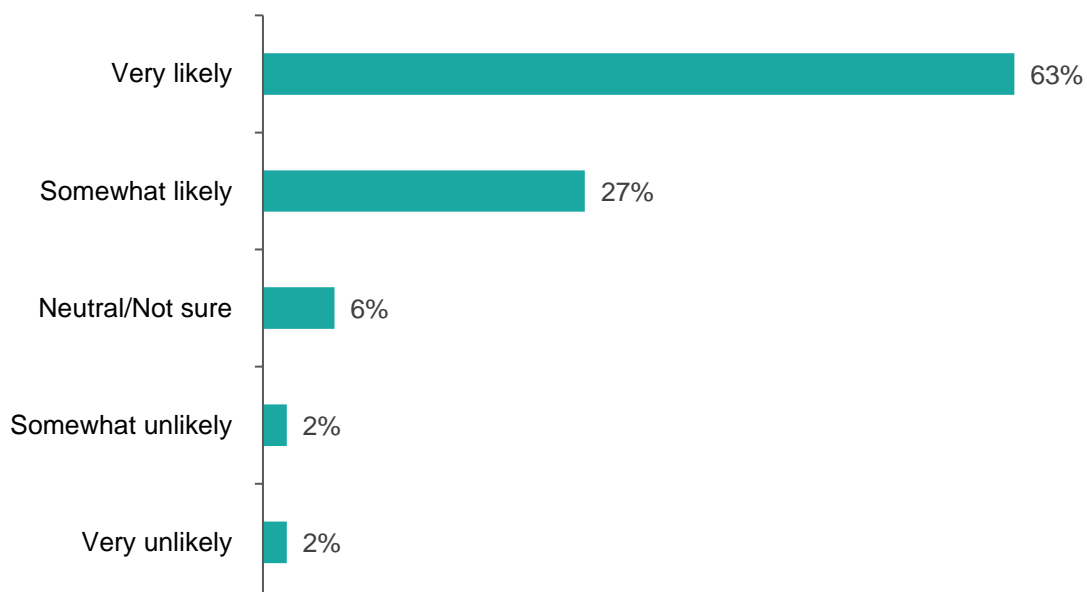
### 6.4-6.6 Anti-mRNA Policies Would Cause Jobs, Facilities and Companies to Move Out of U.S.



**Question 6.5: If the U.S. makes INTERNAL CUTS (loss of jobs and departmental funding) to government healthcare agencies such as NIH, FDA, BARDA, ARPA-H, CDC, and CMS, how likely is it that that innovation, research, programs, jobs, facilities, and companies**



**Question 6.6: If the U.S. implements state or federal mRNA bans or ANTI-mRNA LAWS, how likely is it that innovation, research, programs, jobs, facilities, and companies would move to other countries?**  
(Single Select, N=106)



## 6.7 Specific Risks if Other Countries Lead mRNA Innovation

Question: What specific negative impacts could the U.S. face if other countries gain an advantage in mRNA technology development? Please consider economic, healthcare, national security, and global competitiveness implications. (Open End, N=106, % = percentage who mentioned each theme)

America's leadership in mRNA technology connects national security, economic prosperity, and global influence that, if compromised, could create multiple vulnerabilities across talent retention, healthcare sovereignty, economic competitiveness, and pandemic preparedness capabilities, ultimately transforming the U.S. from a biotechnology innovator dictating global standards to a dependent consumer whose citizens might need to seek life-saving treatments abroad.

### Talent and Innovation Exodus (81%)

Potential migration of U.S. researchers and intellectual property poses a major national risk:

- A dominant concern across all regions and sectors
- "Reverse brain drain" threatens both current expertise and future talent pipelines
- Systematic degradation of the nation's scientific foundation, especially in cutting-edge fields
- Acute vulnerability in advanced areas like novel mRNA chemistries and delivery systems

*"We would become a third-world science destination and experience a reverse brain drain."*

### Global Leadership Decline (71%)

Losing mRNA leadership would weaken America's global position:

- Diminish U.S. ability to shape international biomedical standards
- Reduce global prestige and strategic influence against competitors like China and Europe
- Represent a fundamental shift in geopolitical power beyond technological competition
- Risk relegating the U.S. to "second-tier nation" status in healthcare innovation

*"U.S. citizens will need to travel outside the country to receive life-saving/altering therapeutics... Other geographies will take the lead with respect to the technical know-how for the development and manufacture of this new class of medicines."*

### Economic Vulnerability (61%)

Domestic economic impacts of losing mRNA leadership would be severe:

- Significant job losses across biotech, pharmaceutical manufacturing, and supply chain sectors
- Reduced domestic revenue opportunities as innovation-driven growth shifts abroad
- Financial burden of importing critical mRNA therapies and technologies originally developed in U.S. labs
- Stark economic shift from a producer/seller nation to a consumer/buyer, with billions in revenue and strategic advantage flowing to competitors like China and Europe



*"If mRNA fulfills its promise in multiple therapeutic areas, it could be a game changer for the healthcare industry. We can either be selling our products to other countries or we can be the buyers."*

### **National Security and Pandemic Preparedness Vulnerabilities (41%)**

Losing mRNA leadership would increase U.S. vulnerability to biological threats:

- Reduced capacity for rapid pandemic response and vaccine development
- Compromised ability to quickly address emerging health crises
- Dangerous dependencies on foreign entities, especially China and Russia, for critical technologies
- Heightened strategic vulnerabilities threatening national resilience and security

The COVID-19 pandemic was frequently referenced as evidence of mRNA technology's strategic importance for national resilience.

*"Pandemic preparedness, which is one of the major applications of the mRNA technology, currently is not just a healthcare issue, but it's a national defense issue. So, we need to make sure in the U.S. that we have the technology to be able to deal with outbreaks as they happen."*

*"Imagine a world where there is a major disease outbreak and our vaccine supply or medication necessary to combat the disease outbreak is controlled by countries such as China."*

### **Patient Impact Deterioration (34.9%)**

Potential negative consequences for patients if mRNA leadership is lost:

- Delayed access to innovative and potentially life-saving mRNA therapies, especially for cancer and rare diseases
- Higher treatment costs and reduced availability of advanced therapeutic options
- Need for patients to travel abroad to receive cutting-edge care
- Widening healthcare disparities based on wealth and geographic location, straining U.S. research institutions

These access challenges would affect healthcare research infrastructure as leading institutions might see patient populations seeking treatment abroad.

## **6.8 Internal U.S. Government Cuts May Cause Workforce and Pipeline Disruptions, Forfeiting Biotech Leadership**

Question: How would internal cuts (loss of jobs and departmental funding) to government healthcare agencies such as NIH, FDA, BARDA, ARPA-H, CDC, and CMS affect the mRNA field and the broader biotech/pharma industry? Please try to quantify this impact. (Open End, N=106)

### **Workforce Disruptions**

Government healthcare agency internal cuts would trigger a severe mRNA workforce crisis:

- 50–80% of specialized mRNA researchers could migrate internationally, especially to Europe and Asia

- Simultaneous loss of human and financial capital would compound domestic economic impacts
- Disruption would extend beyond immediate job losses to cripple the entire future talent pipeline
- Reduced PhD enrollments, academic training programs, and lab capacity would impair workforce development for years

*"If from the policy level they ban the mRNA technology, then I believe eighty percent of the people will be seeking for other opportunities in other countries to continue their expertise."*

## Pipeline and Innovation Disruptions

Government funding cuts would severely disrupt the mRNA innovation pipeline:

- NIH supports **over 60%** of preclinical mRNA therapeutic and vaccine development
- Cuts could cause innovation setbacks of **3–5 years** across the field
- A 10% funding reduction could stall or delay **over 200 early-stage mRNA programs nationally**
- Disrupts the critical continuum from discovery to clinical application

*"NIH alone funds at least 130 mRNA-related studies for vaccines and therapies targeting diseases like cancer, HIV, and malaria. Funding cuts would halt these projects, delaying breakthroughs and reducing the pipeline of new treatments."*

## Economic Consequences

Funding cuts would impose substantial economic costs across the mRNA sector:

- Therapy-level delays could cause **\$500 million to \$2 billion in lost revenue** per therapy
- Broader field impacts could result in tens of billions in lost potential revenue
- Foregone healthcare cost savings estimated at hundreds of billions to trillions over five years
- Long-term consequences threaten a projected **\$40–45 billion mRNA market** over the next five years

*"Cuts would slow the whole field of mRNA. This would cost tens of billions in lost potential revenue and hundreds of billions to trillions in potential healthcare cost savings from mRNA medicines that are poised to come online in the next 5 years."*

## Competitive Repositioning

Funding cuts would accelerate a major global shift in mRNA leadership:

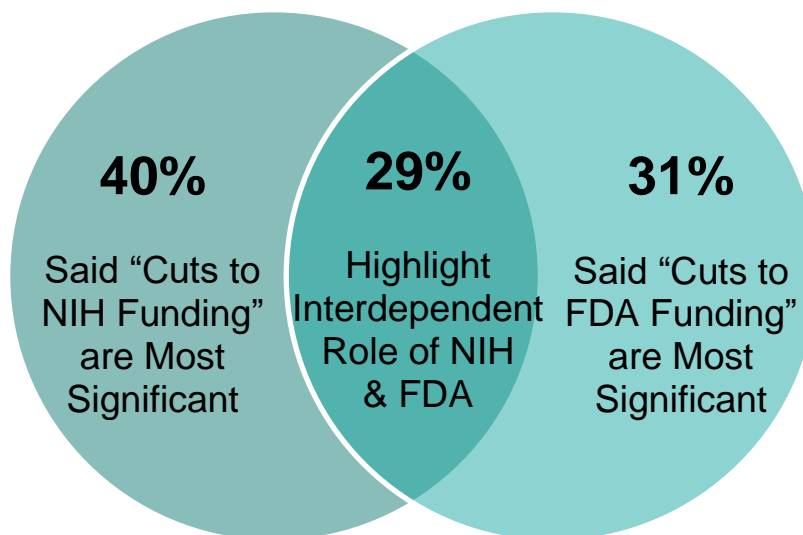
- Research activities, intellectual property generation, and commercial operations would migrate to countries with stronger funding and regulatory support
- Over 50% of U.S.-originated mRNA innovation activities could relocate abroad within a few years
- America would forfeit billions in domestic economic opportunities while boosting the biotech sectors of global competitors
- China, India, and European nations are specifically positioned to gain by attracting both top scientific talent and private investment capital

*"The U.S. would lose billions of potential corporate profits and tax revenues, many thousands of high-paying scientific jobs, and be vulnerable to the decisions of foreign governments in order to access these critical new mRNA therapies. We would lose a key aspect of our global economic power."*

## 6.9 NIH Cuts Seen As Slightly More Damaging for mRNA Long-Term than FDA Underfunding, Though Both Are Detrimental

Question: Do you see potential cuts to FDA internal funding as more or less significant than potential cuts to NIH funding for mRNA research? (Open End, N=106, % = percentage who mentioned each theme)

The tension between NIH and FDA funding priorities reveals a critical strategic dilemma at the heart of mRNA innovation policy: while experts' assessment of significance depends largely on their position in the development timeline, the interconnected nature of the ecosystem means policymakers must balance protecting both the volume of groundbreaking research that lacks alternative funding sources and the speed of regulatory approvals that directly impacts market confidence—recognizing that neither agency operates in isolation and weaknesses in either create compounding vulnerabilities that threaten America's competitive position in this transformative technology.



### Respondents Who Said "Cuts to NIH Funding" are the Most Significant (40%)

Cuts to NIH funding are seen as especially damaging to mRNA innovation:

- NIH is the primary supporter of early-stage, high-risk foundational mRNA research
- Drives the innovation pipeline through novel discovery work that private investors often avoid
- Lack of NIH support could set the field back by a decade or more
- NIH is often the only funding source willing to underwrite preclinical mRNA research critical for future breakthroughs

*"mRNA area is part of the larger biomedical science funding, so NIH funding is critical. Much more than FDA funding. FDA is not issuing grants, but NIH is an absolutely critical source of funding for mRNA as well as all other modalities."*

## Respondents Who Said “Cuts to FDA Funding” are the Most Significant (31%)

Cuts to FDA funding would create critical risks for mRNA development:

- Cause major bottlenecks in the regulatory approval process
- Directly delay patient access to innovative mRNA therapies
- Expose a vulnerable single point of failure, as FDA is the sole U.S. drug approval authority
- Broader economic impacts include eroded investor confidence and redirected investment to countries with faster approval pathways

*"There are other sources of funding other than NIH. There is only one drug approval agency in the US; if FDA is understaffed or underfunded, this will be a health risk to all Americans."*

## Respondents Who Highlighted Interdependent Role of NIH & FDA (29%)

Experts highlight the interdependent roles of FDA and NIH in mRNA innovation:

- NIH and FDA play essential but complementary roles in the research-to-market pipeline
- Funding cuts to either agency weaken the entire mRNA innovation ecosystem
- Without NIH, the flow of novel discoveries slows; without FDA, therapies stall before reaching patients
- Disruption at either the innovation or approval stage compromises patient access and economic progress

*"Both are bad in different ways. I'm probably more concerned about the NIH funding, but if the FDA were to be reduced, then that could slow down progress because you'll need FDA approval to move forward with many of these clinical trials."*

## Short-term Regulatory Impact vs. Long-term Research Consequences

Respondents distinguish between the different impacts of FDA and NIH funding cuts:

- FDA cuts create immediate operational bottlenecks in clinical development and approvals
- NIH cuts cause deeper medium- to long-term damage to the fundamental research pipeline
- Short-term impacts from FDA cuts stall therapies already in progress
- Long-term NIH cuts erode the future pipeline of mRNA innovation

This temporal differentiation reveals that the assessment of which funding cuts are "more significant" largely depends on the timeframe being considered.

*"I think FDA cuts in the short to medium term would be more impactful, whereas the NIH cuts would be more medium to long term. But of course, there are close links between the two, particularly in the training and in support of leading scientists."*

## Section 7: Policy Recommendations

### 7.1 Science-Driven, Coordinated Policy Framework Seen As Critical to Advancing U.S. mRNA Innovation

Question: Overall, what policies do you believe would help advance mRNA in the United States? (Open End, N=106)

U.S. mRNA innovation sits at a crossroads where scientific advancement demands both streamlined regulatory frameworks and sustained federal funding, while increasingly requiring protection from political interference to maintain global competitiveness in a landscape that could reshape the future of this transformative technology.

#### Regulatory Modernization

Stakeholders widely call for streamlined regulatory frameworks to support mRNA development:

- Clearer FDA guidance and expedited review timelines for mRNA products
- Reduced bureaucracy and standardized manufacturing protocols
- Harmonized international regulatory standards to ease global development
- Dedicated FDA task forces and specialized regulatory pathways focused on mRNA innovation

*"I think you need policies on clear guidance from the FDA for how to develop drugs and how to get them through the regulatory cycle so as not to be bogged down by bureaucratic policies."*

#### Sustained Federal Funding

Maintaining or increasing government funding is critical to sustaining mRNA innovation:

- Essential support across the full innovation pipeline, especially through NIH
- Priorities include academic research, rare disease applications, and early-stage innovation
- Investment in specialized research centers to drive scientific advancement
- Long-term funding commitments needed to enable breakthrough innovations and successful clinical trials

*"Continuing NIH funding would allow for a more universal field and then potentially, you know, commercialization of therapeutic drugs. So, I think that the funding is essential by the NIH to continue this and to not cut these funds."*

#### Science-Driven Policy Formulation

Stakeholders emphasize that mRNA policy must be grounded in scientific evidence:

- Advocate for objective, data-driven approaches respecting scientific consensus
- Urge shielding research priorities from partisan and political influence
- Recommend prioritizing scientific merit in funding and policy decisions
- Stress the need for expert scientific voices to guide policymaking

*"Trust the science. Don't mix politics with policy. Support Western values such as humanism, rationalism, and free markets. This will help mRNA innovation and much more."*

### **Domestic Manufacturing Capacity**

Building robust U.S.-based infrastructure is a top priority for mRNA leadership:

- Develop onshore manufacturing capabilities and standardized production processes
- Secure domestic supply chains for critical components and raw materials
- Provide tax incentives and regulatory certainty to stimulate investment
- Support startups and expand public-private partnerships to scale innovation and production

*"Taking a stance of prophylactic preparedness against future pandemics. Investing in onshoring the production of all intermediates and starting materials, e.g., NTPs."*

### **Talent Development and Collaboration**

Developing human capital and collaborative networks is essential for mRNA advancement:

- Invest in STEM education, specialized training programs, and scientist compensation
- Implement inclusive immigration policies to attract and retain international talent
- Strengthen public-private partnerships and academic-industry collaborations
- Expand government-academia research networks to leverage cross-sector expertise

*"More funding for the NIH, fast-tracking these therapies through the FDA, and allowing scientists from other countries into the U.S. without threat to their jobs and ability to live safely in the U.S."*

## **7.2 Top Considerations for Policymakers on mRNA**

Question: What are the most important considerations policy makers should know about mRNA as they evaluate policy, including funding, funding priorities? (Open End, N=106)

### **Economic and National Security Implications**

mRNA technology is a strategic national asset critical to U.S. leadership:

- Extends beyond healthcare into economic competitiveness and manufacturing sovereignty
- Strengthens security preparedness and rapid crisis response capabilities
- Lack of domestic capacity increases vulnerability during public health emergencies
- Risks losing global leadership to international competitors if domestic infrastructure weakens

*"mRNA is also a matter of national security; we need to build more medical/pharma supply chains in the U.S., and mRNA is a great platform to invest in since it has broad application and can be rapidly deployed."*

## Long-Term Strategic Value vs. Short-Term Considerations

mRNA is a foundational platform technology requiring long-term commitment:

- Needs sustained investment beyond short-term political cycles
- Development timelines often exceed private investor horizons, requiring public funding support
- Premature funding cuts risk foreclosing an entire "universe of possibilities" in medicine
- Comparable to abandoning protein-based or small molecule drugs early in their evolution

*"It's in its very early stages as a therapeutic modality. The potential for human health is enormous, but abandoning mRNA now would be like abandoning protein-based drugs or small molecule-based drugs. It's a whole potential universe of possibilities that would be foreclosed on."*

## Therapeutic Versatility Beyond Vaccines

mRNA applications extend far beyond COVID-19 vaccines:

- Transformative potential in oncology, rare diseases, protein replacement therapies, and infectious diseases
- Emerging applications in personalized medicine targeting individual patients
- Shifting treatment paradigms from disease management to effective interventions and potential cures
- Critical opportunities to address significant unmet medical needs across multiple therapeutic areas

*"mRNA does not mean vaccine. Vaccines are just one of the uses. A stance on vaccines should not be a stance against mRNA."*

## More Responses on Regulatory and Manufacturing Frameworks

Policy and regulatory environments are critical to advancing mRNA innovation, which helps address U.S. patients' unmet needs and creates U.S. jobs (including manufacturing jobs):

- Clear regulatory guidance, streamlined approval processes, and manufacturing infrastructure support
- Accelerated development timelines and faster market entry for new therapies
- Investments in scalable manufacturing to overcome shelf-life and production challenges

*"Regulatory guidance for mRNA will support additional research, as it would provide a platform for small research institutes and propel private investments."*

## Patient-Centered and Science-Driven Decision Making

Policymakers should:

- Ensure funding decisions are patient-centered (helping to address unmet need) and science-based
- Help address current knowledge gaps through targeted educational initiatives