



POLICY BRIEF

# RESILIENT NORTH AMERICA:

UNDERSTANDING THE CHALLENGES  
AND OPPORTUNITIES FOR REGIONAL  
COOPERATION ON IMMUNIZATION



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FOR REGIONAL COOPERATION ON IMMUNIZATION**

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## ACRONYMS & ABBREVIATIONS

|                 |   |
|-----------------|---|
| <b>AVMA</b>     | African Vaccine Manufacturing Accelerator                             |
| <b>COFEPRIS</b> | Mexico's Federal Commission for the Protection against Health Risks   |
| <b>CSIS</b>     | Center for Strategic and International Studies                        |
| <b>FDA</b>      | United States Food and Drug Administration                            |
| <b>FUNSAUD</b>  | Fundación Mexicana para la Salud                                      |
| <b>GMP</b>      | Good Manufacturing Practices  |
| <b>HSWG</b>     | NAPAHPI's Health Security Working Group                               |
| <b>IDB</b>      | Inter-American Development Bank                                       |
| <b>IP</b>       | Intellectual Property   |
| <b>NALS</b>     | North American Leaders' Summit  |
| <b>NAPAPI</b>   | North American Plan for Avian/Animal and Pandemic Influenza           |
| <b>NAPAHPI</b>  | North American Preparedness for Animal and Human Pandemics Initiative |
| <b>PAHO</b>     | Pan American Health Organization                                      |
| <b>PREP</b>     | Public Readiness and Emergency Preparedness Act                       |
| <b>USMCA</b>    | United States-Mexico-Canada Agreement                                 |
| <b>SCB</b>      | NAPAHPI's Senior Coordinating Body                                    |
| <b>SPP</b>      | Security and Prosperity Partnership                                   |

# RESILIENT NORTH AMERICA: UNDERSTANDING THE CHALLENGES AND OPPORTUNITIES FOR REGIONAL COOPERATION ON IMMUNIZATION

## EXECUTIVE SUMMARY

This policy paper explores the benefits, challenges, and opportunities of establishing a North American regional immunization strategy to strengthen health security and resilience. Canada, Mexico, and the United States face shared vulnerabilities due to interconnected populations, cross-border movement, and the increasing risk of vaccine-preventable diseases. While previous and ongoing collaborative efforts, such as the North American Preparedness for Animal and Human Pandemics Initiative (NAPAHPI), have laid a foundation for health coordination, further action is needed to address persistent gaps.

The paper identifies five key elements critical to developing this strategy: aligning vaccine priorities, harmonizing regulatory frameworks, enhancing manufacturing and supply chain capabilities, promoting innovation and workforce development, and establishing robust governance and financial mechanisms. If implemented, these elements could reduce vaccine costs, streamline access, and ensure equitable distribution during routine and emergency periods.

Recommendations include conducting feasibility studies to identify regional production opportunities, creating trilateral working groups for regulatory coordination, and fostering public-private partnerships to finance infrastructure investments. Additionally, focusing on priority populations would ensure inclusive and effective immunization efforts. Finally, leveraging successful international models offers valuable insights for building a collaborative framework tailored to North America's unique context.

This paper underscores the importance of joint action in the health sector to address current challenges and leverage regional strengths. A unified approach would not only improve health outcomes across the region but also position North America as a global leader in vaccine collaboration and health security.

## INTRODUCTION

North America is a profoundly interconnected region with extensive cross-border movement. This integration brings benefits and poses shared risks. However, risks related to health issues have proven to be particularly significant, as diseases do not respect borders. Despite this reality, immunization cooperation in the region has largely been limited to emergency periods, leaving Canada, Mexico, and the United States exposed to recurring health challenges.

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### Risks related to health issues have proven to be particularly significant, as diseases do not respect borders

One such challenge is the decline in routine vaccination rates across the three countries. In Canada, the percentage of 2-year-old children who had not received any vaccines in their lifetime increased from 1.7% in 2019 to 2.1% in 2021 (Government of Canada, 2024). In Mexico, from 2018 to 2019, there was a 13% decrease in the number of doses administered for various vaccines included in the national basic immunization schedule (Sotomayor Avilés, n.d.). Similarly, in the United States, national kindergarten vaccination coverage fell from 95% in 2019-2020 to approximately 93% in 2022-2023 (Williams & Kates, 2024). This regional decline in vaccination coverage, coupled with high levels of cross-border movement, amplifies the risk of outbreaks of vaccine-preventable diseases.

In addition to these internal vulnerabilities, global factors such as climate change and migration from outside the region are introducing new health threats, further increasing North America's susceptibility to health crises (Anonymous Interviews, 2024-2025). Without a coordinated immunization strategy, the region's capacity to respond effectively to these challenges will remain strained. The COVID-19 pandemic, for instance, starkly exposed the consequences of uncoordinated health actions. Without a regional vaccination coordination mechanism, the three nations acted independently, leading to delays in vaccine access and suboptimal outcomes for their populations (World Economic Forum & Deloitte, 2024). To prevent similar inefficiencies in the future, it is

essential to strengthen the region's preparedness, even in non-emergency periods.

Recognizing this need, Fundación IDEA, with financial support from Sanofi and guidance from the Wilson Center's Canada and Mexico Institutes, Fundación IMSS, and Andrew I. Rudman (Senior Associate of the Center for Strategic and International Studies (CSIS) Americas Program), has developed this policy paper to explore the benefits, opportunities, and challenges of establishing a collaborative North American regional immunization strategy.

The paper is based on two key assumptions. First, immunization through vaccination remains one of the most effective public health interventions due to its ability to generate life-saving immunological responses (Ortiz-Prado et al., 2021; Xue & Larrimore Ouellette, 2020). Second, regional immunization collaboration during non-emergency periods is essential for ensuring long-term health resilience. Therefore, fostering regional collaboration in vaccination during stable periods is crucial for achieving herd immunity and enhancing overall health security across the three countries (World Economic Forum & Deloitte, 2024).

To develop this document, Fundación IDEA carried out desk-based research on immunization strategies across the three countries and reviewed worldwide good practices in regional cooperation for immunization and other public health areas. Additionally, the team interviewed representatives from government institutions, academia, and civil society organizations in Canada, Mexico, and the United States (see Acknowledgments Section for further details). Readers should note that the research and interviews were completed by January 2025, and any new relevant developments beyond this date are not reflected in this version.

Findings are presented in four sections. The first reviews previous regional efforts to advance health cooperation, providing a foundation for a North American strategy. The second provides an initial overview of the elements necessary for developing a regional immunization strategy, identifying their benefits, opportunities, and challenges in North America. The third section offers concrete recommendations to advance the development and implementation of such a strategy. The last section provides concluding remarks and reflects on the implications of this type of strategy for health cooperation in North America.

## REGIONAL CONTEXT ON HEALTH COLLABORATION

Since the early 21<sup>st</sup> century, Canada, Mexico, and the United States have made efforts to establish frameworks for collaboration and coordination on immunization issues. After the SARS outbreak (2002–2004), the Security and Prosperity Partnership (SPP) —now the North American Leaders’ Summit (NALS)— launched the North American Plan for Avian and Pandemic Influenza (NAPAPI) in 2007. This initiative marked a milestone in recognizing shared vulnerabilities and outlining a comprehensive, coordinated response to pandemics originating outside the region (Rudman & Wood, 2020).

In 2012, drawing lessons from the 2009 H1N1 pandemic, the three countries updated NAPAPI, renaming it the North American Plan for Animal and Pandemic Influenza and expanding its scope to include zoonotic diseases and emphasized cross-sector collaboration, including surveillance, outbreak investigations, and the sharing of resources (Rudman & Wood, 2020).<sup>1</sup>

Most recently, in 2024, NAPAPI evolved into the North American Preparedness for Animal and Human Pandemics Initiative (NAPAHPI). This new framework prioritizes prevention and preparedness during non-emergency periods, creating a stronger foundation for sustainable collaboration. NAPAHPI reinvigorated regional cooperation by making it more flexible and scalable to comprehensively address health security threats (North American Leaders, 2024; Rudman & Wood, 2020).

Other initiatives have also demonstrated collaboration at varying scales —from local efforts to broader cross-border interactions<sup>2</sup> — but NAPAHPI represents the most sustained effort to advance coordination towards shared health threats. This document argues that by building on this plan, North America can create a regional immunization strategy through enhanced collaboration, policy alignment, and joint investments in sustainable health security infrastructure (North American Leaders, 2024; Vogler et al., 2021).

Since the early 21<sup>st</sup> century, Canada, Mexico, and the United States have made efforts to establish frameworks for collaboration and coordination on immunization issues



<sup>1</sup> Finalizing and publishing NAPAHPI required significant time and effort from all three countries. On the one hand, its relevance was questioned after 2019, as statements indicated that although the 2012 NAPAPI version was known, it was not utilized when the COVID-19 pandemic struck. The clearest example of this was the closure of the United States’ borders with Mexico to restrict non-essential travel—a measure that NAPAPI signatories had aimed to avoid in emergencies due to its negative social and economic consequences (Villagran, 2022). On the other hand, regional health cooperation has faced challenges, primarily due to shifting political priorities. The “America First” policies of the United States 45<sup>th</sup> and 47<sup>th</sup> Administrations and Mexico’s domestic focus from 2018 to 2024 redirected attention away from collaborative health initiatives. Instead, efforts centered on trade negotiations and migration management, weakening the cooperative spirit that had previously characterized public health efforts (Rudman & Wood, 2020). Therefore, achieving NAPAHPI was a significant milestone for the three countries and represents a major advancement in health collaboration that should be fully leveraged to strengthen regional health immunity.

<sup>2</sup> Examples of local and cross-border collaborations include the Pan American Health Organization (PAHO) Office in El Paso; the Mexico-US Border Health Commissions; the liaison between the American Academy of Pediatrics Committee on Infectious Diseases and the Canadian Pediatric Society Immunization and Infectious Diseases Committee; and the Mexico-Canada Action Plan’s commitment to collaborate in public health by eliminating unnecessary barriers to trade in medical supplies and focusing efforts on vaccine development (Anonymous Interviews, 2024-2025; Government of Canada, 2023).

# KEY ELEMENTS TO CONSIDER IN THE DEVELOPMENT OF A NORTH AMERICAN REGIONAL IMMUNIZATION STRATEGY

International experiences have demonstrated that implementing a collaborative regional immunization strategy through routine vaccination can bring several benefits. Initiatives such as the Beneluxa Initiative<sup>3</sup> and the Nordic Pharmaceutical Forum<sup>4</sup> have proven effective in lowering vaccine costs, ensuring consistent pricing, reducing administrative processes, strengthening negotiating power with suppliers, and minimizing supply chains disruptions (Vogler et al., 2021; World Economic Forum & Deloitte, 2024). These regional efforts also enhance quality assurance, promote equitable vaccine access, and enable faster responses during pandemics or outbreaks (World Economic Forum & Deloitte, 2024).

However, to fully realize these benefits, it is crucial to address current regional gaps. This includes streamlining regulations, aligning national health priorities with vaccine manufacturing strategies, and investing in technical capabilities (World Economic Forum & Deloitte, 2024). To overcome these gaps, this paper identifies five key elements that can be embedded into a North American regional immunization strategy. Each element is described below, outlining specific challenges and opportunities to be addressed when formulating such a strategy.



## *Key element 1.*

### ALIGNMENT OF NATIONAL VACCINE PRIORITIES AND PUBLIC MESSAGES

Establishing regional vaccine priorities is crucial for developing a regional immunization strategy. This would allow governments to close vaccine access gaps by enabling more efficient resource allocation and better planning. For instance, prioritizing groups —such as children under five or migrants— can ensure that the most vulnerable populations receive timely immunizations (Anonymous Interviews, 2024-2025). Furthermore, it would create stable demand, encouraging manufacturers to invest in vaccine production. This can also strengthen public-private partnerships, promoting long-term resilience in vaccine manufacturing.

However, reaching agreements on target populations and vaccine schedules poses significant challenges. The three countries' varied political and economic contexts often lead to differing approaches to the health sector, which can hinder the establishment of regional priorities (Anonymous Interviews, 2024-2025; World Economic Forum & Deloitte, 2024). Another challenge is the internal health structures in North American countries, which create variations that complicate regional alignment. Unlike Mexico and the United States, Canada

<sup>3</sup> The Beneluxa Initiative is a collaboration between Belgium, the Netherlands, Luxembourg, Austria, and Ireland, aimed at enhancing access to innovative medicines. The initiative focuses on joint pricing and reimbursement decisions, horizon scanning for new pharmaceuticals, and sharing information to strengthen bargaining power with pharmaceutical companies (Vogler et al., 2021).

<sup>4</sup> The Nordic Pharmaceutical Forum is a regional cooperation between Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden) to address common challenges in the pharmaceutical sector. The forum facilitates collaboration on pricing, procurement strategies, and access to medicines, leveraging collective expertise and negotiating power to benefit their healthcare systems (Vogler et al., 2021).



lacks a national vaccine program. Instead, health priorities are managed at the provincial and territorial levels, leading to discrepancies in vaccine schedules across the country (Anonymous Interviews, 2024-2025).

To address these challenges and move toward a unified vaccine schedule, the region can begin by aligning immunization strategies for specific priority populations. Migrant groups, a significant regional concern, provide a logical starting point. Many migrants lack vaccination records, and even when vaccinated, their immunizations often fail to meet host country requirements due to misaligned vaccine schedules and differences in approved vaccines across the region (Anonymous Interviews, 2024-2025). This creates critical coverage gaps that endanger both migrants and the broader population. Implementing flexible, inclusive, and collaborative strategies to integrate migrants into regional immunization efforts would not only strengthen health security in the region but also fulfill the World Health Organization's health security mandate to incorporate migrants into national immunization programs (Anonymous Interviews, 2024-2025; WHO Immunization, Vaccines and Biologicals (IVB), 2021).

### Governments must build public confidence and encourage vaccine uptake by developing a unified message

Finally, increasing public skepticism toward vaccines presents another significant challenge for aligning national policies. Misinformation and inconsistent messaging have fueled doubts about vaccination, resulting in high rates of vaccine hesitancy, particularly in the United States, where acceptance rates for the COVID-19 vaccine ranged from 38% to 49% in mid-October 2020 (Yasmin et al., 2021). To address this issue, governments must build public confidence and encourage vaccine uptake by developing a unified message that provides accurate, understandable, and culturally sensitive information about vaccines. This message should also highlight the health, economic, and social benefits of vaccination to foster individual and community commitment and responsibility to get vaccinated (Anonymous Interviews, 2024-2025; Sepúlveda Amor & Betancourt Cravioto, 2024).



#### Key element II.

## REGULATORY COORDINATION FOR FASTER VACCINE ACCESS

Regulatory coordination is critical for developing a North American regional immunization strategy. This involves harmonizing vaccine standards and approval processes across Canada, Mexico, and the United States to streamline vaccine access in each country.

Currently, each country relies on separate approval pathways, reviews, and submissions, which create administrative and bureaucratic barriers, delaying vaccine procurement and access (Rudman & Wood, 2020; World Economic Forum & Deloitte, 2024). In Mexico, for instance, vaccine procurement processes have historically required planning cycles of up to 24 months for pharmaceutical companies (Sepúlveda Amor & Betancourt Cravioto, 2024). Thus, having a single joint dossier submission and regional multi-year contracts with producers could significantly reduce administrative burdens, stabilize prices, and ensure a reliable vaccine supply across the region (Rudman & Wood, 2020; Sepúlveda Amor & Betancourt Cravioto, 2024; World Economic Forum & Deloitte, 2024).

This regulatory convergence also offers significant benefits for manufacturers, as it can lower costs and risks associated with navigating distinct approval pathways in each country. A streamlined framework would allow manufacturers to dedicate more time to production than redundant inspections or country-specific compliance. Moreover, a predictable regulatory environment could attract investment in regional production facilities, fostering a stable and reliable vaccine supply (Rudman & Wood, 2020; World Economic Forum & Deloitte, 2024).

Mutual recognition agreements across the region could facilitate vaccine sharing among the three countries. For example, adopting standardized categories for product monographs, similar to the European Union model,

could enhance vaccine quality and safety trust. Even if the monographs' content<sup>5</sup> varies to accommodate each country's specific health context and languages, this approach would help ensure timely vaccine availability (Anonymous Interviews, 2024-2025).

The successful experience of the Nordic Pharmaceutical Forum validates the benefits of having regional harmonized regulations and mutual recognition agreements. These regions have expedited vaccine approvals, reduced costs, and upheld rigorous safety and quality standards, ensuring consistent access to high-quality vaccines (Vogler et al., 2021). Furthermore, Mexico's experience with the COVAX mechanism during the COVID-19 pandemic also illustrates how collaborative frameworks can enhance bargaining power, enabling countries to secure vaccines at competitive prices (Sepúlveda Amor & Betancourt Cravioto, 2024).

Some medical professionals already proactively consider vaccine recommendations published by other health institutions in the region (Anonymous Interviews, 2024-2025). However, achieving broad regulatory coordination in North America requires building trust among the agencies involved in vaccine approval and procurement. While Health Canada, Mexico's Federal Commission for the Protection Against Health Risks (COFEPRIS), and the United States Food and Drug Administration (FDA) are all respected authorities, their differing operational mandates present challenges to alignment (Ortiz-Prado et al., 2021; Rudman, 2024).

Overcoming these hurdles requires extensive dialogue, technical capacity-building, and a phased implementation strategy. Additionally, the region can leverage existing mechanisms, such as the Legal Preparedness Action Package of the Global Health Security Agenda, to foster trust and facilitate collaboration (Anonymous Interviews, 2024-2025).



### Key Element III.

## SHARED MANUFACTURING CAPABILITIES AND SUPPLY CHAIN COLLABORATION

Promoting shared manufacturing capabilities and resilient supply chains would facilitate sufficient vaccine production and distribution. No country in the region currently produces enough vaccines to meet its own demand, leaving them vulnerable due to overreliance on international markets. This vulnerability was evident during the COVID-19 pandemic when transportation disruptions and border closures exposed weaknesses in global supply chains and delayed access to vaccines (Anonymous Interviews, 2024-2025; Lexchin, 2023; Lupkin, 2021; Rudman, 2024; Rudman & Wood, 2020). Moreover, global vaccine production still falls short of meeting worldwide demand, exposing the region to delays and shortages in vaccine access. This dependency on global supply-chains is the primary obstacle to achieving vaccine supply security and, if unaddressed, could escalate into a national and regional security risk (Anonymous Interviews, 2024-2025; Sepúlveda Amor & Betancourt Cravioto, 2024).

The three countries could capitalize on the trend toward deglobalization and prioritize a regional approach to manufacturing and supply chain. By aligning their markets and developing shared production capabilities, the region could achieve economies of scale that benefit manufacturers and governments. A consistent baseline demand would lower production costs and advance purchase agreements for manufacturers. This approach would also enable entrepreneurs to invest in building more manufacturing facilities in the region, which could compete in the broader market and potentially export vaccines to other countries (Rudman, 2024; Rudman & Wood, 2020; Sepúlveda Amor & Betancourt Cravioto, 2024; World Economic Forum & Deloitte, 2024).

For governments, this would ensure sufficient stockpiles for routine vaccinations, reduce reliance on the global market and avoid excessive spending on vaccine procurement (Anonymous Interviews, 2024-2025; Sepúlveda Amor & Betancourt Cravioto, 2024).

<sup>5</sup> Vaccine monographs are detailed scientific documents that provide comprehensive information about a specific vaccine, including its composition, manufacturing process, quality standards, clinical data, and administration guidelines.

Additionally, this approach would mitigate risks of supply chain disruptions caused by external factors such as natural disasters, political instability, and pandemics. Regional challenges like climate change, hurricanes, and flooding should be incorporated into planning to create resilient systems capable of withstanding these disruptions (Rudman, 2024). By investing in and supporting infrastructure for regional vaccine production, North America could guarantee a stable and secure vaccine supply to meet population needs (Sepúlveda Amor & Betancourt Cravioto, 2024). Moreover, this effort would align with the regional priority of fostering nearshoring (Berg & Ziemer, n.d.).

Finally, ensuring an uninterrupted and sustainable supply of affordable vaccines would enhance the region's ability to respond effectively to vaccine-preventable health emergencies, prevent the reintroduction of diseases caused by insufficient coverage, and promote equitable access to vaccination (Anonymous Interviews, 2024-2025; Sepúlveda Amor & Betancourt Cravioto, 2024).

Regional collaboration in manufacturing and supply chain systems can undoubtedly enable governments to acquire vaccines affordably and reliably while providing stability for manufacturers (World Economic Forum & Deloitte, 2024). However, achieving it presents specific challenges.

One significant hurdle is the technical and political complexity of vaccine production. Transitioning between vaccine types requires high-level quality control and extensive planning to meet projected demand (Anonymous Interviews, 2024-2025). Developing a robust network of facilities and infrastructure across the region also demands significant investment and long-term political commitment (World Economic Forum & Deloitte, 2024). To address this, the region could establish public-private partnerships to finance necessary investments, similar to the model implemented by the African Vaccine Manufacturing Accelerator (AVMA) (Africa Centres for Disease Control and Prevention, 2023; Anonymous Interviews, 2024-2025). Additionally, strengthening nearshoring vaccine production is a shared priority among the three countries. Notably, the Mexican Government's recently introduced Mexico Plan by the new Mexican administration aims to expand domestic vaccine production and reinforce regional supply chains to promote industrialization and reduce reliance on Asian imports. This initiative offers a valuable opportunity to advance the regional immunization strategy by enhancing self-sufficiency,

creating jobs, and fostering collaboration (Anonymous Interviews, 2024-2025; Prime Minister's Office, 2024; Rodríguez, 2025; Urrutia & Carbajal, 2025).

Another challenge lies in the uneven manufacturing and supply chain capacity among the three countries. Operational and logistical gaps in each country pose significant complexities for vaccine distribution. For instance, Mexico struggles to meet cold chain requirements due to a lack of nationwide ultra-cold freezers, while colder climates in Canada and the United States create difficulties maintaining consistent storage conditions in freezing temperatures (Anonymous Interviews, 2024-2025). Thus, to ensure equitable contributions and benefits from regional collaboration, it will be essential to join efforts and implement strategic planning and capacity-building initiatives (Ortiz-Prado et al., 2021).



#### *Key Element IV.*

## INNOVATION AND WORKFORCE DEVELOPMENT

Investing in skilled workers and promoting research initiatives is essential to accelerating vaccine development and ensuring long-term regional health security. Fostering public-private collaborations in workforce development can help address regional shortages of technical and medical professionals. For example, joint training programs and academic exchanges between universities can prepare a workforce that responds to the vaccine manufacturing sector's needs. Additionally, initiatives such as bilingual nurse training and cross-border licensing agreements can meet the growing demand for healthcare professionals, improving the accessibility and quality of vaccination services. This presents a striking opportunity for professionals working on the US-Mexico border, where medical tourism enables people to receive vaccinations on either side of the border (Anonymous Interviews, 2024-2025; Rudman & Wood, 2020).

Investing in regional research initiatives can drive innovation in vaccine development. For instance, implementing cross-border clinical trials would enable access to larger, more diverse populations, enhance the reliability of trial data, and expedite approval processes. In all three countries, relatively small numbers of children or adults with certain conditions often delay progress in vaccine trials. Coordinated cross-border trials could pool these smaller populations, allowing for more robust evidence-based recommendations from the National Advisory Committees on Immunization (Anonymous Interviews, 2024-2025).

This approach would foster inclusivity and ensure broader protection. During the COVID-19 pandemic, the exclusion of pregnant women from early clinical trials left them without clear guidance or adequate protection for an extended period (Anonymous Interviews, 2024-2025). Regional collaboration could address these gaps, ensuring no population is overlooked in future health crises.

Mexico's growing clinical trial infrastructure and experienced medical professionals present an attractive opportunity for regional collaboration (Rudman & Wood, 2020; World Economic Forum & Deloitte, 2024). Several organizations already lead successful initiatives in this area, which could achieve more significant impact through coordinated efforts. Examples include Good Clinical Trials, the LaRed Initiative, and Accelerating Clinical Trials from Canada. Establishing a collaborative ecosystem among these organizations could advance regional health priorities, enhance competitiveness, reduce costs and risks associated with developing new vaccines, and minimize duplication of efforts (Anonymous Interviews, 2024-2025; Rudman & Wood, 2020; Secretariado de la Red PARF, 2024; World Economic Forum & Deloitte, 2024).

Despite these opportunities, fostering workforce development and innovation faces several challenges in the region. Licensing, certification, and training standards vary widely across the three countries, creating barriers to seamless collaboration (Rudman & Wood, 2020; World Economic Forum & Deloitte, 2024). The high costs and technical demands of vaccine research require substantial investment in workforce development, which all governments may not prioritize. Addressing these challenges entails establishing mutual recognition agreements among academic institutions to ensure that curricula and certifications are comparable across the region. This would facilitate knowledge transfer and the implementa-

tion of competency-based training programs in collaboration with national and transnational companies, ensuring that the workforce is equipped with industry-relevant skills and competencies (Secretariado de la Red PARF, 2024). Leveraging existing educational platforms, such as The American Academy and CASTL Canada, could further support these efforts (Anonymous Interviews, 2024-2025; Sepúlveda Amor & Betancourt Cravioto, 2024).

Another significant challenge is the varying legal requirements and protections during clinical trials. Companies often navigate differing licensing requirements in each country, which forces them to collect distinct data even for joint clinical trials to meet individual regulatory standards. This complexity discourages company participation (Anonymous Interviews, 2024-2025; Secretariado de la Red PARF, 2024).

Furthermore, post-market surveillance, which involves monitoring long-term side effects, varies across countries. For instance, the United States has the Public Readiness and Emergency Preparedness (PREP) Act, which provides liability protection and offers no-fault compensation funds for serious side effects to entities involved in developing, manufacturing, testing, distributing, and administering a vaccine during a declared emergency. In contrast, Mexico lacks such protections, discouraging vaccine testing within its borders (Anonymous Interviews, 2024-2025; Secretariado de la Red PARF, 2024; Xue & Larrimore Ouellette, 2020). To address these issues, the region must establish a unified approach to data collection and clinical trial testing based on shared priorities. This alignment would reduce complexity for companies and encourage innovation.

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Alignment would reduce complexity for companies and encourage innovation.

Some stakeholders are reluctant to cooperate due to concerns about protecting intellectual property (IP) and ensuring equitable benefits. Successful collaboration would require clear agreements on data sharing, IP protections, and the equitable distribution of resources and rewards. Addressing these concerns is critical to building trust and sustaining partnerships (Anonymous Interviews, 2024-2025; World Economic Forum & Deloitte, 2024).



### Key Element V.

## ROBUST GOVERNANCE STRUCTURE AND FINANCIAL SUSTAINABILITY

A robust governance structure and a sustainable financial framework are necessary for implementing and maintaining a North American immunization strategy. First, the strategy requires a governing body to facilitate and oversee joint agreements, including aligning priorities and harmonizing processes and regulations. This governance structure could build on existing entities, such as the NAPAHPI's Senior Coordinating Body (SCB)—which brings together the Health, Security, Agriculture, and Foreign Affairs Ministries from the three countries—and the Health Security Working Group (HSWG) (Anonymous Interviews, 2024-2025; North American Leaders, 2024).<sup>6</sup> As NAPAHPI is an all-hazards plan designed to address various threats to health security in North America, its entities could be leveraged to advance the strategy. However, they must be adapted to meet the specific needs of the immunization strategy.

International practices, such as the Beneluxa Initiative and Nordic Pharmaceutical Forum, underscore the importance of voluntary participation, clearly defined roles, and adequate resources to ensure effective collaboration (Vogler et al., 2021). In North America, it is also essential to include diverse stakeholders—such as state and municipal representatives (particularly from border regions), tribal and First Nations representatives, civil society organizations, academia, and private sector partners—to enhance responsiveness and representation (Anonymous Interviews, 2024-2025).

Second, the strategy requires a dedicated funding mechanism to ensure financial stability. Regional vaccine manufacturing projects have demonstrated a benefit-cost ratio of up to six times higher when implemented regionally rather than nationally (World Economic Forum & Deloitte, 2024). Achieving this would necessitate

pooling financial resources from participating nations, leveraging international development funds, and attracting private investments. Additionally, establishing a trilateral forum for financial discussions could streamline access to global and regional financing instruments (North American Leaders, 2024).

Despite these opportunities, governance and financing frameworks face several challenges. Differences in organizational structures and political priorities across the three countries can hinder collaboration. Furthermore, aligning national immunization panels and ensuring cohesive decision-making would demand significant diplomatic and technical efforts. On the financial side, the high initial investments required and the need for ongoing operational funding could deter participation (Anonymous Interviews, 2024-2025). Therefore, ensuring accountability and transparency in financial management and decision-making should be a top priority when designing the strategy's governance.

Universities and research centers can play a pivotal role in overcoming these challenges. These institutions analyze, monitor, and provide valuable insights to enhance the quality of the strategy. Furthermore, adopting a regional surveillance program—similar to the EudraVigilance system, which uses common definitions and methodologies—could foster data sharing and alignment among the three countries. Establishing such initiatives might encourage collaboration, improve practices, and ultimately strengthen the coordinated effort (Anonymous Interviews, 2024-2025).



<sup>6</sup> The SCB, composed of high-level officials from health, agriculture, security, and foreign affairs ministries, ensures policy alignment and oversight. Meanwhile, the HSWG, involving technical and policy experts, focuses on implementing preventive measures and response mechanisms (North American Leaders, 2024; Rudman & Wood, 2020).

## RECOMMENDATIONS TO ADVANCE THE DEVELOPMENT OF A NORTH AMERICAN REGIONAL IMMUNIZATION STRATEGY

Given the challenges, opportunities, and evolving political context in the region, it is essential to take practical first steps toward advancing the outlined elements and laying the groundwork for a regional immunization strategy in North America. The following actions represent key initial efforts that should be prioritized for implementation:

### Identify vaccine schedules and develop a pilot program for at least one priority group



The first step in aligning national vaccine priorities is to conduct a comprehensive study comparing vaccine requirements across Canada, Mexico, and the United States. This includes mandatory and optional vaccines, schedules, target populations, and policies. A critical element is identifying relevant ministries, agencies, and existing national emergency plans in each country to coordinate actions effectively.

Once this analysis is complete, a high-level trilateral working group should be established to facilitate regular dialogue and agree on at least one shared priority group—such as children under five years old, pregnant women, or individuals living in border regions—to standardize immunization efforts. The upcoming NALS, probably happening in 2025, offers an ideal platform to launch this initiative.

Following the definition of this priority group, it is essential to develop a regional data-sharing system. This system should integrate provincial, state, and federal platforms to improve data accuracy and accessibility, enabling better vaccine coverage, distribution, and efficacy tracking. Offering transparent and reliable information would also strengthen accountability for regional priorities.

Finally, this effort should be accompanied by a public communication campaign to encourage vaccine uptake within the priority group. The campaign should feature a unified central message while allowing adaptations to suit each country's cultural and regional contexts.

### Establish common agreements that help harmonize information requirements



To streamline regulatory frameworks, the region can focus on harmonizing information requirements across the three countries to accelerate processes and reduce complexity. Adopting and integrating Good Manufacturing Practices (GMP) standards across member states would further support this effort. This harmonization would enable mutual recognition agreements, expediting vaccine approval, use, and distribution during emergencies and routine periods. For instance, a unified approach could simplify cross-border vaccine donations during crises. Implementing this strategy would significantly enhance regional health security, aligning with the priorities established at the previous NALS.

### Identify efficiencies and nearshoring opportunities in regional vaccine production



Strengthening manufacturing and supply chain collaboration requires feasibility studies to identify efficiencies and nearshoring opportunities in regional vaccine production. These studies should map existing supply chains, evaluate cost benefits, identify risks, and assess infrastructure readiness and potential barriers to implementation. Third-party validation by experts in bioengineering and regulation can provide critical assurance of the studies, enhancing credibility and attracting investor confidence.

Pilot projects can later test manufacturing and distribution systems proposed by these feasibility studies, offering insights into scalability and regional compatibility. The upcoming NALS and the United States–Mexico–Canada Agreement (USMCA) review, scheduled for not later than July 2026, offer strategic opportunities to present findings, emphasize cross-border economic and health benefits, and advocate for institutionalizing regional manufacturing initiatives. By leveraging both mechanisms, policymakers can drive critical policy changes, secure funding commitments for these initiatives, and create momentum for long-term regional partnerships.

### Assess the cost-effectiveness of clinical trials in the region



To foster innovation and research collaboration, it is vital to assess the different ways clinical trials work and their cost-effectiveness within the region. This analysis can inform the development of targeted incentives, such as joint liability protection, to encourage private-sector investment in research and development. Efforts should focus on emerging diseases and previously defined regional health priorities. Additionally, the region can create networks of clinical investigators and good clinical practice facilities to improve trial design and accelerate regional vaccine development.

### Identify key stakeholders and build upon existing working groups



Building robust governance and sustainable financing should start by identifying key stakeholders from government, civil society, academia, and the private sector. These stakeholders can then be integrated into existing governance structures, such as those under NAPAHP, to evaluate each country's readiness and willingness to implement the strategy. At the same time, governments must engage with their legislatures and initiate dialogues with private sector and international companies to explore funding mechanisms that ensure long-term financial sustainability. Collaborative action will help mobilize investments and optimize resource allocation, laying the foundation for sustained success.

## CONCLUSIONS

A North American regional immunization strategy is critical to ensuring long-term health security and resilience for Canada, Mexico, and the United States. However, the current political landscape and ongoing changes in all three countries create an uncertain path toward a collaborative framework. Given this uncertainty, it is essential to identify shared entry points within each of the elements outlined in this paper and take incremental steps towards the implementation of long-lasting initiatives. This pragmatic approach can pave the way for a structured, cooperative framework that enhances the region's ability to respond to vaccine-preventable diseases and emerging health threats.

One of the first steps in this effort is implementing coordinated communication narratives to emphasize vaccination's health, economic, and social benefits. Tailored public awareness campaigns, adapted to cultural and regional contexts, can build trust, combat vaccine hesitancy, and encourage vaccine uptake, fostering a sense of shared responsibility across borders. Additionally, identifying shared priority groups among the three coun-

tries —such as children under five, pregnant women, or individuals living in border regions— can help focus these messaging efforts while also serving as a starting point to pilot key elements of a regional immunization strategy.

Regulatory harmonization is another key area for early action. Agreeing on minimum common standards for vaccine approval, access, and distribution can streamline processes, reduce bureaucratic delays, and accelerate vaccine access. This step would lay the foundation for more efficient cross-border collaboration, ensuring timely and equitable immunization across the region.

Start advancing workforce development and innovation is equally important. Expanding training programs, public-private partnerships, and academic exchanges can help address existing technical and medical expertise shortages. Moreover, creating networks of clinical investigators and promoting the sharing of good clinical practices can attract private-sector investment in research and development, particularly through cross-border clinical trials.

Establishing an initial governance mechanism that builds trust and fosters sustained engagement can be achieved with minimal additional effort by leveraging existing structures, such as NAPAHP. Through this platform, the region can promote a collaborative decision-making framework that ensures accountability and transparency among the three nations. Additionally, financial sustainability can be supported by leveraging nearshoring opportunities, public-private partnerships, pooled resources, and regional investment funds. Taking these first steps will help lay the groundwork for the long-term success of a regional immunization strategy.

By working together now to advance common interests, Canada, Mexico, and the United States can lay the foundation for a unified regional system that addresses health immunization needs, strengthens health security, and positions North America as a global leader in vaccine innovation and distribution in the future. While the political context remains uncertain and the global shift toward deglobalization gains momentum, incremental steps toward regionally centered collaboration can drive meaningful progress. Developing a regional immunization strategy presents a transformative opportunity to enhance preparedness, resilience, and health equity across North America.





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POLICY BRIEF

# RESILIENT NORTH AMERICA:

UNDERSTANDING THE CHALLENGES  
AND OPPORTUNITIES FOR REGIONAL  
COOPERATION ON IMMUNIZATION

