1DAY SOONER

OWS 2.0

OPERATION WARP SPEED

ACCELERATING THE NEXT GENERATION OF COVID VACCINES AND TREATMENTS

About 1Day Sooner

1Day Sooner was founded in response to the COVID-19 pandemic in order to represent volunteers for COVID-19 challenge trials who wanted to rapidly accelerate the deployment of the most effective COVID-19 vaccines possible. Since then, 1Day Sooner continues to represent volunteers for high impact medical studies, while also advocating for other approaches to accelerate the arrival of medical countermeasures.

Warp Speed 2.0 Campaign

Operation Warp Speed was the US government effort to concentrate funding and regulatory support on the development of the COVID-19 vaccines. With OWS, the world saw successful, cutting-edge mRNA vaccines deployed in record time—not even a year after the pandemic was declared. 1Day Sooner advocates for the adoption of the Operation Warp Speed model for other diseases, especially ones we know have high pandemic-causing potential.

For more information, please visit **1daysooner.org**

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EXECUTIVE SUMMARY

Operation Warp Speed revolutionized vaccine development. In the spring of 2020, President Trump announced the $18 billion public-private partnership to accelerate the development and subsequent production of vaccines against COVID-19. On December 11, less than 8 months after the program's announcement, the first vaccine was authorized by the U.S. Food and Drug Administration (FDA). Prior to Operation Warp Speed, the fastest vaccine to have ever been developed took four years.

The public health and economic benefits of the Operation Warp Speed vaccines are indisputable. Within just 6 months of their authorization, it has been estimated that the Operation Warp Speed vaccines saved nearly 140,000 American lives. The magnitude of the benefits were so great that it's estimated that Operation Warp Speed would still have paid for itself if it had cut the duration of the pandemic by merely 12 hours.

Despite the incredible achievement of these vaccines, COVID-19 continues to pose a substantial problem three years later with the continuing threat of emerging variants. Furthermore, experts warn of the increasing likelihood of new pandemics, with estimates that the annual probability of an extreme epidemic could increase threefold in the coming decades.

The Biden Administration's Project NextGen—a $5 billion initiative to accelerate next generation COVID-19 vaccines and treatments—is a great leap forward toward quashing COVID-19 and protecting America against future pandemics. Applying lessons learned from Operation Warp Speed will be key to the successful execution of Project NextGen's goals.

In this white paper we establish the "Warp Speed model" which we apply to Project NextGen, with a primary focus on regulatory and market-shaping mechanisms. Entwined with our Warp Speed model is a series of policy recommendations for advancing Project NextGen as well as building a strong foundation for future medical countermeasure development.

SUMMARY OF RECOMMENDATIONS

| Create and Fund FDA's Emerging Pathogens Preparedness Program

| Create Advance Market Commitments for Pan-sarbecovirus Vaccines

| Use Human Challenge Trials to Measure Transmission Reduction

| Create a NextGen Immunoassay Challenge

| Integrate NextGen Vaccines with the Annual Flu Campaign

| Publish Target Product Profiles for NextGen Vaccines

1. INTRODUCTION

Secretary Alex Azar

At the end of March 2020, Dr Robert Kadlec and I had a call with the CEO of a vaccine manufacturer. The next day there would be an announcement that the Biomedical Advanced Research and Development Authority (BARDA) was investing $450 million into their COVID-19 vaccine candidate and that manufacturer would be investing a similar amount. However, during the call it quickly became apparent that this program was to function much more like a traditional HHS grant than a biomedical development public-private partnership with tight timelines for accountability and delivery. The company anticipated that it would start Phase 1 for its vaccine candidate in September. We had no idea how this novel virus would evolve, and whether a Phase 1 would even be of any value to us in six month's time. This conversation and subsequent assessments of the pharmaceutical industry's self-formed development timelines are what ultimately spurred Dr Kadlec, Dr. Peter Marks (of FDA), Paul Mango (my deputy chief of staff), and me to challenge these assumptions and develop what would become Operation Warp Speed. My thesis was the following: Congress had just spent over $2 trillion on COVID relief, so literally any amount of money we could credibly spend to deliver vaccines or therapeutics faster would have essentially an infinite return on investment if even modestly successful. So I told the team: Take money off the table; be guided only by the laws of science and physics. I'll get you whatever money is needed.

At the core of Operation Warp Speed was an understanding of pharmaceutical companies and their incentive structures. The old joke is that the pharmaceutical industry is the riskiest on earth, run by the most risk-averse people on earth. By nature, pharmaceutical development relies on placing billion- dollar bets on a binary outcome. As a result, de-risking investments is essential for a pharmaceutical company's survival. First, companies create a broad portfolio of products and mechanisms of action in order to diversify their investments. Second, companies de-risk vertically via incremental investments. Only after they've gathered enough information in support of a product's likelihood of success will they fund the next phase of study. Finally, companies will not invest in figuring out commercial scale manufacturing until at least phase 3, when they are almost certain of their product's success; not a major source of delay with small molecules, but a huge risk factor when dealing with protein and biologic manufacturing, which is as much art as it is science. This risk-averse approach ultimately results in extremely lengthy development timelines that last between 10 to 15 years. If we were going to develop a vaccine in time to fight the pandemic, we would have to completely disrupt the status-quo of vaccine development and manufacturing.

The success of Operation Warp Speed ultimately relied on our ability to solve seven critical problems:

1. Mission and buy-in. In the face of the incredible challenge that we faced, having a unifying goal was crucial for the success of Operation Warp Speed. Our first step was setting a stretch target of having enough authorized vaccines to vaccinate every American by the end of the year. In order to achieve this goal, inter-agency collaboration was key. This required not only the largest biomedical public-private partnership in history, but also a cross-government effort involving the heads of any department with a link to biological countermeasures. Defense Secretary Esper and I decided that we would co-lead the effort, reporting directly to the President so that we could avoid bureaucratic layers and unnecessary distraction for the team. HHS would provide the scientific and regulatory expertise, while DoD would bring its experience in logistics, operations, and procurement. My idea was to model the collaboration and personnel after the original Manhattan Project, with a General Leslie Groves as the project leader and a Robert Oppenheimer as the scientific leader. (Indeed, my original name for OWS was "Manhattan Project 2," but the team felt that wasn't a great name for a project aimed at saving the lives of millions of people.)

2. People and Organizational Capabilities. In assembling a team, we decided to focus on the main capability needs for Operation Warp Speed, and to select the best leadership accordingly, whether from the government or the private sector, using the model of the "dollar-a-year men" of World War II, where business leaders provided critical leadership to the war effort. We needed three different skill sets: drug development expertise, biologic manufacturing expertise, and government procurement, operations, and logistics expertise.

As development lead, we were fortunate enough to secure Moncef Slaoui, the former head of research and development at GlaxoSmithKline, who had remarkably led the successful development of 14 vaccines over 10 years. We were also able to persuade Carlo de Notaristefani to be the head of manufacturing, bringing with him his vast experience as head of manufacturing for Bristol Myers, and most importantly for our purposes of speed and agility, as global head of manufacturing for the giant generic company, Teva. To complete the team, Secretary Esper and Chairman Milley secured us the incredible four-star General Gustave Perna, the head of U.S. Army Materiel Command, as the overall government project leader and coordinator of operations, procurement, and logistics.

3. Execution Risk. One of our key guiding principles was to always leverage proven, repeatable systems as opposed to reinventing the wheel. The success of Operation Warp Speed was ultimately the result of the team effort between the public sector and the private sector, and the government's willingness to support industry leaders to undertake what they do best. Another critical success factor to ensure not a single day was wasted, was the removal of unnecessary bureaucracy, removing barriers for the team and enabling them as needed.

4. Development Risk. We decided to use the pharmaceutical portfolio model, placing multiple bets on the table to increase the odds of winning. Under Dr. Slaoui's leadership, we invested in three different platform technologies: mRNA, adenovirus, and protein subunit. Furthermore, we selected two vaccine candidates for each platform to mitigate our risk across each of the platforms. Following selection, we fully funded the development of the vaccine candidates up front, if that's what the companies needed to move quickly. (We didn't use a one-sized fits all model, but rather met companies where they were and where they needed us.) In doing so, we undertook all the financial risk on behalf of the pharmaceutical companies, enabling them to transition from Phase 2 to Phase 3 clinical trials within days. We ensured that clinical trial sites were established in anticipation, we had primary investigators on stand-by, and had the enrollment processes for clinical trials already underway. Last, we funded some of the largest clinical trials (minimum of 30,000 volunteers each) in human history for each vaccine, which sped the availability of statistically significant trial results.

5. Manufacturing Risk. We began the commercial- scale manufacturing of tens of millions of doses of vaccines as early as June 2020, when the vaccines were only in Phase 2 of their clinical trials. Within the following seven months, we stood up 27 different manufacturing facilities. Using the Defense Production Act where needed, we secured equipment and raw materials. Last, we co-located military logistics at many of these commercial manufacturing facilities to enhance the visibility and partnership between government and manufacturer.

6. Commercial Risk. Over the years, pharmaceutical companies have invested hundreds of millions of dollars in vaccine and therapeutic programs for tackling MERS, SARS, Zika, Ebola, and other emerging diseases, only to see the market disappear for each of those products by the time they reach late- stage development. How can you build a market to incentivize vaccine development?

Our solution was to create a market by providing a guarantee. We gave guaranteed purchase orders for 900 million doses of vaccine with options for another 2.1 million doses across the six selected candidates. Even if COVID-19 had been mitigated by the time these vaccines were authorized, we would have bought the qualified vaccines.

7. Distribution Risk. As early as the spring of 2020, we secured over a billion needles and syringes and hundreds of millions of vials, within an incredibly competitive global market. Mapping all the necessary components within the delivery mechanism from day one was critical to this success. Regardless of how safe and effective our vaccines were, without sufficient stocks of key components for delivering these vaccines into American arms, they would be completely useless. Adhering to a key principle of Operation Warp Speed, we decided to leverage existing expertise and capabilities within the private sector, by partnering with industry leaders to execute shipping and distribution.

Just seven months following the announcement of Operation Warp Speed, two of the safest and most effective vaccines in human history were authorized by the FDA with many tens of millions of doses available for distribution. In addition, as predicted, by the second quarter of 2021, we had a surplus of vaccines in the United States.

Operation Warp Speed was undoubtedly the greatest biomedical public-private partnership in history, and the most important public-private partnership since the Apollo Project and the Manhattan Project. Thanks to the unprecedented collaboration of government departments, the expertise and skills of the private sector, and the willingness of the OWS team members to give everything they had to this remarkable effort, millions of lives were saved.

Secretary Alex Azar

2. THE WARP SPEED MODEL

Operation Warp Speed was one of the most successful government-led programs in recent memory, causing a paradigm shift in vaccine development. We have been presented with an unique opportunity to apply lessons learned over the past three years and integrate them into our systems for the benefit of national security and medical innovation. However, as of yet, there have been no significant institutional shifts that reflect this opportunity.

With a view to ensure Operation Warp Speed's legacy and utility for future applications, we identify the following to be key success factors of Operation Warp Speed with the greatest potential for replication towards future uses, including Project NextGen:

Defined Timeline and Targets

Operation Warp Speed had a clear goal and deadline: to have enough authorized vaccines to vaccinate every American by the end of the year (2020). This clarity of purpose not only galvanized all stakeholders but also fostered a deep sense of accountability, motivating federal agencies, pharmaceutical companies, researchers, and healthcare providers to collaborate tirelessly toward this common objective.

The urgency of this timeline turned the impossible into the possible. The presence of a fixed deadline facilitated resource allocation, enforced prioritization, necessitated meticulous risk management, and provided a tangible measure of success. Moreover, the alignment of efforts among various stakeholders was achieved through this shared timeline and target.

Independent Leadership

Operation Warp Speed was directed by an independent leader outside government. Unlike typical government programs, this unconventional leadership structure did not tether the operation to any single bureaucratic agency. This approach was instrumental in fostering teamwork and cross-cutting collaboration. By operating outside the established bureaucratic silos, Operation Warp Speed was able to break down traditional barriers, promoting a sense of unity among various stakeholders. The absence of entrenched agency-specific interests allowed for a nimble and efficient response to the urgent demand for COVID-19 vaccines.

Furthermore, Operation Warp Speed's independent leadership brought private sector expertise within government, amplifying the power of public-private partnerships. Leveraging the strengths of both the public and private sectors not only delivered Operation Warp Speed's goals but also set a precedent for future partnerships in addressing global challenges.

Bipartisan Consensus

A success factor for Operation Warp Speed was its broad, bipartisan support from politicians, experts, and the public. This bipartisan backing ensured that Operation Warp Speed received the necessary funding, resources, and legislative support, allowing it to operate with agility and efficiency. The shared recognition of the urgent nature of the COVID-19 pandemic enabled the program to function with a unified focus on vaccine development and distribution.

Regulatory Acceleration

The Food and Drug Administration (FDA)'s role in accelerating the development of COVID-19 vaccines through Operation Warp Speed has not received proper recognition. Staff worked tirelessly to prioritize rapid processing and review of COVID-related submissions to the Agency. Review processes were streamlined, and, where possible, steps which are normally performed in sequence were parallelized to speed up the development timetable significantly. This resulted in the authorization of four safe and effective COVID-19 vaccines in record time.

The FDA's response to COVID-19 provides an excellent proof of concept for how regulatory reform can accelerate a drug's arrival to market without compromising information on product safety. Key FDA activities during Operation Warp Speed include: accelerated and streamlined processes; accelerated production of guidance; and early and frequent FDA-sponsor dialogue.

Market Shaping and Pull Incentives

Vaccines are one of the most cost-effective investments in health and economic development. However, their social value is often much greater than the private value for pharmaceutical companies. The development of vaccines is a risky and lengthy business and without clear financial returns, pharmaceutical companies are—understandably—reluctant to invest. Operation Warp Speed recognized these misaligned incentives and the need for a market shaping solution. The approach in the end was simple—the U.S. government would create the market for these vaccines, in the form of guaranteed purchase agreements.

These agreements committed the U.S. government to buying the vaccines at a preset price regardless of whether the threat posed by COVID-19 had waned by the time of authorization. This approach proved incredibly successful, giving pharmaceutical companies the confidence to rapidly progress through late-stage development and production, by ensuring a return on their investments.

3. PROJECT NEXT GEN

The Need

Despite the enormous success of Operation Warp Speed, SARS-CoV-2 has continued to evolve over the past three years, requiring different types of vaccines and treatments. Current covid vaccines, while conferring excellent protection against severe disease and death, are unable to block transmission and lack durability of protection, leading to the unabated evolution of SARS-CoV-2 and its devastating social and economic impact.

The Biden Administrations Project NextGen—a $5 billion initiative to accelerate next-generation covid vaccines and treatments—seeks to address this need.

NextGen's priorities include:

- More durable vaccines with broader protection against emerging variants
- Transmission reducing vaccines
- Pan-coronavirus vaccines
- More durable monoclonal antibodies against emerging variants

Challenges

Project NextGen faces an unclear market, confusing regulatory environment, and ambiguous targets:

Unclear Timeline and Target: While Project NextGen has a guiding mission, it lacks concrete targets and timelines, without which the standard assumption in the field seems to be that developing next-generation vaccines and treatments will take years. This expectation creates compounding delays by decreasing urgency for each actor at each stage of development.

Market Uncertainty: Any new product would be competing with existing licensed vaccines. Consumer demand for a new vaccine or booster is unclear (particularly given uncertain timing), and it's additionally unclear whether a pan-sarbeco vaccine would be rolled out broadly or kept in reserve for future pandemics.

Regulatory Uncertainty and Burden: The product specifications next-generation covid vaccines and treatments would have to meet are unclear as are the types of evidence required for approval.

4. WARP SPEED FOR NEXT GEN

DEFINED TIMELINE AND TARGETS

Target Product Profiles for NextGen Vaccines

| Authored by Rebecca Kirby

Given the levels of uncertainty faced by product developers, it would be valuable to outline the characteristics needed for next generation COVID-19 vaccines in a Target Product Profile (TPP).

A Target Product Profile (TPP) is a strategic document that summarizes the features of an innovation needed to address an unmet need.[1] A TPP outlines the desired characteristics of a target product by defining the intended use, target population(s) and other desired attributes of products, including safety and efficacy-related characteristics. [2]The TPP development process facilitates an open dialogue between the supply side (i.e., product developers, manufacturers, innovators) and the demand side (i.e., government regulatory agencies, international NGOs, end-users). Beginning with the end goal in mind, clearly defining the characteristics to address an unmet need through careful engagement with relevant stakeholders, will help to ensure that the clinical and economic benefits are appropriately demonstrated and the innovation will ultimately be adopted.

Aman Patel has led efforts to draft TPPs for next-generation coronavirus vaccines, with the contribution of expert stakeholders. Following a consensus meeting held in January 2023, TPPs have been published for mucosal COVID-19 booster vaccines and pan-sarbecovirus vaccines (both U.S.-focused versions and internationalized versions). A protocol for developing these TPPs is also publicly available.

We were encouraged to see BARDA include a draft Target Product Profile for next-generation COVID-19 vaccines as part of their recent Request for Information entitled Project NextGen: Potential Market Shaping Strategies for Vaccine Development and encourage the prompt publication of the final draft.

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1 Cocco, Paola et al. "Target Product Profiles for medical tests: a systematic review of current methods," BMC Medicine 18, no 19. (May 2020):1-12.

2 WHO Target Product Profiles (who.int)

DEFINED TIMELINE AND TARGETS

Integrating NextGen Vaccines with the Annual Flu Campaign

| Authored by Josh Morrison

Project NextGen should have defined target goals, including a proposed timeline for successfully having products available to the public.

A goal should be set to supply a total of ten million doses of NextGen coronavirus vaccines to Americans taking their annual flu shot in 2024 (roughly 7.5% of the 170 million Americans who receive a flu shot each year). A further ten million doses would be supplied to foreign partners such as Israel, Canada, and the United Kingdom. This would aim to create a regular cadence of 3-4 “slots” for new products in the flu vaccine rollout each year, which the most vaccine-enthusiastic part of the population would choose to utilize. The product rollout and partner countries chosen would be selected to generate real world evidence as to safety and effectiveness, validating existing trial methods and leading to broader product rollout over time. This strategy would also provide guaranteed demand for candidates and build a warm base capacity for rapid manufacture.

REGULATORY ACCELERATION

FDA's Emerging Pathogens Preparedness Program

Within its legislative proposals ahead of the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA), FDA included an Emerging Pathogens Preparedness Program (EPPP) within its Center for Biologics Evaluation and Research (CBER). On July 13, Senators Hickenlooper and Bud introduced a bill to create EPPP. The Senate Health, Education, Labor and Pensions (HELP) committee voted for its inclusion within its PAHPA bill on July 20th, 2023.

An Emerging Pathogens Preparedness Program would be a permanent team specifically dedicated to "defend against emerging pathogens so the agency is better positioned to respond to identified threats of concern and focus experienced resources to work quickly on medical countermeasure development."[1] Such a program would be well-positioned to formally embed the key success factors of Operation Warp Speed critical to the expedited authorization of the covid vaccines. In addition to increasing institutional expertise and preparedness, having a dedicated team would decrease disruption to regular processes during emergency outbreaks.

The Biden Administration's Project NextGen is a perfect case study for an Emerging Pathogens Preparedness Program. Allocating just 1% of Project NextGen's $5 billion to fund the creation of this new program would enable CBER to support Project NextGen vaccine candidates through product development, help establish critical immunoassays and correlates of protection, and execute expedited regulatory processes at a similar pace to Operation Warp Speed, which would be key to Project NextGen's success.

While the current proposal for EPPP is located within CBER, we are supportive of replicating the program within other centers, such as the Center for Drugs Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH), should EPPP prove successful within CBER.

1 *Summary of FY 2024 Legislative Proposals* (fda.gov)

REGULATORY ACCELERATION

Measuring Transmission Reduction through Human Challenge Studies

In a human challenge study, also called a human challenge trial (HCT), healthy, adult participants volunteer to be deliberately exposed to a disease. This is usually done to test a vaccine, but can also test treatments or reveal other important information about a disease. HCTs offer several advantages over traditional field trials. These controlled studies provide a precise and controlled environment for monitoring a vaccine or treatment's effectiveness, allowing researchers to observe the vaccine's impact in a relatively short timeframe. Moreover, they require smaller sample sizes compared to field trials, making them cost-effective and logistically feasible. They also play a crucial role in advancing our understanding of disease pathogenesis, immunity, and transmission dynamics. While ethical considerations and participant safety must be paramount, human challenge trials continue to be a valuable tool in advancing medical science and public health.

For Project NextGen, the benefits of HCTs are twofold. Firstly, they can help measure transmission reduction induced by mucosal vaccines. For mucosal vaccines to be effective, they need to reduce infection in the upper respiratory tract and inhibit subsequent viral shedding to effectively minimize virus transmission, however these reductions are challenging to assess in field studies. Challenge studies can help determine whether the immune response generated is likely to correlate with protection from infection and onward transmission due to the controlled nature of the challenge experiment and intensive data collection it facilitates. Secondly, HCTs are uniquely positioned to generate efficacy data prior to a viral outbreak. By using a betacoronavirus challenge agent,[1] researchers will be able to predict the efficacy of broadly protective next-generation covid vaccines against future variants. CEPI's recent call for proposals[2] to establish a HCT platform for testing mucosal vaccines against betacoronaviruses is a great advancement in the utility of challenge trials for medical countermeasures. To unlock the full potential of these efforts, it will be important for regulatory bodies to promptly publish clear guidelines that set-out a well-defined regulatory pathway for HCTs, to further encourage developers to pursue this approach.

1 A "challenge agent" refers to the infectious agent or pathogen that is deliberately administered to human volunteers in order to study the disease and test potential vaccines or treatments.
2 *Using "human challenge" studies in the hunt for virus-blocking vaccines*. (cepi.net)

MARKET SHAPING AND PULL INCENTIVES

Advance Market Commitments for Pan-sarbecovirus Vaccines

| Authored by Thomas Kelly

An advance market commitment is a contract where a sponsor agrees to purchase a specified quantity of a product at a specified price, provided it meets some qualifications. Because it encourages the creation of a product, without directly funding research or development or production of a product, advance market commitments are considered a type of "pull funding." Advance market commitments reduce the risk to the sponsor, since the sponsor only pays for a product if it exists and is produced. In contrast, loan guarantees, research grants, subsidies, and other types of "push financing" sometimes result in no value for the sponsor.

At this stage of the COVID-19 pandemic, private firms face substantial uncertainty about how profitable a pan-sarbecovirus vaccine would be. One source of uncertainty is around vaccine pricing. Political pressure, either explicit or implicit, could encourage pharmaceutical companies to price the vaccine at such a low price that the expected profits are insufficient to incentivize investment in developing such a vaccine. Another risk is that faced with the expectation of low prices, where pharmaceutical companies do develop the vaccine but devote relatively little manufacturing capability to producing such a low-profit product. In this case, some Americans may receive the vaccine (and the most vulnerable Americans could be prioritized) but the overall potential benefits of the vaccine would not be maximized. Other sources of uncertainty for potential vaccine manufacturers include the risk of low vaccine demand due to vaccine fatigue, competition from strain-specific boosters, competition from highly effective and widely available antiviral medicines, or perhaps even widespread natural immunity or potential declines in new COVID-19 infections.

MARKET SHAPING AND PULL INCENTIVES

In our recent paper, *An Advance Market Commitment to Incentivize a Universal Coronavirus Vaccine Before the Next Variant*, Rachel Glennerster, Christopher Snyder, and I argue that, in order to encourage the rapid production of a pan-sarbecovirus vaccine, the United States should provide an advance market commitment to vaccine manufacturers, where the federal government or a group of funders, promises to buy vaccine doses at a pre-agreed price, on the condition that the pan-sarbeco vaccine meets certain efficacy criteria and receives FDA approval. This reduces risk for the manufacturer by guaranteeing a market for their vaccines. Since an advance market commitment is a commitment to buy a certain number of vaccines provided the vaccine is actually effective, the financial risk to the funders is minimized. We estimate the value of such an advance market commitment to be approximately $ 700 billion to the United States alone. We argue that the cost of such an advance market commitment could be less than $5 billion although the ideal advance market commitment would cost approximately $10 billion.

Prizes for Establishing Correlates of Protection

Correlates of protection are immune responses that are responsible for and statistically interrelated with protection. Once a correlate is known, vaccines which reliably produce the correlate can be approved without testing efficacy in humans directly (in costly phase 3 studies). Project NextGen should use a multi-stage prize competition to incentivize steady progress on establishing correlates of protection for breadth, transmission reduction, and durability. This competition could be modeled after the KidneyX prize. It would involve identifying promising immunoassays, utilizing those immunoassays on BARDA-funded phase 2b studies and other approaches such as human challenge studies to correlate them to efficacy, and providing large prizes to submissions that establish regulatorily sufficient correlates of protection. This prize would both address (a) a market failure that the information has broad value to the public that is not internalized by any-one vaccine developer and (b) a coordination problem around establishing and testing hypotheses to a standard acceptable to the FDA.

CONTRIBUTORS

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