A woman with dark curly hair, wearing a white lab coat over a teal top, is looking down at a document in a binder. She is holding a red pen. The background shows a laboratory with various pieces of equipment and a microscope on the right. A yellow banner is overlaid on the top right of the image.

Surmounting the
insurmountable:
four keys to success in
deploying a COVID-19
vaccine at scale

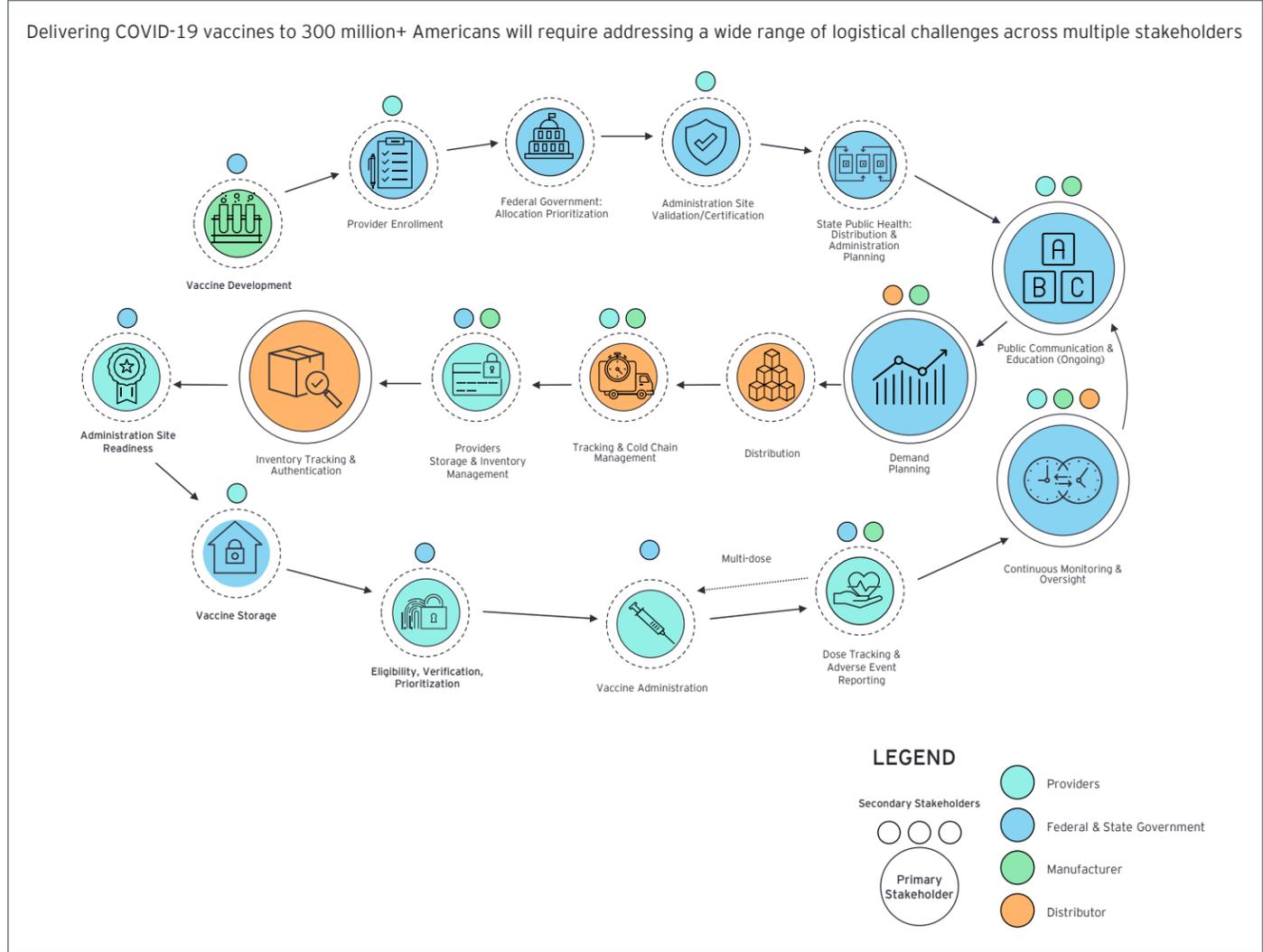
The EY logo, consisting of the letters 'EY' in a bold, black, sans-serif font. A yellow triangle is positioned above the 'Y'.

Building a better
working world



Surmounting the insurmountable: four keys to success in deploying a COVID-19 vaccine at scale

- 1 A command center built on integrated data infrastructure
- 2 Secure supply chain management of vaccine flows into the ecosystem
- 3 An integrated approach to patient engagement
- 4 Support for vaccine administrators/health care providers and integrated demand forecasting



Surmounting the insurmountable: four keys to success in deploying a COVID-19 vaccine at scale

Surmounting the insurmountable: four keys to success in deploying a COVID-19 vaccine at scale

As the race to create a vaccine for COVID-19 may be nearing the finishing line, all eyes turn to the logistical challenges at the heart of a mass immunization effort. Drug manufacturers and the federal government – via the Operation Warp Speed public-private partnership – have focused on the hyper-fast development of safe and effective COVID-19 vaccines, but this is just the beginning.¹ Once the vaccine has been approved, authorities will attempt to get over 300 million Americans vaccinated as quickly as possible – with an immediate focus on populations deemed most at risk. At a time of tremendous uncertainty, the storage, shipment, distribution, administration, tracking and monitoring that are key to an effective program must be carefully orchestrated. In these unprecedented times, there is a need for unprecedented solutions – challenging both the public and private sectors to execute individually and collaboratively in entirely novel ways.

Trust gaps and potential risks exist at most points in a multimodal supply chain that is massive in scale: consider delivering 400 million doses to the US population in a carefully timed and accurately tracked process. This will require stakeholders to utilize advanced technologies (technology at scale) that put humans first (humans at center). The latest science tells us, roughly 70% of the population (about 200 million Americans) will need to be vaccinated twice (first vaccines approved require two doses) for the virus to be effectively contained.² This will have to occur in a process that is meticulously tracked, prioritizes access to those populations most in need and secures data privacy

for patients.

It is this very complexity that highlights several “must-win” points within the COVID-19 vaccine value chain, where success is critical to the entire operation. In assessing these critical points, including the underpinning role of robust data and tracking platforms as well as overall program management, we have identified strategies that safeguard the integrity of the value chain. As part of this de-risking approach, the coordination of multiple stakeholders, data points and capabilities will be critical to create a successful COVID-19 vaccination program.

While there is no existing playbook for overcoming the COVID-19 vaccine challenge, there are relevant lessons learned from other complex public health crises, the pharma industry’s deep experience deploying vaccines at scale, and complex supply chain delivery both within and outside health care. The key to unlocking the current challenge is to synthesize existing competencies into a new set of protocols that provide safety, security, transparency and positive experiences for patients. Only by addressing these points, and surmounting these seemingly insurmountable execution challenges, will stakeholders close the trust gap and enable vaccine uptake at the rate needed to halt the pandemic.

¹ “Operation Warp Speed More Than Halfway to Enrolling Participants in Vaccine Trials,” *Department of Defense website*, <https://www.defense.gov/Explore/News/Article/Article/2329597/operation-warp-speed-more-than-halfway-to-enrolling-participants-in-vaccine-trial/>, August 28, 2020.

² “What is Herd Immunity and How Can We Achieve It With COVID-19?,” *Johns Hopkins School of Public Health website*, <https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html>, April 10, 2020; “Immunological considerations for COVID-19 vaccine strategies,” *Nature Research website*, <https://www.nature.com/articles/s41577-020-00434-6>, September 4, 2020.

1 A command center built on integrated data infrastructure

The Centers for Disease Control and Prevention (CDC) is in the process of determining prioritization criteria and allocations per jurisdiction for the initial limited vaccine doses once they are approved under emergency use authorization.³ Working with the Department of Defense, the CDC will then activate a national framework for distribution and safe administration, the outline of which has already been released.⁴ Jurisdictions are already enrolling vaccine providers, determining administration sites and establishing protocols that maximize throughput while maintaining social distancing and safety protocols.⁵ Each administration site (including temporary, off-site and mobile clinics) will need a dedicated administration protocol. At the core, states are being asked to establish highly complex vaccine command centers (with some support from the federal government), with deep program management needs, that will manage all aspects of vaccine distribution, administration and tracking.⁶

In order for each point in this journey to run smoothly, public sector command centers will need to deploy advanced analytics to coordinate the outflow of information to providers and local administration sites, as well as the inflow of data from vaccination programs – including wasted vaccine data, any adverse reaction data and patient tracking. The data will be essential in adjusting the program and adapting plans as the rollout develops.

In parallel, epidemiological data and pandemic analytics can be reported back to the command center to inform decision-making and demand forecasting. Without accurate demand forecasting, all stakeholders will be forging ahead without the key information needed to make informed decisions about access and aligned supply. In addition, because several of the vaccines rely on complex cold-chain systems,⁷ accurate demand forecasting down to the county level will avoid significant wastage, especially in the critical first six months of vaccine availability.

The command center and demand forecasting tools will be at the

heart of the immunization program as a whole and leveraged to communicate to supply chain partners where shifts and changes need to be made. Scenario planning will be an essential tool as uptake within and across communities evolves, new vaccine-related policies emerge and public sentiment continues to shift. Additionally, managing the multi-dose requirements creates capture/recapture challenges that are inherent in any vaccine program, but exacerbated by the scale and politicization of the COVID-19 response. The command center and underlying data platform provide the decision-support tools for leaders to plan for key scenarios and communicate implications for the whole multilayer ecosystem.

While the need for a strong digital platform that serves to coordinate multiple stakeholders is critical, in many cases existing structures can be utilized. Jurisdictions that are already suffering from change fatigue can integrate these tools and capabilities within their systems, decreasing the scale and complexity of the task.

The command center approach, and the data layer underpinning it, creates a responsive feedback loop among jurisdictions and federal agencies, multiple providers, distribution partners and individual administration sites that is essential to successful execution.

³ “The FDA’s Scientific and Regulatory Oversight of Vaccines is Vital to Public Health,” *Food and Drug Administration website*, <https://www.fda.gov/news-events/fda-voices/fdas-scientific-and-regulatory-oversight-vaccines-vital-public-health>, September 11, 2020.

⁴ “COVID-19 vaccine prioritization: Work Group considerations,” *CDC website*, <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-08-Dooling.pdf>, August 26, 2020.

⁵ *Ibid.*

⁶ “C.D.C. Tells States How to Prepare for Covid-19 Vaccine by Early November,” *The New York Times website*, <https://www.nytimes.com/2020/09/02/health/covid-19-vaccine-cdc-plans.html>, September 2, 2020.

⁷ “How to prepare a cold chain for looming COVID-19 demands,” *Pharmaceutical Commerce website*, <https://pharmaceuticalcommerce.com/cold-chain-focus/how-to-prepare-a-cold-chain-for-looming-covid-19-demands/>, September 25, 2020.

2 Secure supply chain management of vaccine flows into the ecosystem

Securing and building UPON public trust and confidence in the supply chain related to COVID-19 vaccines is a necessity. With large-scale supply chains and patient-related data collection once administration starts, there are risks of software vulnerabilities to cyber attack. Additionally, attacks on climate-control smart sensors, for instance, could compromise vaccine efficacy. There will need to be effective authentication processes for everyone who has access to sensitive data, along with security that prevents credentials from being stolen. Risk management routines to manage possible security breaches while limiting and controlling the impact of any such breach will be essential. Cybersecurity underpins the entire value chain and is essential for public confidence. Overall, sustaining public confidence and trust in the quality and delivery of the vaccine will require consistent and dependable supply chain oversight to mitigate disruption and support seamless execution.

Each dose of the vaccine will need to be securely tracked and matched to the individual receiving it for security and post-dose monitoring. Managing this will require newly developed tracking platforms that share data across a multimodal and complex supply chain. In other challenges, blockchain technologies have proved invaluable by bringing transparency and order to complex, even chaotic, supply chains. Today, the salmon someone eats for dinner can be traced back to the specific

stream in western Scotland where its eggs were spawned; blood supplies are tracked from point of donation all the way to the end administration of each related blood product. Blockchain ledgers can be updated hundreds of times a day, tracking large sets of encrypted data, such as vaccine batches, medical supplies or medical records, with both transparency and security. As such, their use within the COVID-19 vaccine context could have significant positive impact.

However, integrating advanced technologies, including blockchain, with legacy systems that hold patient data will not be straightforward. All data will need to be encrypted to manage patient records securely, and the various stakeholders who hold the data will need to agree on common ways of inputting to the ledger. Typically, life sciences companies are experts at managing entire processes, but they have less experience in sharing and collaborating with multiple public agencies at launch. The COVID-19 vaccine challenges provide a unique opportunity for both life sciences companies and other stakeholders to buy into advanced technologies that offer end-to-end visibility of the supply chain, plugging into systems that add data to the common ledger and safeguarding any individual data via encryption.

Collaboration, while key, can only work in an atmosphere of full transparency and trust.

3 An integrated approach to patient engagement

With many already skeptical of vaccines, distrust of a newly approved COVID-19 vaccine may compel as much as a third of the population to opt out of an immunization program, including many of the most vulnerable.⁸ In addition, other patient-centered challenges are likely to arise, potentially leading to fraudulent attempts to jump the line. This could lead to a mistrust of prioritization criteria for receiving the vaccine. Moreover, a multi-dose regimen introduces additional complexity.⁹ Research shows that completion rates for multi-dose vaccinations are significantly reduced, creating the potential for lower efficacy as well as vaccine waste.¹⁰ For example, in one study, only 27% of hepatitis A vaccine recipients adhered to the two-dose schedule.¹¹ Where trust and engagement are already tenuous, any disconnect or disruption between demand and supply would exponentially increase distrust in the entire vaccination effort.

Public health organizations at the federal and state level will be responsible for the majority of patient education and engagement regarding COVID-19 vaccines. They will need to manage the complexity of reaching the population at large, while also targeting specific at-risk and underserved populations. Leveraging best practices for targeted digital engagement will help these organizations to deploy messaging at scale while also meeting individualized needs.

For life sciences companies accustomed to managing all aspects of a product launch, the COVID-19 vaccine launch will be very different. They will need to integrate their approach to patient engagement with public health agencies, insurers and providers, with each performing a non-duplicative role that complements the others. Government agencies, for the first phase of commercialization, will manage and/or dictate many practices that are typically in the domain of manufacturers, such as distribution, allocation and customer engagement.¹¹ Nonetheless, this presents a significant opportunity for vaccine manufacturers to improve the overall process and experience. One major challenge for participating organizations will be

determining where to collaborate and where to act on their own. Life sciences companies can excel by harnessing their expertise in patient engagement to address any trust concerns.

To play their part, life sciences companies will need to do much of the heavy lifting in communication to overcome concerns, provide targeted education around adherence to multi-dose regimes and adequately address the special needs of high-risk and high-priority communities. Public health agencies, primarily charged with developing and disseminating patient education tools, also can consider how to leverage collaborations with manufacturers to expand their reach and impact, especially among vulnerable and underserved populations. Ongoing sentiment analysis will be critical to understand uptake, gain insights into general public confidence and trust, and help stakeholders align to overall strategy and policy.

⁸ "One in Three Americans Would Not Get COVID-19 Vaccine," *Gallup website*, <https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx>, August 7, 2020

⁹ "Adherence with and completion of recommended hepatitis vaccination schedules among adults in the United States," *ScienceDirect website*, <https://www.sciencedirect.com/science/article/pii/S0264410X18307886>, August 23, 2018.

¹⁰ *Ibid.*

¹¹ *Ibid.*

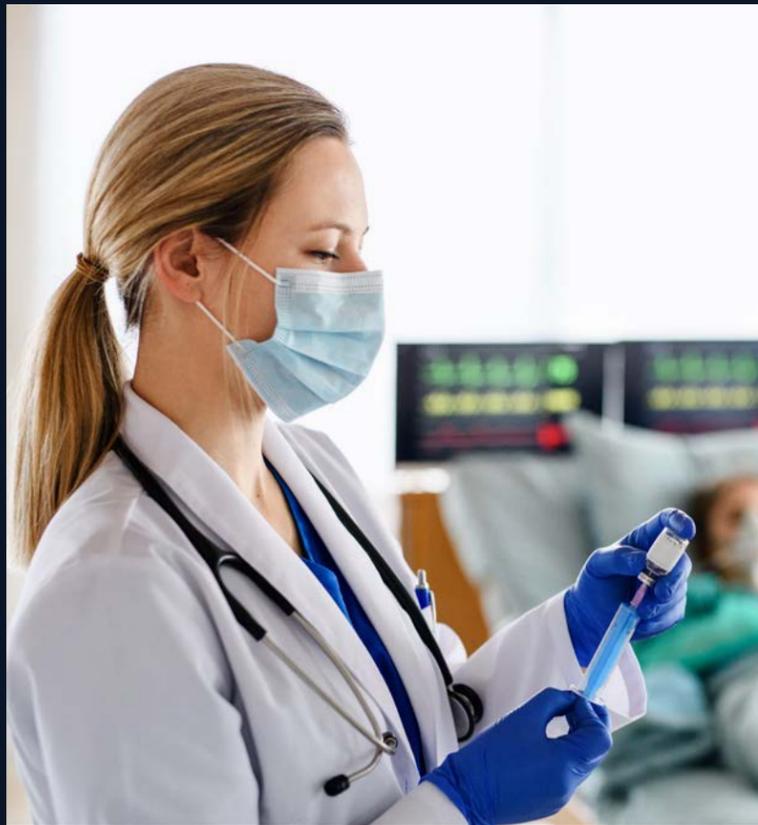
¹² "Pandemic Vaccine Program Distribution, Tracking, and Monitoring," *CDC website*, <https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf>, April 20, 2020.

4 Support for vaccine administrators/health care providers and integrated demand forecasting

Creating a fluid vaccine administration experience relies on several factors. The public sector, alongside private sector companies, will need to manage the effective distribution of non-vaccine administration materials, such as personal protective equipment, to align with local demand. Provider enrollment and the recruitment and training of medical and nonmedical staff to support administration are also critical first steps to meeting the administration demands that will emerge once vaccines are available. All vaccination sites need to create environments that safeguard those administering the vaccine, the patients waiting in line for vaccinations and any administration staff. This depends upon the effective development of protocols, communication to administration sites, and site readiness and preparation.

Once administration occurs, there needs to be meticulous record-keeping with regard to the vaccine delivery itself (and any wastage) and individual vaccine responses. This data will need to be provided through state jurisdictions to the state command center and potentially its federal counterpart in order to forecast demand and track any adverse events. Unknown variables (e.g., uptake by high-risk, high-priority groups) can become more predictable as data becomes available to help inform the whole immunization program.

Integrated, data-driven demand forecasts will help public sector, private sector and health care providers plan more effectively so that the complex system is optimized for evolving demand curves.



Call to action

The COVID-19 crisis is the largest and most destructive pandemic to strike in the 21st century: the human and economic cost continue to rise. We know that fear and distrust are substantive obstacles that both public and private organizations need to overcome. If the rollout of vaccines is mismanaged and the public chooses to wait on the sidelines as opposed to getting vaccinated, the pandemic will continue to ravage the health of the population and the economy – both domestically and globally. As healthcare stakeholders respond to the pandemic, coordination and risk mitigation are essential.

This unprecedented challenge calls for big ideas and significant collaboration. When we recognize key “must-win” challenges, and create the systems and infrastructure needed to overcome them, success is possible. The four areas outlined above require immediate focus, and by leveraging technology, building safer and more transparent systems, addressing the last-mile challenges and committing to educating patients, stakeholders will be empowered to overcome the seemingly insurmountable challenges associated with deploying COVID-19 vaccines at scale to end the pandemic. That is a prize worth fighting for.

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