



Review Article

Platform Readiness in the Pandemic Era: Vaccine Technology and Adaptive Regulatory Science after COVID-19

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ABSTRACT

The COVID-19 pandemic compressed a development cycle once measured in decades into less than twelve months, exposing the latent maturity of platform-based vaccinology. This review argues that the pandemic acted not as the origin of that capability but as a forcing function that converted decades of preparatory science—nucleoside-modified mRNA, lipid-nanoparticle (LNP) delivery, reverse vaccinology, and rational adjuvant design—together with adaptive regulatory architecture, into a durable shift from product-based to platform-based vaccine development. Following PRISMA-ScR guidance, literature from PubMed, Scopus, and Web of Science (2000–2025, focus 2019–2025) was synthesised across platform, adjuvant, computational-design, regulatory, and emerging-technology domains. We compare the six platforms authorised against SARS-CoV-2; trace the mRNA breakthrough from Karikó and Weissman's nucleoside modification to oncology applications; examine reverse vaccinology and AI-guided structural prediction; and analyse adjuvant innovation from alum to AS01, CpG 1018, and Matrix-M. We then dissect the regulatory science of acceleration—parallel processing, rolling review, interim Phase 3 thresholds, and pharmacovigilance—using India's DCGI Covaxin authorisation as a case study in decision-making under uncertainty. We conclude by appraising emerging modalities, noting that much of this evidence remains early-phase. The central finding is that scientific and regulatory architecture, not improvisation, enabled pandemic speed—and that this architecture now defines preparedness.

Keywords: COVID-19; mRNA vaccines; vaccine platforms; adjuvants; reverse vaccinology; regulatory innovation; pandemic preparedness.

1. Introduction

Vaccines remain among the most cost-effective interventions in public health, priming the immune system to respond before pathogen encounter rather than treating disease after onset. Economic analyses estimate a return of approximately US\$44 for every US\$1 invested in immunisation in low- and middle-income countries.¹ The COVID-19 pandemic, which began in Wuhan, China, in late 2019, exposed deep weaknesses in global health systems while simultaneously driving extraordinary progress in vaccine science, regulation, and manufacturing.² By September 2023, more than 770 million confirmed cases and over 6 million reported deaths had been recorded worldwide, with excess-mortality estimates approaching 18 million.³

The speed of the response was unprecedented. Within roughly a year, the field moved from viral identification to regulatory authorisation of several safe and effective vaccines—a timeline widely considered impossible beforehand. That acceleration rested on years of prior work in mRNA stability, viral-vector technology, and protein-subunit production, combined with flexible regulatory systems, sustained financing, and global scientific collaboration. Design drew on structural immunology, computational antigen selection, formulation science, and systems vaccinology, yielding vaccines effective against a rapidly evolving virus.²

This review advances a single thesis: the pandemic did not create platform vaccinology but revealed and consolidated it, converting latent capability into a permanent operating model. Earlier reviews have tended to treat individual platforms or technologies in isolation. Here we integrate platform diversity, the mRNA breakthrough, computational antigen design, adjuvant engineering, and regulatory acceleration into one argument about how—and how durably—the science of making vaccines changed.^{4,5}

2. Review Methodology

This narrative review followed PRISMA-ScR guidance for scoping reviews. We searched PubMed, Scopus, and Web of Science, supplemented by WHO, CEPI, and Gavi repositories, for publications from January 2000 to December 2025, with emphasis on peer-reviewed sources from 2019–2025. For this article, search strings prioritised the technological and regulatory domains: “COVID-19 vaccine” OR “SARS-CoV-2 vaccine”; “adjuvant systems” AND “pandemic preparedness”; “reverse vaccinology” AND “AI”; “regulatory innovation” AND “platform technology”. Inclusion was limited to peer-reviewed original research, systematic reviews, meta-analyses, and authoritative institutional reports. Conference abstracts without full texts, non-peer-reviewed opinion pieces, industry newsletters as primary sources, and items lacking verifiable authorship were excluded.



3. Historical Foundations of Vaccine Technology

The pandemic response was the culmination of more than two centuries of advances in immunology, microbiology, and molecular biology. Jenner's 1796 demonstration that cowpox inoculation conferred protection against smallpox laid the empirical groundwork.⁶ Pasteur advanced this into laboratory science with live attenuated vaccines against cholera (1879), anthrax (1881), and rabies (1885) through systematic attenuation, while Koch's germ theory supplied a framework for identifying causative agents and designing targeted interventions.⁷

The twentieth century brought toxoid vaccines for diphtheria and tetanus and the cell-culture techniques of Enders, Weller, and Robbins (Nobel Prize, 1954) that enabled the Salk and Sabin polio vaccines, followed by measles, mumps, rubella, varicella, and hepatitis B vaccines.⁸ Recombinant DNA technology in the 1970s and whole-genome sequencing in the 1990s transformed antigen design, safety evaluation, and large-scale production. The 1918 influenza pandemic, with an estimated 500 million infections and 50–100 million deaths, remains a stark reminder of respiratory-virus severity in the absence of vaccines.⁹

Critically, the 2014–2016 Ebola outbreak was a direct precursor to COVID-19 preparedness. Delayed deployment of the already-researched rVSV-ZEBOV vaccine exposed systemic gaps in funding, regulatory coordination, and manufacturing capacity.¹⁰ In response, the Coalition for Epidemic Preparedness Innovations (CEPI) was founded in 2017 to fund platform technologies—mRNA and viral vectors among them—with the explicit aim of compressing development from over a decade to one to two years. These proactive platform investments proved to be a prerequisite for the rapid COVID-19 response.^{2, 11}

4. The Six COVID-19 Vaccine Platforms

The pandemic acted as a powerful stimulus for the parallel maturation of multiple vaccine technologies. Between December 2020 and December 2021, vaccines across six distinct platforms were authorised against SARS-CoV-2, demonstrating unprecedented translational breadth. mRNA vaccines, Comirnaty, Pfizer–BioNTech, 11 December 2020; Spikevax, Moderna, 18 December 2020, led the field.^{12, 13} Viral-vector vaccines (Oxford–AstraZeneca/Covishield; Janssen Ad26.COVS.2S) and recombinant protein-subunit vaccines (Novavax/NVX-CoV2373) followed, alongside inactivated whole-virus vaccines (Bharat Biotech's Covaxin/BBV152; Sinovac's CoronaVac) and the first authorised DNA-plasmid vaccine, Zydus ZyCoV-D, 20 August 2021.¹⁴

The plant-derived virus-like particle (VLP) vaccine Covifenz (Medicago/GSK) illustrates how governance and ownership structures intersect with platform diversification: authorised by Health Canada in February 2022, it was excluded from WHO Emergency Use Listing owing to the manufacturer's tobacco-industry links and was discontinued in early 2023 after Mitsubishi Chemical Group halted

production. It remains an instructive case in platform diversification and regulatory governance.^{15, 16}

5. mRNA: The Platform That Changed Everything

The success of mRNA vaccines against COVID-19 is a landmark in modern vaccinology. Work by Karikó and Weissman showed that nucleoside modification—notably N1-methylpseudouridine—reduces innate immune activation while improving mRNA stability and translation, providing the scientific foundation for clinical use. This work earned the 2023 Nobel Prize in Physiology or Medicine, underscoring how basic research directly enabled life-saving vaccines; the urgency and financing of the pandemic then converted discovery into approved product.^{17, 18}

Lipid nanoparticles (LNPs) were the second decisive advance, protecting fragile mRNA from degradation, enabling endosomal escape, and ensuring efficient cytoplasmic delivery and antigen production. Comirnaty became the first mRNA vaccine authorised for human use (11 December 2020), followed by Spikevax (18 December 2020), with pivotal Phase 3 efficacies of 95% and 94.1% against symptomatic COVID-19.^{12, 13} Unlike DNA vaccines, mRNA acts entirely in the cytoplasm, avoiding the nucleus and any prospect of genomic integration.¹⁹

The platform's versatility extends well beyond infectious disease. Personalised neoantigen vaccines such as BNT111 (BioNTech) and mRNA-4157/V940 (Moderna/Merck) are in advanced trials for melanoma. The Phase 2b KEYNOTE-942 trial reported a statistically significant 44% reduction in recurrence or death versus pembrolizumab alone in high-risk stage III/IV melanoma—the first positive Phase 2b result for a personalised mRNA cancer vaccine, with three-year follow-up indicating a 49% risk reduction. Phase 3 trials in melanoma and non-small-cell lung cancer are ongoing.^{20, 21, 22}

6. Reverse Vaccinology and Computational Antigen Design

Reverse vaccinology (RV) is a transformative computational strategy for antigen discovery through *in silico* analysis of an entire pathogen genome. Pioneered by Rappuoli and colleagues for the meningococcal B vaccine (Bexsero), RV identifies protective immunogenic epitopes without laboratory cultivation—a decisive advantage for dangerous or unculturable agents.²³

Integrating RV with mRNA platforms enables rapid, precise design against emerging threats. AI-driven deep-learning models such as AlphaFold2 further accelerate the process by providing high-fidelity structural predictions of antigen conformation.²⁴ This computational synergy allows optimised antigen design within days of genome sequencing, compressing the “pathogen-to-product” timeline to historically unprecedented levels and forming the conceptual backbone of CEPI's 100 Days Mission.

7. Adjuvant Innovation: Engineering Durable Immunity

Vaccine adjuvants have emerged as a strategically important component of modern immunization science.



Beyond enhancing the magnitude of the immune response to a given antigen, adjuvants are engineered to prolong and diversify that response, thereby improving recognition and immunological memory of the target pathogen.

This enhanced immunogenicity confers a further practical advantage: dose sparing. By amplifying the immune response elicited by reduced quantities of antigen, adjuvants allow manufacturers to extract a greater number of doses from a fixed antigen supply. This capacity is of value during supply constraints or public health emergencies, when antigen production capacity is insufficient to meet demand.

Adjuvants additionally address a persistent limitation in vaccine efficacy: diminished immune responsiveness in older adults and immunocompromised populations. Adjuvanted formulations have been shown to improve immunogenicity in these groups, partially offsetting age- or immunosuppression-related declines in vaccine responsiveness. Collectively, these properties position adjuvants not merely as auxiliary components of vaccine formulation, but as strategic assets in global health preparedness.²⁵

This expanding role is reflected in market trends. The global human vaccine adjuvants market, valued at USD 4.16 billion in 2025, is projected to reach USD 5.62 billion by 2035, corresponding to a compound annual growth rate (CAGR) of 3.2% over the 2026–2035 forecast period.²⁶

7.1 The Resilience of Alum

Since the 1920s, aluminium salts have anchored adjuvant science.²⁷ Once viewed simply as depot-forming agents,

alum formulations are now understood to engage multiple innate pathways, including NLRP3 inflammasome activation, shaping downstream adaptive responses. Their durable appeal lies in a rare combination of safety, stability, and low cost: alum adsorbs proteins onto its crystalline surface, prolongs antigen exposure, and converts soluble proteins into particulates that antigen-presenting cells engulf more efficiently. It remains the global benchmark for established platforms—DTP and hepatitis B vaccines—and for the inactivated SARS-CoV-2 vaccine BBV152.²⁷

7.2 Advanced Adjuvant Systems and COVID-19 Applications

The pandemic accelerated clinical adoption of advanced adjuvant systems, underscoring that adjuvant selection is as consequential as antigen design for safety, potency, and durability. **MF59**, the first non-aluminium human adjuvant (1997), is a squalene oil-in-water emulsion that recruits monocytes, macrophages, and dendritic cells and carries a strong safety record across more than 100 million doses, including in pregnancy and young children. **AS03**, an α -tocopherol-enriched emulsion, drives innate activation and cytokine release (CCL2, IL-6, CXCL1) and underpins the GSK CoV2-preS dTM-AS03 subunit vaccine. **AS01** combines MPL with QS-21 for potent innate activation, especially valuable in older adults; it features in Mosquirix (RTS,S), Shingrix, and the RSV vaccine Arexvy. **AS04** pairs MPL with alum to combine novel immune activation with prolonged antigen retention. **CpG 1018**, a synthetic 22-mer TLR9 agonist, activates plasmacytoid dendritic cells to generate strong Th1 CD4+/CD8+ responses and durable B-cell memory, and serves as a model for scalable, LMIC-friendly manufacturing in HEPLISAV-B and Corbevax.^{27, 28}

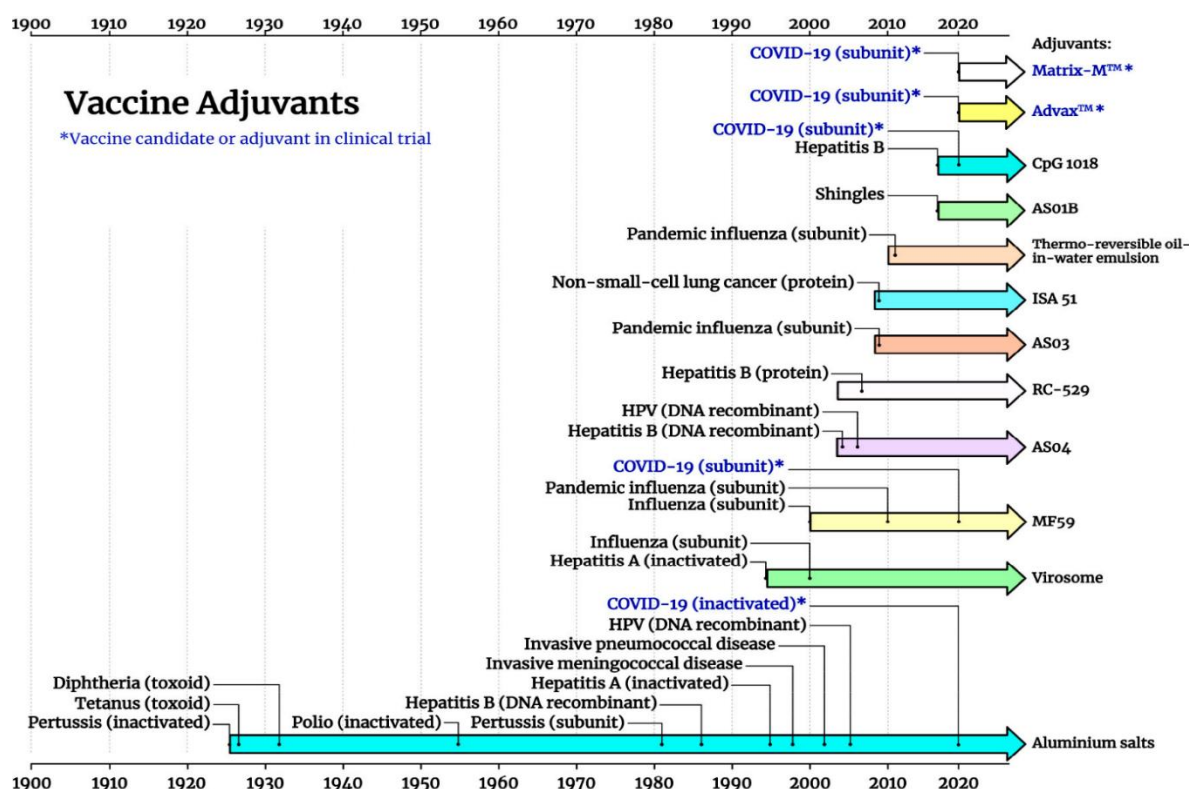


Figure 1: Timeline of adjuvants used in human vaccine development.²⁹

7.3 Nanotechnology and Rational Design

The post-COVID era has shifted adjuvant science from empirical formulation toward rational immune engineering. LNPs in mRNA vaccines act as dual-purpose systems, both protecting mRNA and contributing to innate activation.³⁰ Machine-learning models trained on immunoprofiling datasets can now predict adjuvant-specific immune signatures, enabling more precise matching of adjuvant to antigen and to target population—pointing toward intelligently engineered, population-tailored protection.³¹

8. The Regulatory Science of Acceleration

A transformative pillar of the response was the rapid evolution of regulatory frameworks. The pandemic forced a paradigm shift toward parallel processing—restructuring the regulatory lifecycle to eliminate dead time between clinical and manufacturing milestones. Leading authorities (US FDA, EMA, UK MHRA, India's CDSCO, and WHO) synchronised oversight to support overlapping clinical phases and at-risk manufacturing.

8.1 The Parallel Processing Framework

Acceleration came not from bypassing scientific milestones but from replacing a sequential “gated” model with an overlapping one.

- **Overlapping clinical phases:** Phase 1, 2, and 3 trials enrolled concurrently; preliminary immunogenicity data triggered immediate late-stage efficacy trials, eliminating inter-phase administrative delay.³²
- **At-risk manufacturing:** Industrial scale-up began before trial completion, decoupling commercial production from final clinical results so that millions of doses were ready the moment authorisation was granted.³³

8.2 Rolling Regulatory Reviews

The mechanism underpinning this model was “rolling” review, which recast the regulator from static evaluator to real-time collaborator assessing data modules as generated, an approach validated across major regulatory systems during the pandemic.

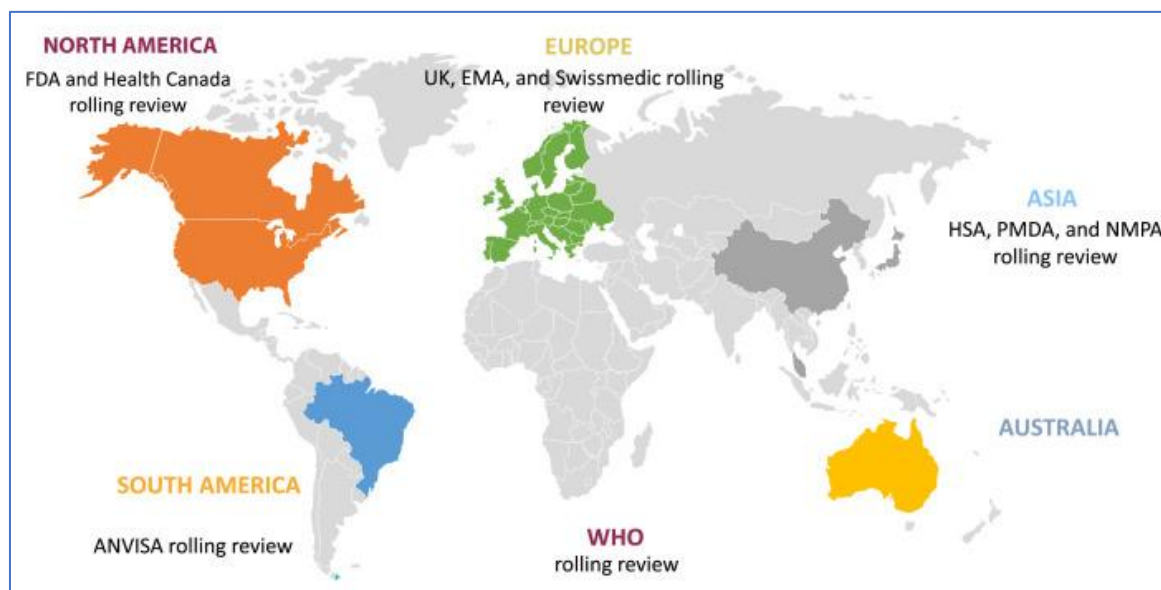


Figure 2: Rolling regulatory review architecture during the COVID-19 pandemic.

Pictogram, showing the health authorities around the globe that introduced or offered a rolling review process to applicants for the evaluation of COVID-19 treatments and vaccines. ANVISA = Brazilian Agencia Nacional de Vigilância Sanitária; EMA = European Medicines Agency; FDA = US Food and Drug Administration; HAS = Health Science Authority; MHRA = UK Medicines and Healthcare Products Regulatory Agency; NMPA = Chinese National Medical Products Administration; PMDA = Pharmaceuticals and Medical Devices Agency; WHO = World Health Organization.³⁴

- **Non-clinical module:** In vivo models establish safety margins and dose-ranging, allowing proactive identification of safety signals; challenge studies provide biological proof of concept before human trials conclude.³⁵
- **CMC module:** Reviewing chemistry, manufacturing, and controls during ongoing trials surfaces purity or stability issues in real time, reducing late-stage rejection risk and ensuring facilities are authorised for distribution immediately upon demonstrating efficacy.³⁶
- **Review efficiency:** By the time final efficacy data arrive, biological and manufacturing hurdles have cleared in parallel, compressing a six-month bottleneck to days.³⁷

8.3 Interim Phase 3 Efficacy and Decision Thresholds

Interim Phase 3 analysis—a prespecified statistical evaluation conducted before scheduled completion—marks the shift from a focus on safety and immunogenicity to

definitive clinical efficacy. Executed by an independent data and safety monitoring board, it tests whether the intervention meets its primary endpoint against control, enabling early detection of benefit and expedited authorisation.

It also functions as a stopping rule: a demonstrably ineffective or harmful candidate can be halted early to limit participant exposure. Interim results supply the statistical proof of concept required for emergency use authorisation, providing essential risk–benefit evidence during a crisis despite involving fewer events than final analyses.³⁸

8.4 Safety Safeguards: AEFI Monitoring

The primary safety net remains surveillance of Adverse Events Following Immunisation (AEFI)—any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease occurring within a defined window after vaccination. Continuous AEFI monitoring allows health authorities to detect potential safety signals quickly, recognise rare or unexpected reactions, and act to protect recipients, sustaining public confidence in immunisation programmes worldwide.³⁹

8.5 Case Study: India's DCGI and the Covaxin Authorisation

India's DCGI demonstrated notable regulatory maturity by authorising Covaxin (BBV152) on 3 January 2021 under a bespoke "Restricted Emergency Use" framework (CDSO/DCGI, 2021) a key case study in decision-making under extreme uncertainty.⁴⁰

- **Scientific gap:** Unlike the FDA and EMA, which typically require interim Phase 3 data, the DCGI's initial authorisation preceded Phase 3 efficacy results, resting instead on robust Phase 1–2 immunogenicity confirming variant-neutralising capacity.
- **Restricted-mode protocol:** Authorisation in "clinical trial mode" meant every recipient was tracked with trial-level rigour, effectively creating a large real-world Phase 3 extension to mitigate clinical risk.
- **Validation:** The calculated risk was statistically vindicated when Phase 3 results showed 77.8% efficacy against symptomatic and 93.4% against severe COVID-19.⁴¹

8.6 Regulatory Legacy: The 100 Days Mission and NRA Capacity

The pandemic is reshaping WHO's Emergency Use Listing pathway and CEPI's 100 Days Mission, which aims to move from pathogen identification to authorisation within 100 days. Two enablers stand out: **platform-based dossiers**, using "master files" for established platforms (mRNA, viral vectors) so that only the pathogen-specific insert requires new data; and **NRA capacity building**, strengthening National Regulatory Authorities in LMICs to support independent assessment and global equity.⁴²

9. Emerging Technologies and Future Directions

The post-COVID landscape is defined by converging technologies that shorten timelines, improve thermostability, broaden protection, and extend access to resource-limited settings. The central enabler is the transition from product-based to platform-based vaccinology, in which a single architecture adapts rapidly to new pathogens, delivery routes, and non-infectious targets.

9.1 Self-Amplifying RNA (saRNA)

saRNA encodes both the target antigen and an RNA-dependent RNA polymerase, allowing intracellular amplification from a substantially lower starting dose and reducing raw-material requirements while preserving immunogenicity.⁴³ Kostaive (also known as ARCT-154) is a self-amplifying mRNA COVID-19 vaccine developed by Arcturus Therapeutics and CSL, approved by Japan's Ministry of Health on 28 November 2023, and became the world's first authorised saRNA vaccine.⁴⁴

9.2 Mucosal Vaccines

Mucosal vaccines address a key limitation of intramuscular immunisation: although parenteral vaccines prevent severe disease, they less effectively block infection at the point of entry or curb transmission. India's INCOVACC (Bharat Biotech), the world's first authorised intranasal COVID-19 vaccine (DCGI, September 2022; launched 26 January 2023), primes nasal-associated lymphoid tissue toward sterilising immunity that could interrupt community transmission.⁴⁵

9.3 Thermostable Formulations and Microneedle Delivery

Thermostable formulations target cold-chain dependence, a longstanding equity barrier. Advances in lyophilisation, nanoformulation, and solid-state delivery now stabilise vaccines outside strict refrigeration, particularly valuable in tropical and remote settings.⁴⁶ Microneedle patches extend this by depositing antigen directly into skin rich in Langerhans and dermal dendritic cells, enabling efficient antigen capture, dose sparing, reduced sharps waste, and simplified administration.⁴⁷

9.4 Next-Generation Platforms

circRNA, ferritin and other nanoparticle antigen-display systems, and CRISPR-based concepts illustrate the field's growing speed and sophistication. AI-guided antigen design, computational epitope mapping, and mosaic immunogens are expanding platforms beyond traditional infectious disease. The post-COVID industry is now defined by platform-based innovation, computational design, and translational speed.⁴⁸

DISCUSSION

Read together, these advances support a single conclusion: pandemic speed was engineered, not improvised. Nucleoside-modified mRNA, LNP delivery, reverse vaccinology, and rational adjuvant design had each matured over years; the pandemic supplied urgency and financing that fused them with adaptive regulation. The durable



legacy is structural—master-file dossiers, rolling review, and platform-readiness investment—rather than any single product. Yet the paradigm's breadth should not be overstated: much of the emerging-technology pipeline remains preclinical or early-phase, immune correlates of protection are incompletely defined across platforms, and reactogenicity and durability trade-offs persist. The central open question is whether platform readiness can be sustained between pandemics, when commercial and political urgency recede.

CONCLUSION

The COVID-19 pandemic compressed vaccine development from a decadal endeavour into under twelve months by activating latent platform science and pairing it with adaptive regulation. Six platforms reached authorisation; nucleoside-modified mRNA with LNP delivery emerged as the defining breakthrough, validated by 95% and 94.1% Phase 3 efficacies and now extending into oncology. Reverse vaccinology and AI-guided structural prediction shortened the pathogen-to-product timeline, while adjuvant engineering—from alum to AS01, CpG 1018, and Matrix-M—expanded the design space for durable, dose-sparing immunity. Regulatory science matured in parallel through parallel processing, rolling review, and interim-efficacy decision-making, exemplified by India's restricted-emergency-use authorisation of Covaxin. Emerging modalities point toward predictive, platform-based preparedness, though much evidence remains early-phase. The enduring lesson is that scientific and regulatory architecture—not crisis improvisation—enabled the response, and that maintaining this architecture is now the core task of pandemic preparedness.

LIMITATIONS

As this is a structured narrative rather than a systematic review with meta-analysis, source selection reflects the authors' judgement and cannot exclude selection bias. The evidence base for several emerging technologies (circRNA, ferritin nanoparticles, CRISPR vaccine design) is largely preclinical or early-phase, limiting generalisable clinical conclusions. Additionally, the literature search was predominantly restricted to English-language publications, introducing a possible language bias.

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