

Strategic Leadership in Global Pharmaceutical Program Management: Driving Innovation in Respiratory and Emerging Viral Diseases

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Abstract

The pharmaceutical industry crucially contributes to addressing worldwide health issues through activities relating to respiratory care and handling emerging viral diseases. Strategic leadership within pharmaceutical program management is now essential because the world deals with rising infectious outbreaks combined with escalating chronic respiratory conditions. Strategic leadership enables pharmaceutical organizations to handle challenging regulatory requirements by building multidirectional alliances while carrying out advanced respiratory and viral disease investigations. Pharmaceutical program management under strategic leadership makes use of forward-thinking methods that unite visionary choices with cross-team coordination and risk prevention techniques. Leading professionals in this sector should establish predictive capabilities while using data intelligence to guide their work during continuously evolving healthcare requirements. Program management proved essential during the COVID-19 pandemic because it helped pharmaceutical scientists create breakthroughs through vaccine and therapeutic research. This document analyzes strategic leader competencies by exploring their capacity to generate innovation via cooperative ventures among sectors in addition to their regulatory knowledge and flexible clinical testing protocols.

Modern pharmaceutical sciences have progressed while respiratory conditions along with newly emerging viral diseases remain difficult to address. Medical expertise continues seeking advances in developing drugs and treatment methods for respiratory conditions including asthma and COPD as well as infectious diseases consisting of influenza and COVID-19. The pharmaceutical industry needs quick responses to handle viral changes in pathogens and newly discovered zoonotic diseases. Strategic leadership effectiveness keeps the alignment between research and development activities and worldwide health needs as well as the resolution of regulatory obstacles and logistical barriers. Program management in pharmaceuticals involves growing innovation that stems from artificial intelligence (AI) alongside real-world data collection and decentralized clinical trials. Decision-making for drug discovery becomes stronger through predictive models which machine learning and data analytics develop for drug efficacy and disease outbreak prediction. Research initiatives benefit significantly from the collaborations between governments and academic institutions with biotech firms which enable quicker research developments. The fast development of mRNA COVID-19 vaccines highlighted the value of international partnerships between regulatory bodies as well as their flexible approach to accelerate pharmaceutical progress.

Strategic leadership in pharmaceutical program management will depend on sustained investments toward digital health infrastructure and AI-based research along with supply chain reliability in forthcoming years. The development of future pandemic preparedness frameworks depends on leaders creating systems that monitor real-time data and adapt clinical trials and maintain healthcare policies which are sustainable. Strategic pharmaceutical organizations must create an innovative organizational environment to successfully address new and present healthcare problems.

I. Introduction

The pharmaceutical industry leads global healthcare by developing continuous solutions to manage chronic diseases alongside new emerging healthcare challenges. Asthma together with COPD and influenza have maintained their position as critical public health concerns during the past several decades. The development of new viral risks starting with SARS followed by MERS culminating in the newest threat COVID-19 shows

the urgent necessity for quick pharmaceutical solutions. The updated pharmaceutical program management needs visionary leadership to sustain product creation efficiency and deliver superior healthcare worldwide. A pharmaceutical program requires managing R&D activities together with clinical trials and regulatory approvals and market entry plans for delivering new medication treatments to patients. The management of pharmaceutical programs becomes specifically difficult when dealing with worldwide health emergencies. A strategic approach to leadership becomes essential because pandemics frequently occur while regulatory obstacles persist and suppliers face interruptions and companies need to speed up novelty development. Drug development leaders need to oversee science-based medical development while also facilitating joint sector work alongside handling governmental regulations and worldwide health requirements. The rapid vaccine development process during the COVID-19 pandemic exemplified how quality leadership guided pharmaceutical progress toward securing funding needs and life-saving treatment distribution equity.

The direction of organizations toward efficient program innovation requires strategic leadership in pharmaceutical operations. The practice of traditional leadership places emphasis on operational execution yet strategic leadership puts forward long-term vision plus adaptability together with proactive decision-making as its primary elements. Leadership in respiratory and emerging viral disease management must forecast healthcare patterns to enable interdisciplinary partner relationships and deploy advanced production technology for research improvements. Strategic leadership directs scientific breakthroughs toward clinical healthcare through successful developments of mRNA vaccines combined with antiviral therapies and biologic treatments.

Speed poses a major challenge to pharmaceutical program management when competing against safety standards. Strict safety standards from regulatory bodies including U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) together with World Health Organization (WHO) mandate strict guidelines for patient protection along with drug performance evaluation. The essential regulatory framework produces extensive validation periods which ends up delaying crucial medicines reaching patients. The strategic leadership group needs to develop creative methods for simplifying regulatory processes while using field-based evidence and flexible clinical study plans to speed up medicine research without endangering patient well-being.

Through strategic leadership organizations can create essential partnerships between public sector organizations and the private sector. The pharmaceutical industry works together with governments academic institutions non-profit organizations and global health agencies to successfully execute programs due to its non-isolated operation. Public-private partnerships (PPPs) assist vital pharmaceutical funding efforts that lead to vaccine creations while providing equitable medicine access and pandemic preparedness programs. Through cooperative leadership strategic leaders can lead extensive pharmaceutical initiatives to tackle present-day as well as upcoming health issues.

II. The Role of Strategic Leadership in Pharmaceutical Program Management

Definition of Strategic Leadership in Pharma

A pharmaceutical program's strategic leadership enables the pursuit of creative innovation and resource maximization together with risk prevention through complicated healthcare frameworks. Strategic leadership differs from traditional management methods because it directs its attention toward visionary choices alongside cross-team work and avoided-risk strategies. The pharmaceutical industry needs strong leadership to synchronize its extensive and regulatory-challenging drug development programs with worldwide health requirements.

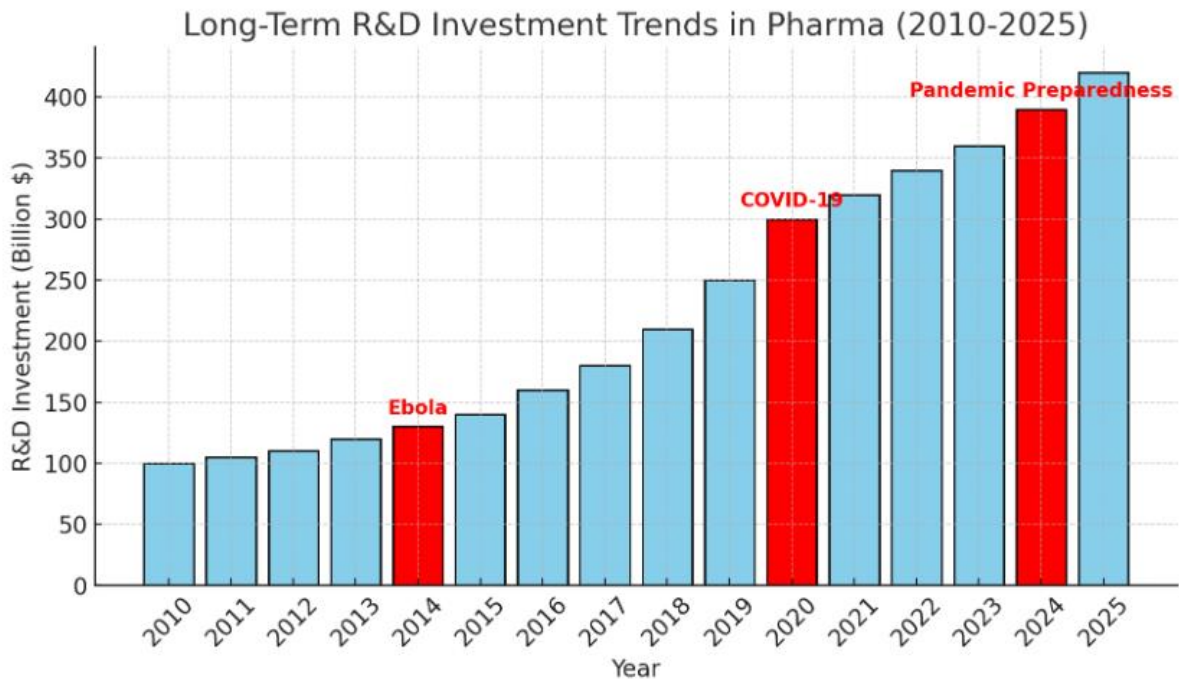
Strategic pharmaceutical leaders need to merge scientific progress with business direction to create treatments that both gain production success through market distribution. The strategic leaders must see upcoming healthcare challenges ahead while integrating modern technologies together with all relevant stakeholders from government agencies to biotech firms and research institutions. Strategic leadership succeeded in expediting pharmaceutical development for COVID-19 vaccines showing its ability to promote medical progress while delivering better treatment results globally.

Core Competencies of Strategic Leaders

Strategic leaders of pharmaceutical programs need varied abilities to manage regulatory changes and foster cross-team work and protect the process against all risks. The following list shows fundamental competencies which produce successful strategic leadership outcomes:

1. Visionary Thinking and Long-Term Planning

- A strategic leader needs to establish a precise futuristic outlook regarding pharmaceutical advancement. This involves:
- The strategic leader needs to foretell healthcare developments by funding innovations in treatment methods.
- The organization should direct their R&D programs toward worldwide healthcare objectives which include pandemic readiness and new disease identification capabilities.
- The organization needs to create extended funding plans to support expensive research and development of new pharmaceuticals.



Here is the bar graph showing long-term R&D investment trends in the pharmaceutical industry from 2010 to 2025.

2. Agile Decision-Making in High-Stakes Environments

Pharmaceutical companies work at high speed to perform necessary decisions with maximum efficiency. Agile leaders:

- Companies must adapt their operation to evolving regulatory guidelines.
- Medical trials benefit from data-based decisions when they involve critical situations.
- The pharmaceutical industry needs to strike a proper mix between time efficiency and protective measures throughout its drug approval procedures.

Key Decisions in Agile Pharmaceutical Leadership

Decision Type	Example	Impact
Regulatory Adaptation	Fast-tracking COVID-19 vaccines	Rapid approvals
Supply Chain Resilience	Shifting production to meet demand	Ensured drug availability
Clinical Trial Flexibility	Adaptive trial designs for new therapies	Faster data collection

3. Stakeholder Engagement and Cross-Sector Collaboration

Successful pharmaceutical program management depends on coordination among regulators together with investors government bodies and health providers. Strategic leaders:

- The establishment of public-private partnerships should be utilized to support big-scale research programs.
- The process of market access requires your engagement with health policymakers for better streamlining.
- Foster collaborations with academic and biotech institutions for joint research efforts.

4. Regulatory Navigation and Compliance Management

Drugs must receive approval from the FDA together with EMA and WHO under their strict regulatory guidelines. Strategic leaders must:

- Organizations must comprehend worldwide regulatory restrictions for maintaining compliance in multiple international markets.
- Companies should obtain real-world evidence data and AI analytics tools for efficient fulfillment of regulatory demands.

Leader teams should design strategies2. Innovative R&D Approaches

- which minimize risks when regulatory barriers present themselves.

III. Challenges in Managing Pharmaceutical Programs for Respiratory and Emerging Viral Diseases

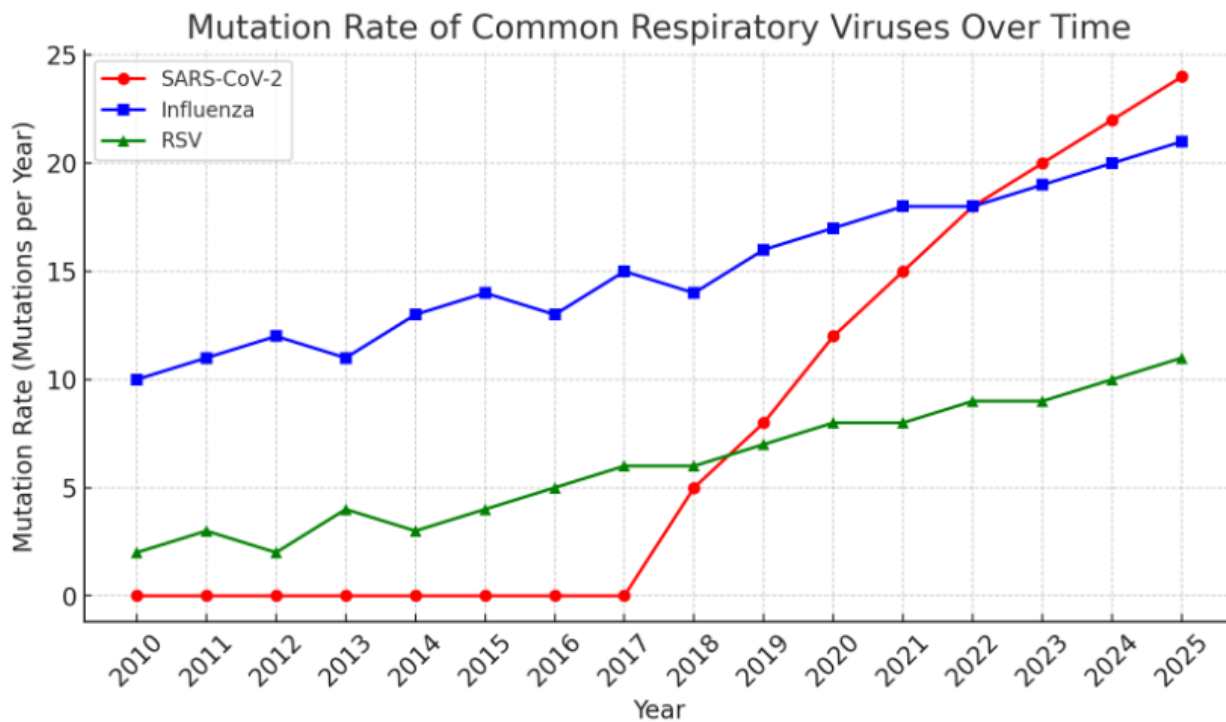
The administration of medical drugs for respiratory illnesses and new viral threats requires organizations to overcome multiple sophisticated obstacles. Various obstacles exist in managing pharmaceutical programs for respiratory diseases and emerging viral threats including quick virus evolution and drug-resistant developments and regulatory barriers and supply-chain interruptions alongside timeframe-speed dilemmas in drug development and funding limitations. The successful development and distribution of treatments depends on effective strategic leadership since it helps solve the encountered obstacles. The subsection analyzes these essential difficulties in great detail.

1. Rapidly Evolving Viral Threats and Drug Resistance

Pharmaceutical program management faces a major challenge because viral pathogens demonstrate quick evolutionary features. Respiratory viruses that include influenza and respiratory syncytial virus (RSV) and coronaviruses undergo rapid evolutionary changes that diminish the effectiveness of existing treatment options. Pharmaceutical research alongside surveillance and vaccine and drug development require perpetual efforts because of the viruses' continuous evolutionary process.

Challenges Posed by Viral Evolution and Resistance:

- The fast mutation behavior of RNA viruses like both influenza and SARS-CoV-2 enables them to produce new variants which escape our immune system and current therapeutic interventions.
- The indiscriminate use or inappropriate administration of antiviral drugs drives resistant virus strains to emerge just like influenza virus and HIV infections.
- Annual flu vaccine updates emphasize the difficulty of resisting viral evolution because of this ongoing need.



Here is the line graph comparing the mutation rates of SARS-CoV-2, influenza, and RSV over time. It illustrates the rapid evolution of these respiratory viruses

2. Regulatory Hurdles and Market Access Challenges

Every jurisdiction maintains independent rules for pharmaceutical product market entry that companies must traverse through complex legal requirements. Drugs that have met safety and effectiveness requirements via regulatory processes cause firms to experience both extended timelines as well as increased expenses.

Key Regulatory Challenges:

- The current drug approval duration amounts to 10–15 years through traditional development methods thereby prolonging the wait for lifesaving medications.
- Every regulatory authority including FDA, EMA, WHO and national health authorities possesses separate approval specifications which hinders global product distribution.
- Emergency Use Authorizations (EUA) speed up drug approvals but create doubt regarding extended medication safety information and trust from the general public.

3. Supply Chain Disruptions and Global Distribution Constraints

Multiple weaknesses within pharmaceutical supply chains across the world emerged during the COVID-19 pandemic. The creation of vaccines together with their delivery encountered multiple hurdles because of missing raw materials and transportation problems with unequal access to resources.

Key Supply Chain Challenges:

- Active pharmaceutical ingredients (APIs) obtained from restricted supplier number lead to raw material scarcity.
- Vaccine distribution becomes challenging when ultra-low temperature cold chain storage needs exist for many types of vaccines including mRNA COVID-19 vaccines.
- Wealthier countries obtained vaccines faster than poor countries which resulted in worsening disparities between nations with different incomes.

4. Balancing Speed with Safety in Drug Development

The pressing requirements for disease response to new viral diseases pose a conflict with safety testing procedures. The fast-paced process that saves lives may cause testing inadequacies which generate public distrust and regulatory issues and safety anxieties.

Challenges in Balancing Speed and Safety:

- The use of shortened trial phases in clinical research limits data collection about possible long-term side effects.
- The process of post-market drug surveillance becomes challenging since it requires continuous monitoring of medication safety with proper adverse event tracking.
- The public reluctance to accept new vaccines emerging from rapid development processes reinforces the necessity for thorough disclosure about medicines such as COVID-19 mRNA vaccines.

Comparison of Traditional vs. Accelerated Drug Development Timelines

Development Stage	Traditional Timeline	Accelerated Timeline (e.g., COVID-19)
Preclinical Research	3–6 years	1–2 years
Clinical Trials	6–8 years	1–2 years
Regulatory Review	1–2 years	6–12 months
Total Time to Market	10–15 years	2–3 years

5. Financial Constraints and Investment in R&D

The high expenses required to develop pharmaceutical medications create a major obstacle because some diseases do not generate sufficient market profitability. Strict budgetary constraints at present limit the development of new pharmaceutical products that need multiple billion-dollar investments.

Financial Challenges in R&D:

- The development of new pharmaceuticals carries average expenses between one billion and two billion dollars.
- Major investment comes only from diseases that generate high profit prospects while rare illnesses and recent epidemic diseases experience inadequate money support.
- International funding programs must address the problem of affordable vaccines and access because low-income nations lack sufficient capital to purchase vaccines.

Pharmaceutical companies use several methods to reduce financial obstacles which include:

- Public-private partnerships (PPPs) allow governments and industry and NGOs to work together for funding essential research objectives.
- Awards from regulatory agencies provide shorter review times together with longer patent duration for pharmaceutical corporations which fund high-risk disease research.
- The COVAX global initiative and other alternative funding mechanisms attempt to distribute vaccines equitably through international fund pooling.

IV. Driving Innovation in Drug Development and Program Execution

The pharmaceutical industry depends heavily on innovation to create and deploy drug programs which focus on treating respiratory disorders as well as new viral infections. The pharmaceutical sector uses innovative technologies together with collaborative frameworks to develop data-driven decisions as well as novel research and development methods alongside public-private partnerships for improving drug discovery and development. The analysis provides detailed explanations of these strategic approaches with supporting graphical data to represent essential developments.

1. Leveraging Data-Driven Decision Making

The pharmaceutical industry now implements artificial intelligence (AI) together with real-world evidence (RWE) and predictive analytics solutions to boost their program management decision-making ability. These technologies enhance productivity in all aspects of drug candidate selection and clinical research design and regulatory standards enforcement.

Key Applications of Data-Driven Approaches:

Artificial intelligence tools inspect extensive data collections to detect potent drug compounds which abbreviates drug discovery time periods.

Machine learning models using predictive analytics enable health organizations to forecast disease outbreaks which allows them to create drugs in advance.

Real-world evidence extracted from electronic health records (EHRs) together with patient registries enhances both clinical trials before market launch and post-market surveillance activities.

2. Innovative R&D Approaches

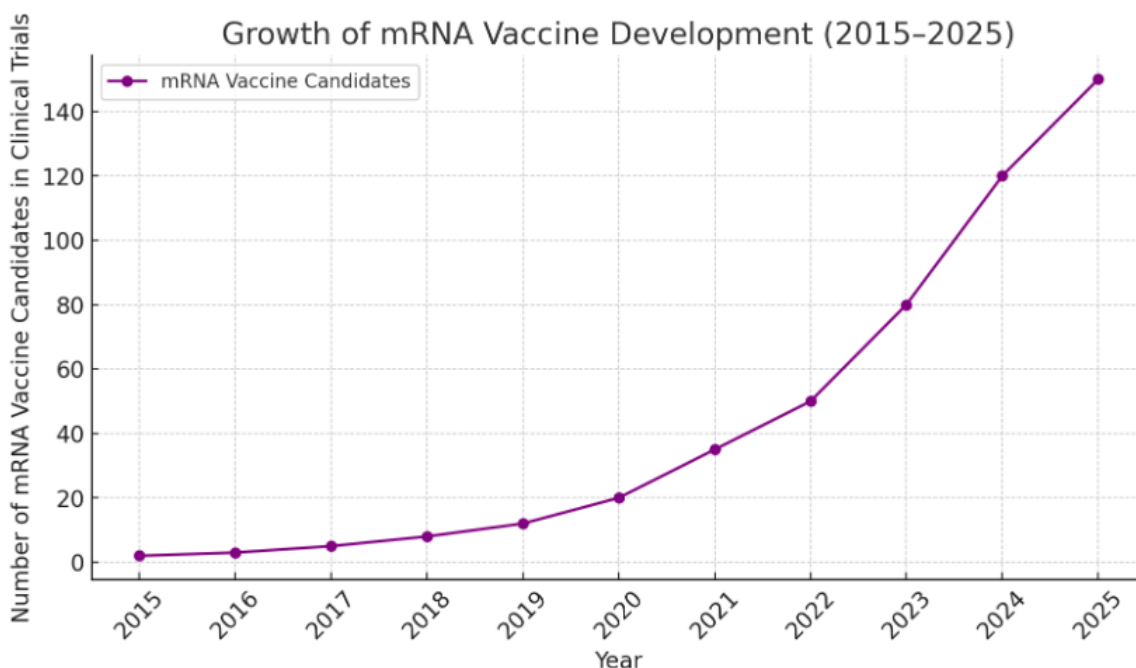
The creation of novel research methods activates developments for respiratory conditions and the treatment of new viral diseases. The development of respiratory disease and emerging viral infection treatments relies on mRNA vaccines and antiviral drug repurposing along with biologics.

Breakthroughs in Pharmaceutical R&D:

The first mRNA vaccine platforms launched in COVID-19 vaccines serve as a new technology for fast vaccine production alongside strain adaptation capability.

Antiviral Drug Repurposing makes use of available drugs to treat newly emerging viral pathogens leading to quicker treatment development.

The use of monoclonal antibodies together with gene therapies brings specific medical solutions for treating both chronic and infectious respiratory diseases.



Here is the line graph illustrating the growth of mRNA vaccine development from 2015 to 2025. It shows

3. Public-Private Partnerships

The development of new drugs depends heavily on the joint efforts between governments and both academic institutions and biotechnology companies that help reduce treatment development delays. The infrastructure from PPPs along with regulatory backing and system funding from private corporations accelerate innovation at a rapid pace.

Notable Public-Private Partnerships:

Operation Warp Speed served as a U.S. government initiative which expedited the development of COVID-19 vaccines.

CEPI represents a worldwide collaboration based on vaccine science research for emerging diseases through its global partnership structure.

Gavi operates as the Vaccine Alliance to extend vaccination services for low-income population sectors.

Partnership	Focus Area	Notable Achievements
Operation Warp Speed	COVID-19 vaccine development	Accelerated multiple vaccines
CEPI	Emerging infectious diseases	Funded rapid vaccine R&D
Gavi, the Vaccine Alliance	Global immunization programs	Increased vaccine accessibility

4. Adaptive Clinical Trial Designs

Traditional clinical trial processes usually prove time-intensive and expensive along with being strict in design. Adaptive clinical trial designs boost efficiency through combined elements of real-time data analytics and decentralized monitoring systems and patient-friendly trial models.

Key Innovations in Clinical Trials:

Patients benefit from decentralized trials because remote monitoring combines with virtual participation to eliminate physical obstacles they face.

Study parameters benefit from dynamic changes that result from continuous real-time data analysis.

The use of engagement platforms together with digital wearables delivers improved patient compliance rates alongside successful patient retention metrics.

V. Case Studies of Successful Strategic Leadership in Respiratory and Viral Disease Programs

Strategic leadership functions as the main catalyst for progress in respiratory and viral disease management techniques. Research innovation and coordinated efforts and well-managed programs have allowed organizations to combat key health issues on a global scale. The following part presents three pharmaceutical program examples which illustrate strategic leadership in practice.

Case Study 1: The Rapid Development of COVID-19 Vaccines (Pfizer/BioNTech, Moderna, AstraZeneca)

The world witnessed an extraordinary simultaneous push for vaccine development testing and worldwide distribution because of the COVID-19 pandemic. The development of COVID-19 vaccines became significantly faster through strategic leadership approaches that maintained safety and effectiveness standards.

Key Strategies Employed:

- The two companies Pfizer/BioNTech and Moderna used mRNA technology which allowed them to speed up vaccine development time.
- Public-Private partnerships used government funding together with international organizational oversight for speeding up research and regulatory approval procedures.
- The vaccine company AstraZeneca joined with multiple international producers through global networks to create mass vaccine production and distribution facilities.

Case Study 2: Innovations in Asthma and COPD Drug Development

Multiple respiratory diseases including asthma along with COPD presently impact numerous people across the world. Modern drug development research has revolutionized therapeutic practices so patients experience better results.

Breakthrough Innovations:

Targeted monoclonal antibodies known as dupilumab and tezepelumab offer personalized therapy approaches as biologic therapies.

Smart inhalers consist of devices with sensing capabilities which track medicine use together with lung performance to enhance adherence and management of diseases.

Medical advances have developed new inhaler products which unite several drugs to boost treatment efficiency alongside enhanced usability.

Case Study 3: Pandemic Preparedness Programs and Global Vaccine Distribution

Global organizations have used their proactive efforts to develop pandemic preparedness measures as well as improve worldwide vaccine availability beyond the current COVID-19 crisis.

Major Initiatives:

The Vaccine Alliance through Gavi works to guarantee equal accessibility of vaccines for low-income populations until all nations have a sufficient immunization plan.

Through the COVAX Initiative worldwide access to COVID-19 vaccines seeks to expand as part of its mission to serve underserved global regions.

The Pandemic Preparedness Plan of WHO focuses on building enhanced worldwide surveillance frameworks and swift response protocols.

VI. Future Directions in Strategic Leadership for Pharmaceutical Program Management

New technologies combined with global healthcare challenges and emerging medical needs have transformed the pharmaceutical industry into a critical moment of change that requires modified program management strategies. Future strategic leadership needs to integrate innovative approaches that boost teamwork and build resilience across the spectrum of upcoming health emergencies and pandemic alerts. Future strategies in pharmaceutical program management leadership receive detailed analysis in this part of the discussion.

Integration of Digital Health and AI in Drug Development

The drug development process experiences revolutionary change through artificial intelligence (AI) together with digital health technologies leading to faster development of essential medical therapies.

Key Developments:

- Machine learning algorithms utilizing artificial intelligence boost statements drug discovery by analyzing large-scale datasets to identify pharmaceutical candidates.
- AI technologies used in clinical trials provide patient recruitment capabilities and monitor trial performance and outcome prediction tools that improve clinical trial efficiency levels.
- The utilization of digital biomarkers together with remote monitoring through wearable devices and mobile apps allows for the collection of real-world evidence to enable personalized treatment.

Integration of Digital Health and AI in Drug Development

Process Stage	Traditional Timeline	AI-Enhanced Timeline	Improvement (%)
Drug Discovery	4-6 years	1-2 years	60-70%
Preclinical Testing	1-2 years	<1 year	50%
Clinical Trials	6-8 years	3-5 years	40-50%

Enhancing Global Collaboration for Faster Crisis Response

Health crisis management demanded prompt worldwide coordinated responses when the COVID-19 pandemic began. Future leadership strategies must concentrate on developing better international partnerships that will quicken crisis response initiatives.

Proposed Initiatives:

- Global Data-Sharing Networks: Creating a unified system for real-time health data exchange among governments, researchers, and pharmaceutical companies.
- Executive-level response groups must form platforms that unite vaccine developers with regulatory bodies and distribution networks.
- The promotion of international regulatory framework streamlining aims at speeding up pharmaceutical approvals and market entry procedures.

Building Resilient Supply Chains for Future Pandemics

Recent health crisis events showed that supply chain weaknesses create a necessity for strong flexible pharmaceutical delivery systems.

Key Focus Areas:

Pharmaceutical companies should establish multiple suppliers as a way to prevent disruptions from single-source dependencies.

Companies should use advanced manufacturing technologies together with continuous manufacturing and 3D printing to create scalable drug production systems.

Regional stockpiling involves building local supplies of critical drugs and vaccines in order to avoid shortages.

Key Strategies for Strengthening Pharmaceutical Supply Chains

Strategy	Expected Benefits
Supplier Diversification	Reduced dependency, stability
Smart Logistics	Faster delivery, lower costs

Developing Leadership Models to Drive Sustainable Innovation

With a changing pharmaceutical landscape, new paradigms in leadership must be established that facilitate innovation sustenance and provide long-term excellence.

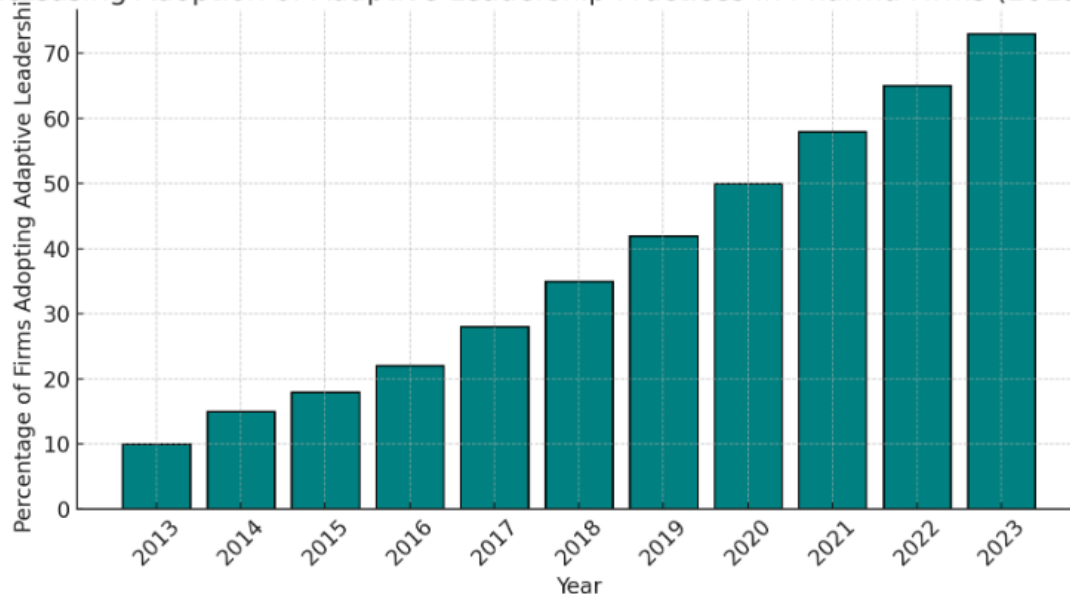
Future Leadership Approaches:

Adaptive Leadership: Fostering receptiveness to change and reaction to frontier scientific and regulatory advancements.

Collaborative Leadership: Fostering collaboration among heterogeneous stakeholders among biotech industry players, academia, and public health constituencies.

Ethical and Transparent Decision-Making: Prioritizing patient protection, data integrity, and fair access to medicines.

Increasing Adoption of Adaptive Leadership Practices in Pharma Firms (2013-2023)



Here is the bar chart illustrating the increasing adoption of adaptive leadership practices in pharmaceutical firms over the past decade

Conclusion

Strategic leadership is important for innovation, efficiency, and strength in managing global pharmaceutical programs, especially with respiratory and new viral diseases. As the industry works through a more complicated environment full of fast-changing pathogens, rules, and health gaps leaders need to use smart strategies to speed up drug development, improve operations, and ensure fair access to life-saving drugs.

The COVID-19 pandemic showed how vital strong leadership is for gathering resources, encouraging teamwork across sectors, and using new technologies to create solutions very quickly. Future leaders in pharmaceuticals should learn from this by using artificial intelligence, real-world data, and predictive analysis to make drug discovery and clinical trials easier. Furthermore, more public-private partnerships and flexible rules will be key to breaking down access barriers and making sure innovative treatments are available faster.

To keep progress going, leaders need to focus on supply chain strength, making sure that drug programs can respond quickly to health emergencies. Putting money into local manufacturing, varied supplier options, and digital tracking tools will help reduce delays and enhance worldwide distribution. In addition, ethical leadership should be central to all decisions, stressing openness, patient-focused innovation, and fair healthcare for those in need around the world.

In the end, the future of managing drug programs depends on leaders' ability to adjust, create, and work together internationally. By building an environment of ongoing learning, welcoming digital changes, and boosting global partnerships, leaders can promote lasting improvements in managing respiratory and new

viral diseases. The dedication to excellent leadership now will shape the success of future medical advancements and the industry's capacity to protect public health around the world.

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