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SEPTEMBER 30, 2024

VACCINES – GLOBAL CLINICAL TRIAL LANDSCAPE (2024)

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VACCINES

GLOBAL CLINICAL TRIAL LANDSCAPE (2024)

#DYK
Did you know?

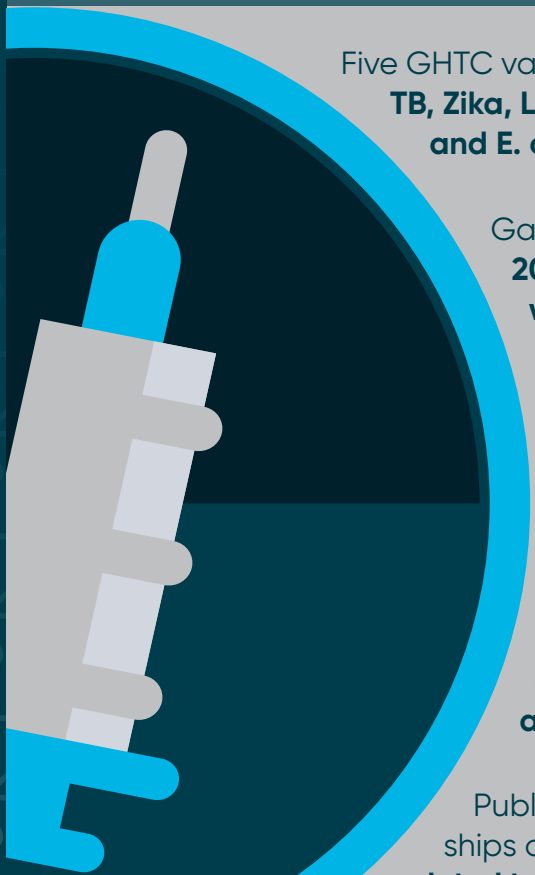
The evolving vaccine landscape **integrates both prophylactic and therapeutic solutions,** advancing global disease management

Prophylactic trials:
37% in Phase III, 32% in Phase II, 30% in Phase I, and 1% in Phase 0, led by COVID-19 and RSV

Therapeutic trials:
51% in Phase II, 36% in Phase I, 10% in Phase III, and 3% in Phase 0, focused on cancers

Asia-Pacific recruits ~4x faster

mRNA and **viral vector** platforms drive vaccine innovations



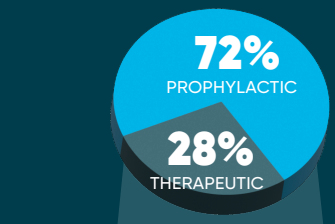
Five GHTC vaccines target **TB, Zika, Lassa Fever, Nipah, and E. coli**

Gavi supports **20 vaccines, with plans until 2030**

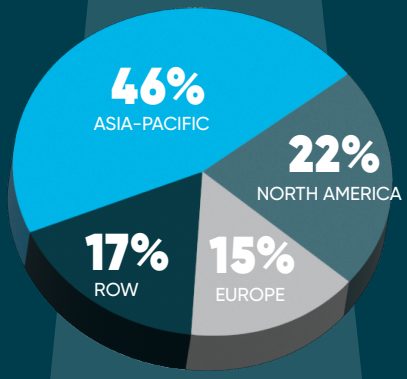
WHO declared **Mpox a global health emergency**, boosting vaccine efforts

Evolving trial designs **enhance safety and efficiency**

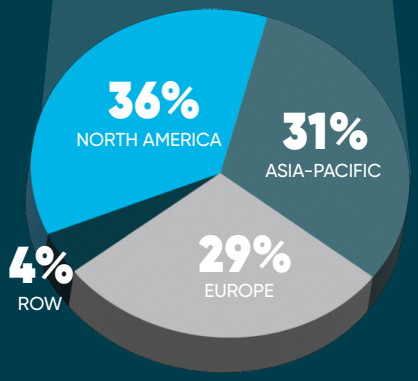
Public-private partnerships and funding ensure **global health security**



PROPHYLACTIC TRIALS:



THERAPEUTIC TRIALS:



Prophylactic vaccine trials are **growing at 54.9% CAGR**, while **therapeutic** trials are expanding at **21.2% CAGR**

The **U.S. and China lead in vaccine trials**, followed by Australia, the UK, and Europe

CONTENTS

1. INTRODUCTION

The global landscape of vaccine development has undergone significant changes in recent years, influenced largely by the COVID-19 pandemic. This unprecedented health crisis demonstrated the potential for rapid innovation, while also revealing critical gaps in vaccine access and distribution infrastructure. As the world moves forward, the vaccine development sector is evolving, with technological advancements, regulatory changes, and increased contributions from regions like Asia-Pacific playing a pivotal role in shaping the future of global health.

One of the most notable outcomes of the pandemic was the accelerated adoption of new vaccine technologies. The development and widespread use of mRNA vaccines, which had previously been an area of exploration, quickly became a cornerstone of the global response. This success story has paved the way for further innovations, such as intranasal vaccines and microneedle array patches (MAPS). These new delivery methods offer promising alternatives for respiratory diseases, including COVID-19, as well as for improving vaccine accessibility in resource-limited regions due to their stability at room temperature.

In addition to technological advancements, COVID-19 highlighted the importance of equitable vaccine distribution. International organizations like WHO, Gavi, and UNICEF are working to address disparities, ensuring that underserved populations receive access to vaccines. Innovations such as MAPS could play a crucial role in overcoming logistical challenges and expanding access to life-saving vaccines in developing nations.

Beyond mRNA, the field of vaccine development continues to explore new modalities. DNA-based vaccines, protein peptide-based vaccines, and lipid nanoparticle-based vaccines are among the innovative approaches being explored for their potential to enhance immunogenicity and durability. Technologies such as electroporation, which can improve the delivery and efficacy of vaccines, are also gaining attention.

Genomics, which played a key role in tracking COVID-19 variants, is becoming an integral part of public health surveillance. The ability to rapidly sequence and analyze pathogen genomes can lead to quicker identification of emerging threats and faster development of targeted vaccines. This genomic approach is expected to be crucial in preventing future pandemics and improving responses to existing infectious diseases.

The pandemic also prompted significant regulatory evolution, with countries across the globe adopting more agile frameworks to expedite vaccine approval processes. Regulatory bodies demonstrated flexibility, reducing approval timelines and streamlining protocols. This allowed the development of COVID-19 vaccines to progress from concept to delivery in just 260 days, an impressive achievement compared to the typical ten-year timeline for vaccine development.

In the Asia-Pacific region, regulatory agencies responded to the crisis with rapid review processes and local expertise. This, along with a growing trial infrastructure, positions Asia-Pacific as a key hub for vaccine development. Its large population, diverse demographics, cost-effective trials, and high recruitment success make it an attractive destination for vaccine trials. Continued government investment will further strengthen the region's role in the global vaccine development landscape.

The lessons learned from COVID-19 are reshaping the future of vaccine development. While technological and regulatory advances have brought significant progress, challenges such as vaccine equity and hesitancy remain. As this white paper explores ongoing and emerging trends in the global vaccine trial landscape for both prophylactic and therapeutic vaccines, it also delves into funding mechanisms, new therapeutic areas, and regulatory evolution. To ensure continued progress in vaccine development, maintaining global collaboration, fostering regulatory flexibility, and embracing innovative approaches will be essential.

While prophylactic vaccines remain a cornerstone of public health, with innovations such as mRNA and viral vector platforms driving advancements in combating diseases like HIV, malaria, and RSV, the field of therapeutic vaccines is rapidly gaining momentum. Therapeutic vaccines, designed to treat existing diseases such as cancer and chronic infections, are being developed through cutting-edge technologies like immunotherapy and checkpoint inhibitors. This white paper will explore these innovations, along with the global clinical trials landscape, regulatory trends, and the latest funding and licensing deals shaping the industry. By analyzing key clinical developments, emerging platforms, regulatory frameworks, and commercial activity, this white paper aims to equip biotech stakeholders with insights into the opportunities and challenges in the evolving field of vaccines. [1,2]

2. GLOBAL CLINICAL TRIALS LANDSCAPE

The vaccine clinical trial landscape from 2019 to 2024 shows significant growth and diversification, reflecting the increasing focus on both prophylactic and therapeutic vaccines. The data from ongoing and planned trials (totaling approximately 1,000) highlights several key trends:

Growth Trends

- The number of clinical trials for prophylactic vaccines shows a robust 54.9% CAGR, increasing sharply from 15 trials in 2019 to an expected 207 trials in 2024.
- Therapeutic vaccine trials have also grown significantly with a 21.2% CAGR, rising from 23 trials in 2019 to an anticipated 73 trials by 2024. (Figure 1)

Vaccine Types in Clinical Trials

- Prophylactic vaccines dominate the landscape, constituting 72% of the total clinical trials.
- Therapeutic vaccines account for the remaining 28%, showing a growing but still smaller share compared to prophylactic vaccines.(Figure 2)

Regional Distribution of Vaccine Trials

- Asia-Pacific leads with the highest number of trials, particularly for prophylactic vaccines (357 trials), indicating strong regional involvement and capabilities.
- North America and Europe follow, with 168 and 115 prophylactic vaccine trials, respectively.
- In therapeutic vaccine trials, North America shows the highest involvement (115 trials), followed by the Asia-Pacific (99 trials) and Europe (95 trials). (Figure 3)

Prophylactic Vaccine Trials Regional Share

- Asia-Pacific accounts for the majority share at 46%.
- North America and Europe hold 22% and 15%, respectively, indicating significant activity but less dominance compared to Asia-Pacific.
- The Middle East and Africa, and South and Central America contribute 11% and 6%, respectively, reflecting emerging regions for vaccine trials. (Figure 4)

Therapeutic Vaccine Trials Regional Share

- North America leads with 36% of therapeutic vaccine trials, indicating a strong focus on developing therapeutic modalities.
- Asia-Pacific follows closely with 31%, while Europe accounts for 29%.
- The Middle East and Africa, and South and Central America each represent a smaller share (2% and 2%), showing less involvement but potential for future growth. (Figure 5)

Figure 1: Growth trends of vaccine trials (2019-2024)

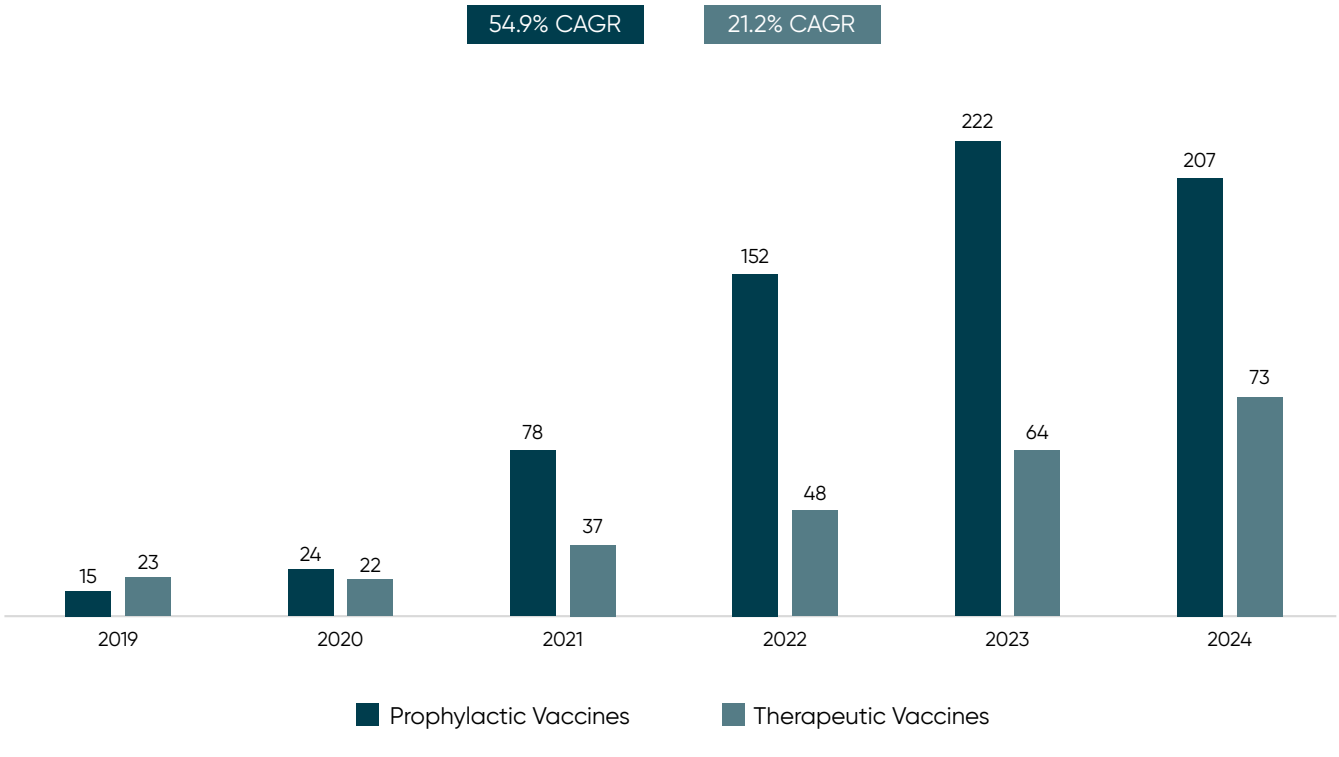


Figure 2: % Share of vaccines types in clinical trials

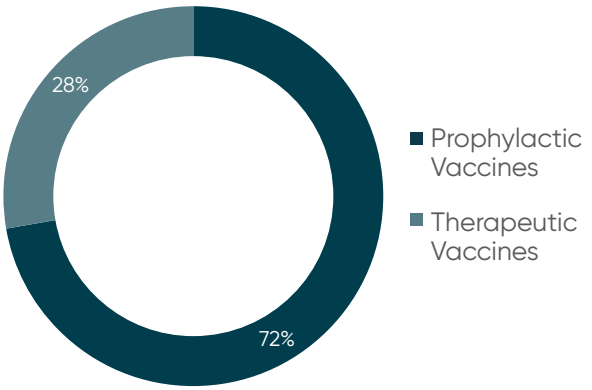


Figure 3: # Vaccine trials by regions

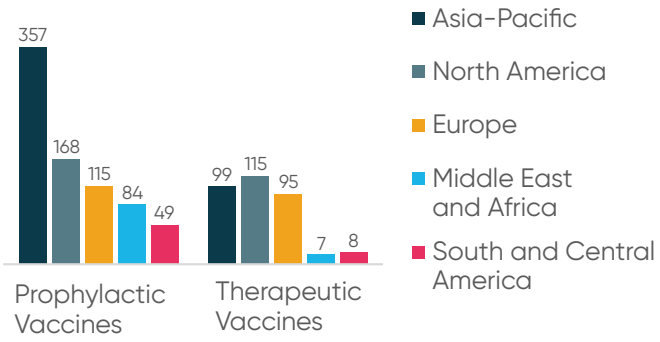


Figure 4: Prophylactic vaccine trials % share by regions

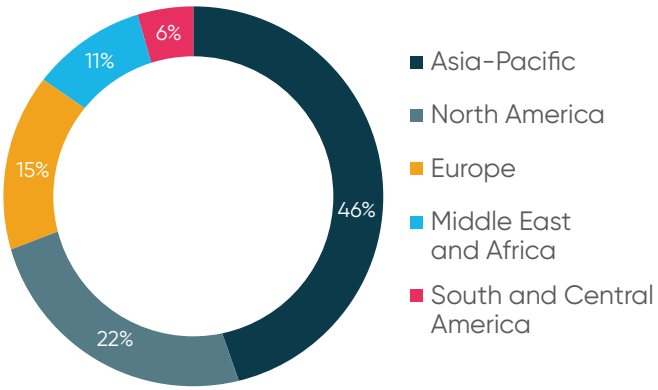
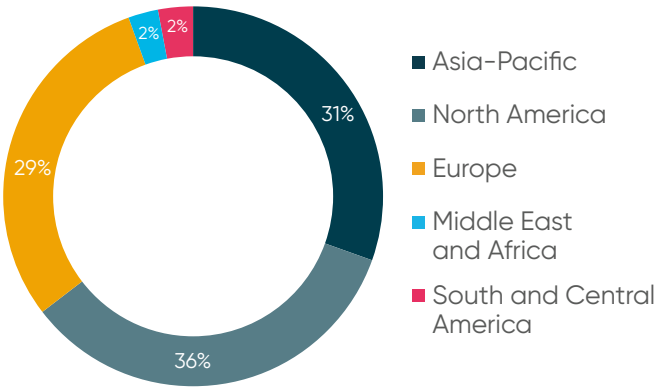


Figure 5: Therapeutic vaccine trials % share by regions



Source: GlobalData October 2024

Following the growth trends, the geographical spread of vaccine trials from 2019 to 2024 highlights a strategic effort to diversify clinical research globally. (Figure 6)

Leading Regions:

- The United States remains the most active site for vaccine trials, showing a consistent approach to both prophylactic and therapeutic vaccines.
- China closely follows, reflecting its significant investment and participation in vaccine development. Both prophylactic and therapeutic trials are well-represented, illustrating a comprehensive strategy.
- Australia has become an important player in the Asia-Pacific, particularly in therapeutic vaccine trials, underlining its increasing role in the region.

European Contributions:

- Countries like the United Kingdom, Spain, Germany, and France are major participants, actively involved in trials for both vaccine types. Their activity affirms Europe's position as a central hub for clinical research.

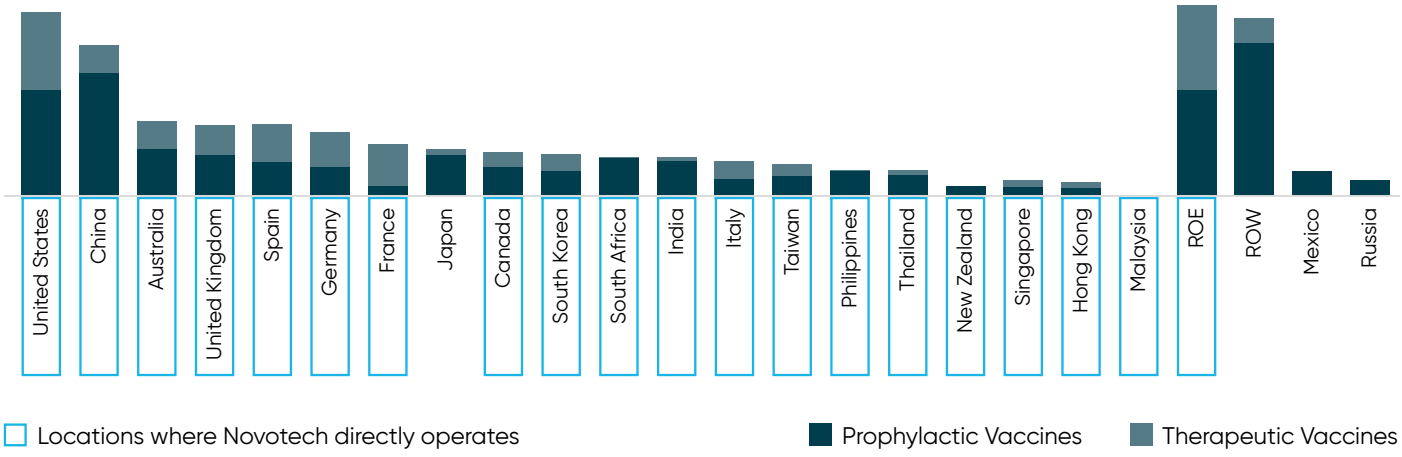
Trends in the Asia-Pacific:

- Japan, South Korea, India, and Malaysia are also key players, with Malaysia mainly focusing on prophylactic vaccines, while Japan and South Korea are involved in both types.
- China and Australia lead the region's efforts, with their high trial numbers placing them at the forefront of vaccine research in the Asia-Pacific.

Growing Reach of Emerging Markets

- Emerging markets such as South Africa, Mexico, and parts of Eastern Europe are showing increased activity, indicating an expansion of clinical research beyond established centers.
- Southeast Asian countries like Thailand, Singapore, and the Philippines are gaining traction, particularly in prophylactic vaccine trials, suggesting regional growth and progress in clinical research.
- The rising number of trials in these locations reflects an effort to broaden geographical reach and include diverse populations in clinical studies.

Figure 6: # Vaccine trials by locations



Source: GlobalData October 2024

In terms of percentage (%) share of trials within each region from 2019 to 2024, the vaccine clinical trial landscape presents a diverse regional distribution.

Asia-Pacific:

Prophylactic Vaccines: China leads the region, accounting for 41% of trials, highlighting its significant capacity for large-scale research. Other top contributors include Australia (11%), Japan (10%), and India (8%), with rest of the Asia-Pacific locations contributing the remaining 30% of trials, thus showcasing widespread regional participation. (Figure 7)

Therapeutic Vaccines: China also dominates here, with 28% of trials. Australia follows with 24%, South Korea with 17%, and Taiwan contributing 10%. The rest of the Asia-Pacific locations contribute the remaining share of roughly 30%, reflecting a concentrated focus on therapeutic development within the region. (Figure 8)

Figure 7: Prophylactic Vaccines - Asia Pacific

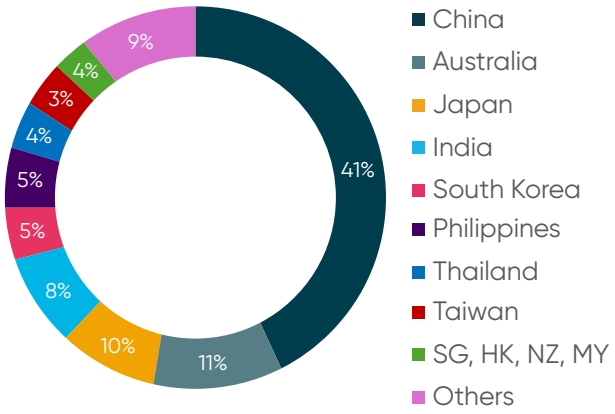
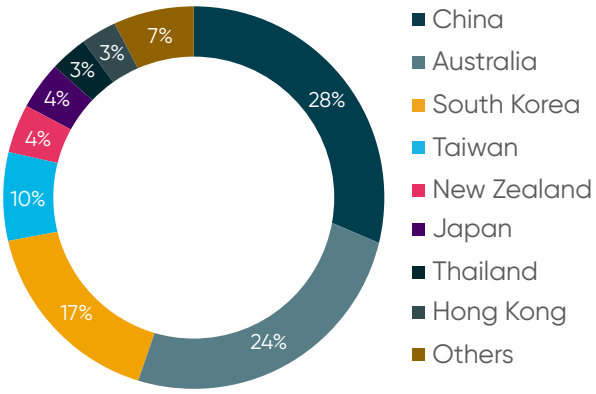


Figure 8: Therapeutic Vaccines - Asia Pacific



Source: GlobalData October 2024

North America:

The United States takes the lead, holding 73% of prophylactic and 87% of therapeutic vaccine trials, indicating its dominant role. Canada and Mexico together make up the remaining shares, indicating their more modest involvement in comparison. (Figures 9 and 10)

Figure 9: Prophylactic Vaccines - North America

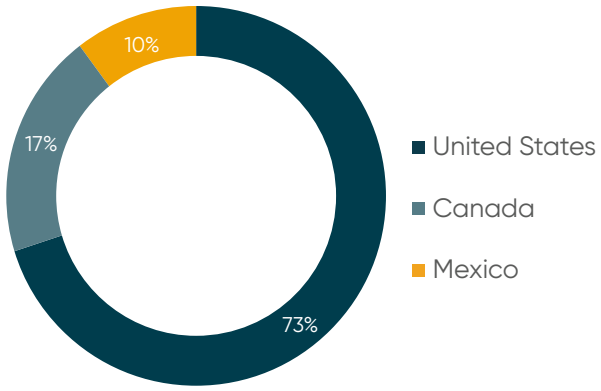
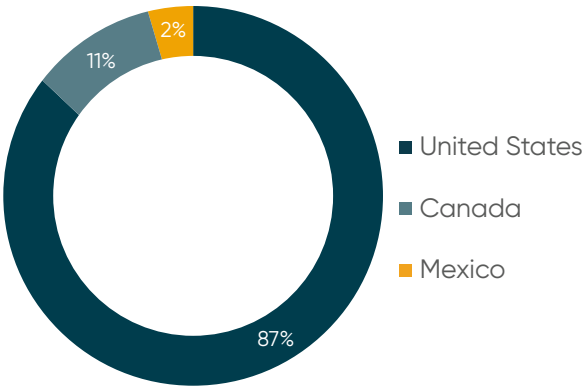


Figure 10: Therapeutic Vaccines - North America



Europe:

For prophylactic vaccine trials, the United Kingdom leads with 14% of share, followed by Spain at 11%, and Germany and Belgium, each at 10%. Finland contributes 7%, while France, Netherlands, Poland, and Russia each account for 5%. The Rest of Europe (ROE) collectively holds the reminder share at 28%, reflecting widespread participation across various countries. This distribution highlights the diverse and collaborative efforts within Europe to advance prophylactic vaccines. (Figure 11)

Therapeutic vaccine trials show Spain leading with 15%, followed by both Germany and the United Kingdom at 12%. France holds 11%, while Belgium and Poland contribute 7% and 6% respectively. Italy and the Netherlands each account for 5%, with Sweden at 4%. The Rest of Europe (ROE) stands at 22%, while Russia holds 1% of the trials. This breakdown indicates a well-distributed effort across key European nations, with significant contributions from both larger and smaller countries for therapeutic vaccine development. (Figure 12)

Figure 11: Prophylactic Vaccines - Europe

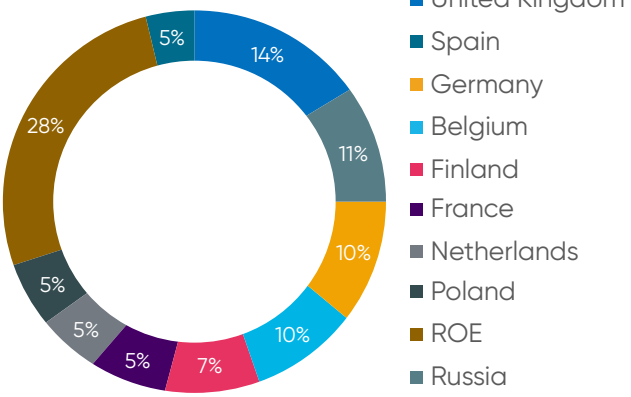
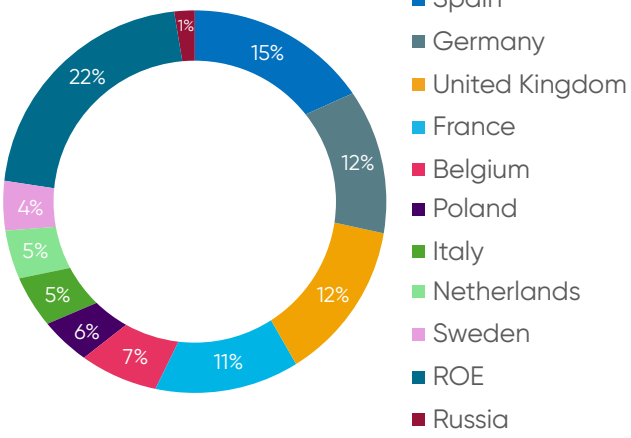


Figure 12: Therapeutic Vaccines - Europe



ROW:

Prophylactic Vaccine Trials: South Africa leads the region with 18% of trials, positioning itself as a key player. Brazil and Colombia each contribute 9%, followed by Kenya at 8%, while Argentina holds 6%. The remaining 50% of trials are conducted across other countries regions indicating their growing participation. (Figure 13)

Therapeutic Vaccine Trials: Chile holds 18%, followed by Argentina with 15%. Brazil and Israel each contribute 12% to the regional efforts, while South Africa and Colombia account for 9% each. The remaining 25% of trials are distributed across other countries. This breakdown highlights Chile's leading role, with significant contributions from other key countries in South America and beyond. (Figure 14)

Figure 13: Prophylactic Vaccines - ROW

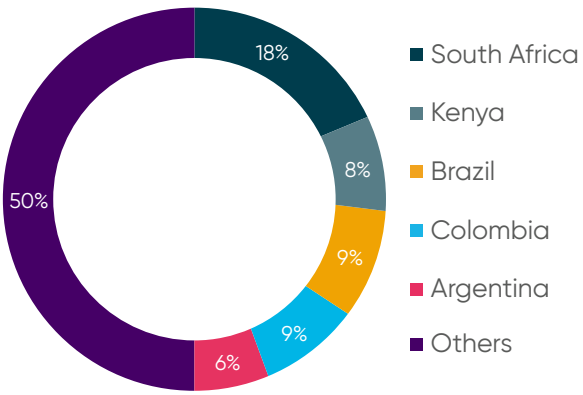
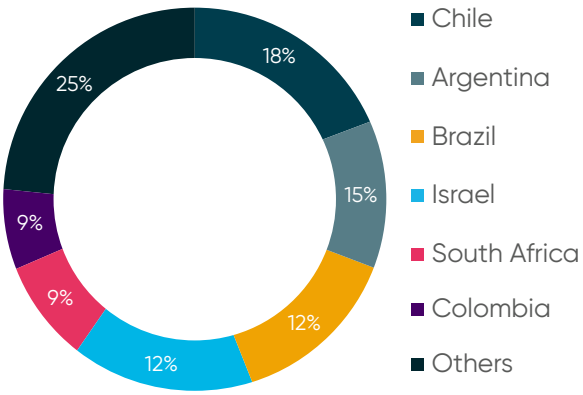


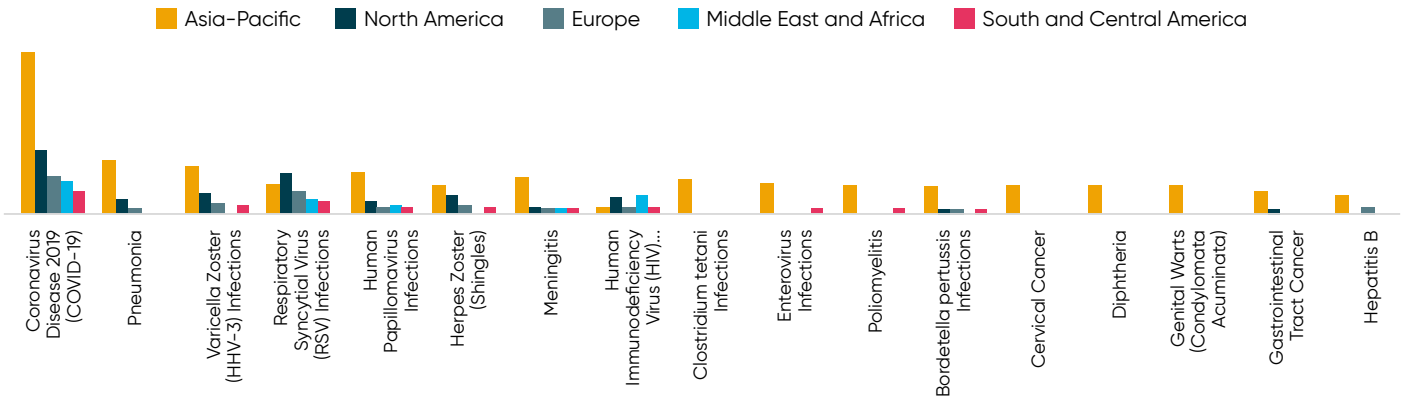
Figure 14: Therapeutic Vaccines - ROW



Top indications

Prophylactic vaccine trials are dominated by infectious disease indications, particularly COVID-19 across all regions, with the Asia-Pacific leading significantly. Respiratory Syncytial Virus (RSV) infections see strong activity in North America. Other notable indications such as Human Papilloma virus, Pneumonia, Varicella Zoster, Herpes Zoster (Shingles) and Meningitis infections are largely concentrated in the Asia-Pacific region. (Figure 15)

Figure 15: Prophylactic vaccine trials – top indications by regions



Therapeutic vaccine trials are largely focused on Gastrointestinal Tract Cancer, with North America Asia-Pacific and Europe as key regions. Head and Neck Cancer and Non-Small Cell Lung Cancer are also prominent in Europe and North America. HPV-Associated Cancer and Pancreatic Cancer trials are led by North America, while Melanoma see robust participation in Europe followed by North America and the Asia-Pacific. Other targeted cancer indications in North America and Europe include Urinary tract cancer, Ovarian cancer and Colorectal cancers. Overall, Asia-Pacific shows lower participation in therapeutic vaccine trials compared to prophylactic trials, with a regional focus on select cancer types. (Figure 16)

Figure 16: Therapeutic vaccine trials – top indications by regions

Source: GlobalData October 2024

Vaccine trials by phase

For prophylactic vaccine trials, the majority are in Phase III at 37%, followed by Phase II at 32% and Phase I at 30%. Only 1% of trials are in Phase 0, indicating early research stages are less common as most vaccines are already advancing toward later phases. (Figure 17)

For therapeutic vaccine trials, the distribution is more heavily skewed toward Phase II with 51% of trials, followed by Phase I at 36% and Phase III at 10%, with a small portion (3%) in Phase 0. (Figure 18)

Prophylactic vaccines, particularly for well-established targets like infectious diseases, often advance to Phase III quicker as they have a clearer regulatory path and large-scale demand. Conversely, therapeutic vaccines, which are often developed for complex diseases like cancer, see a larger focus in Phase II, reflecting ongoing investigation into safety and efficacy before advancing to larger trials. The higher proportion of earlier-phase therapeutic trials highlights the challenges of developing treatments for more complicated and diverse diseases.

Therapeutic vaccine trials face significant recruitment challenges compared to prophylactic vaccines, which directly impacts their phase distribution. While prophylactic vaccines target larger populations, such as those at risk of infectious diseases, therapeutic vaccines are often developed for specific conditions like cancer, limiting the patient pool.

Strict eligibility criteria, such as the need for specific genetic or molecular markers, further narrows the recruitment base. Additionally, in competitive areas like oncology, patients may have multiple treatment options, including other experimental therapies, which can lead to competition for the same patient pool. These challenges result in a higher concentration of therapeutic vaccine trials in Phase I and II, where smaller patient cohorts are required, compared to Phase III, which demands larger, more diverse populations.

Geographical constraints also play a role, as many patients may not have access to trial sites, especially in regions with fewer clinical trial centers. This contrasts with prophylactic vaccine trials, where recruitment is often easier, leading to a higher proportion of Phase III trials.

Figure 17: Prophylactic vaccine trials by phase

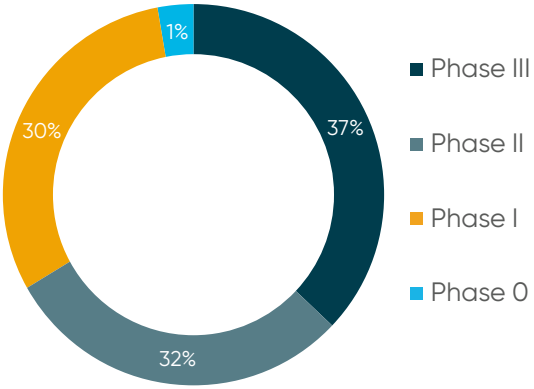
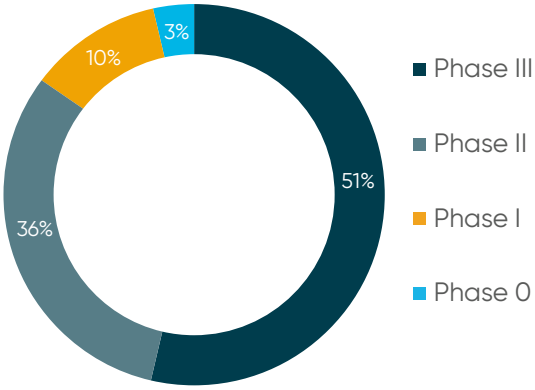


Figure 18: Therapeutic vaccine trials by phase



Source: GlobalData October 2024

Therapeutic vaccine clinical trials

Clinical trials for therapeutic vaccines are distinct from those for preventive vaccines as they focus on treating patients already diagnosed with diseases. These trials assess the effectiveness of vaccines in conjunction with existing treatments and require extensive follow-up to measure immune response durability and overall outcomes, as summarized in the chart below. The complex design of these trials and safety protocols are especially critical when combining vaccines with other treatments like immunotherapy.

Patient Population and Study Design

Patient Population:
Includes individuals already diagnosed with specific diseases like cancer or chronic infections, with varying disease stages, treatment histories, and immune profiles.

Study Design:
Evaluates vaccine efficacy alongside standard treatments, increasing complexity and requiring careful management of treatment interactions.

Regulations:
Ethical considerations in placebo-controlled trials or add-ons to standard care are essential.

Endpoints and Personalized Approach

Clinical endpoints:
Focus on outcome like tumor response, progression-free survival, and viral load reduction.

Immunological endpoints:
Measure immune response to assess the vaccine's mechanism of action.

Personalized approach:
Tailors vaccines to patient-specific disease characteristics, immune status, and genetic profiles, requiring precise patient selection and monitoring.

Laboratory and logistics:
Vaccine handling requires strict environmental controls due to sensitivity, with complex laboratory sample management and specific assays for immunogenicity testing.

Long-Term Follow-Up and Safety Monitoring

Long-term follow-up:
Necessary to evaluate immune response durability and vaccine impact on disease progression, often requiring periodic dosing.

Combination therapies:
Assesses vaccines in combination with chemotherapy, radiation, or immunotherapy.

Safety monitoring:
Critical for tracking adverse events and potential interactions, with extracare required in handling and transporting sensitive vaccine materials.

Therapeutic vaccines mark a significant breakthrough in the treatment of cancer, infectious diseases, and autoimmune conditions by harnessing the immune system for more personalized and targeted therapies. They hold promise for reducing side effects and providing longer-lasting disease control. However, challenges such as tumor heterogeneity, immune evasion, and intricate clinical trial designs must be addressed. Ongoing research and innovation are crucial to fully realizing the potential of therapeutic vaccines in revolutionizing healthcare and enhancing patient outcomes. [4]

Patient recruitment landscape

Prophylactic vaccine trials show shorter enrolment periods in the Asia-Pacific (4.78 months) and Europe (5.06 months) compared to the United States (6.20 months). However, Asia-Pacific leads in recruitment efficiency, enrolling 24 subjects per site per month, significantly higher than Europe at 9.83 and the United States at 5.66. This trend suggests that Asia-Pacific excels in faster and more efficient recruitment for prophylactic vaccines. (Figures 19 and 20)

Therapeutic vaccine trials present longer enrolment periods, especially in Europe (14.87 months) and the United States (14.47 months), with Asia-Pacific having a comparatively shorter period at 11 months. However, Asia-Pacific still leads in recruitment efficiency, enrolling 4.35 subjects per site per month, far ahead of Europe (1.61) and the United States (1.25). These figures indicate that, despite longer trial durations, Asia-Pacific maintains a strong edge in patient recruitment for therapeutic vaccine trials. (Figures 21 and 22)

Patient recruitment for therapeutic vaccine trials takes longer and involves fewer patients compared to prophylactic vaccine trials due to several factors. Therapeutic vaccines often target specific diseases, such as cancers, where the eligible patient pool is smaller and more selective, with strict inclusion criteria like specific genetic markers or disease stages. In contrast, prophylactic vaccines typically target broader, healthier populations, making recruitment easier and faster. Additionally, therapeutic trials often involve complex protocols, more intensive monitoring, and competition with other trials, further slowing recruitment efforts.

Figure 19: Prophylactic vaccine trials (2021-2024 YTD) - Enrolment period (months)

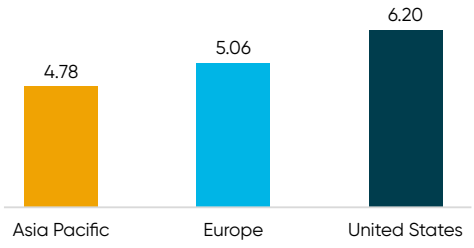


Figure 20: Prophylactic vaccine trials (Subjects/Site/Month)

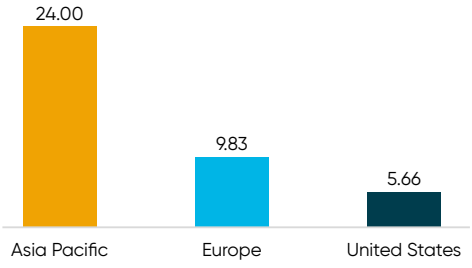


Figure 21: Therapeutic vaccine trials (2019-2024 YTD) - Enrolment period (months)

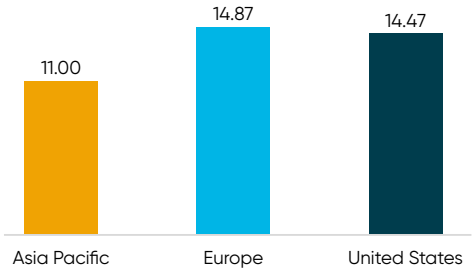
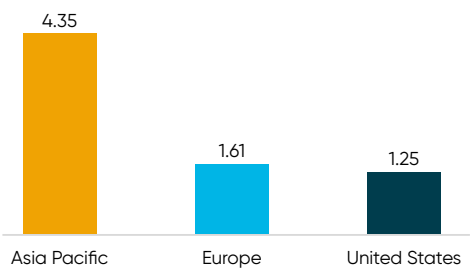


Figure 22: Therapeutic vaccine trials (Subjects/Site/Month)



Source: GlobalData October 2024

3. PROPHYLACTIC VACCINES AND THERAPEUTIC VACCINES DEVELOPMENT PIPELINE

PROPHYLACTIC VACCINES

The field of prophylactic vaccines is experiencing exciting developments. The COVID-19 pandemic significantly accelerated vaccine research and production technologies, particularly with the rapid deployment of mRNA and viral vector platforms. These innovations are not only improving the efficacy and speed of vaccine production but are also being applied to target other challenging diseases like HIV, malaria, and respiratory syncytial virus (RSV). Continuous refinement of adjuvants, delivery mechanisms, and multi-valent vaccines are key areas being explored to enhance the effectiveness of prophylactic vaccines and expand their coverage.[2]

The prophylactic vaccine pipeline currently has over 800 candidates, in various clinical phases, with the majority (41%) in Phase I, followed by 33% in Phase II, and 25% in Phase III. (Figure 23)

In terms of vaccine subtypes, subunit vaccines make up the largest portion (32%), followed by mRNA vaccines (18%), and inactivated vaccines (12%). mRNA vaccines rank second in the prophylactic pipeline due to their rapid development, strong immune responses, and adaptability to quickly target emerging pathogens. Their proven success, especially during the COVID-19 pandemic, has driven significant industry investment, positioning them as a key technology for future vaccines. The pipeline also includes recombinant vector vaccines, live attenuated vaccines, DNA vaccines, and toxoid vaccines. (Figure 24)

Figure 23: Pipeline vaccines by phase

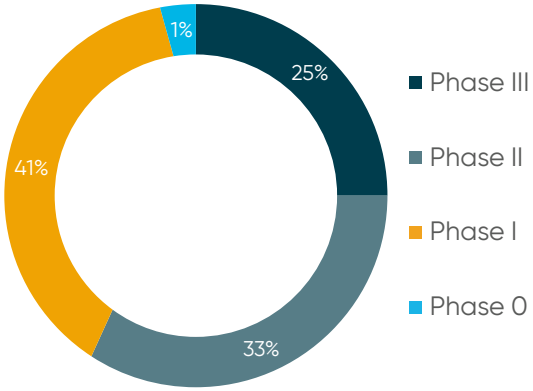
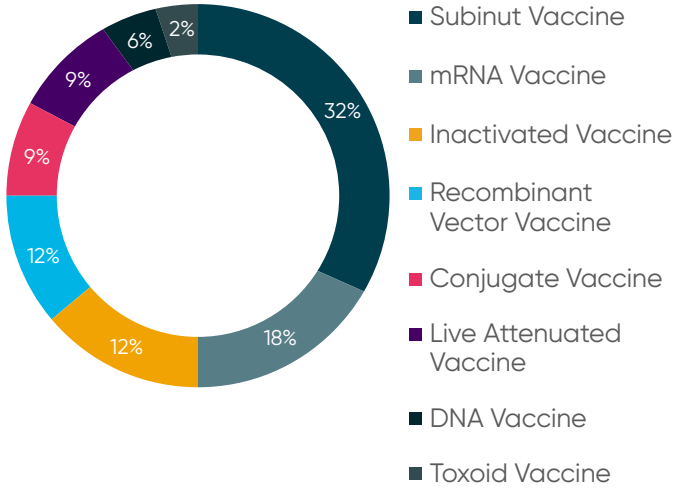


Figure 24: Pipeline vaccines by subtypes



Source: GlobalData October 2024

THERAPEUTIC VACCINES

Vaccines have long been associated with the traditional prophylactic approach, where they help build immunity to prevent infections before they occur. Prophylactic vaccines have been a cornerstone of public health, effectively controlling many infectious diseases such as polio, measles, and influenza. However, the field of vaccines is evolving beyond just prevention. Recent advances in immunology have opened the door to therapeutic vaccines, which aim to treat existing diseases by harnessing the body's immune system to fight against pathogens or cancer cells.

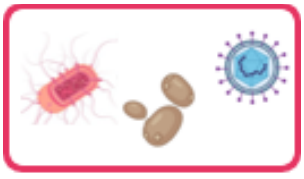
While prophylactic vaccines are widely known and utilized, therapeutic vaccines represent a newer, less established frontier. Therapeutic vaccines, unlike their preventive counterparts, aim to boost or redirect the immune system's response to control or eliminate existing diseases such as cancer, chronic infections, or autoimmune conditions. Recent innovations in immunotherapy, checkpoint inhibitors, and mRNA technology have propelled the development of therapeutic vaccines, particularly in oncology and chronic infectious diseases like hepatitis B and herpes simplex virus. [2]

Therapeutic vaccines are categorized into three main types: molecular-based, vector-based, and cell-based vaccines, as shown in the representation below. Molecular-based vaccines, including peptide, DNA, and mRNA vaccines, use neoantigens or proteins to trigger immune responses. Vector-based vaccines employ genetically engineered bacteria, viruses, or yeast to express antigen transgenes. Cell-based vaccines involve dendritic or genetically modified cells to deliver antigens.

These vaccines aim to deliver antigens, often with adjuvants, to activate dendritic cells and stimulate T or B cells, enhancing the immune system's ability to target infections or produce neutralizing antibodies. [3]

Molecular-based vaccines - Uses neo-antigens or proteins to directly activate immune system

- Peptide/protein vaccine
- DNA vaccine
- mRNA vaccine Therapeutic vaccines



Vector-based vaccines - Uses naturally or genetically engineered to express antigen transgene

- Bacterial vectors vaccine
- Virus vectors vaccine
- Yeast-based vaccine

Cell-based vaccines - Uses dendritic cells or genetically modified cells to express or deliver antigens

- Dendritic cells vaccine
- Genetically modified cell vaccine

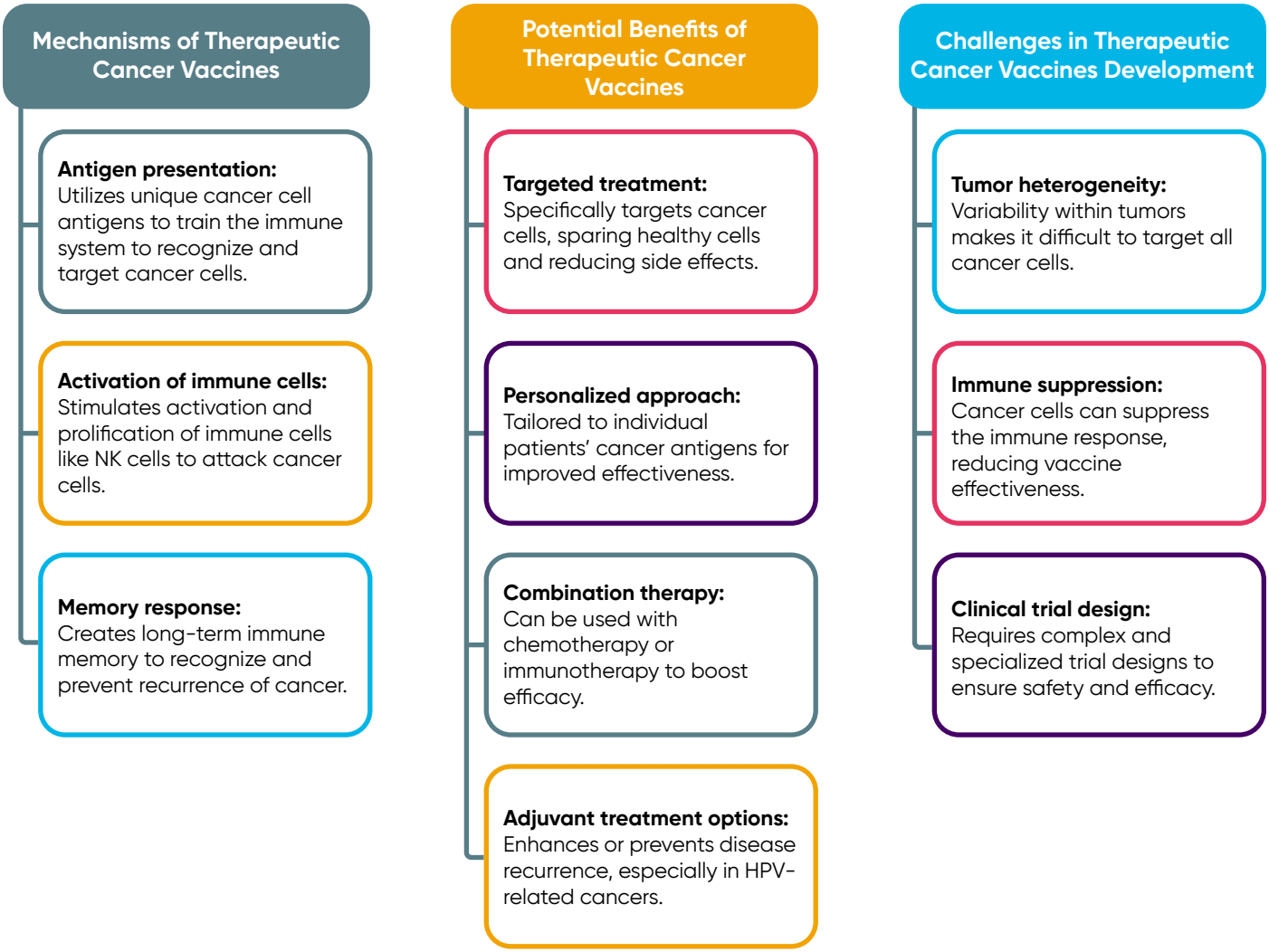
The following section will discuss in detail about the emerging trends and innovations in therapeutic vaccines.

Therapeutic vaccines activate the immune system to identify and attack specific cancer cells, infectious agents, or other antigens, serving as a treatment option to alter or potentially cure diseases. Unlike immunotherapies such as monoclonal antibodies, therapeutic vaccines induce active immunization by stimulating an immune response. These vaccines are used to target proteins or antigens present on the surface of cancer cells and can be designed to treat various cancers, including melanoma, breast cancer, and prostate cancer. They can be created from a patient's own tumor cells or synthetic peptides that imitate the tumor's antigens.

Similarly, therapeutic vaccines for infectious diseases stimulate the immune system to attack the infectious agent and can be used for chronic viral infections like HIV, hepatitis B, and hepatitis C. They can also be developed for autoimmune diseases by targeting self-antigens associated with these chronic conditions. A major benefit of therapeutic vaccines is that they can be customized to each patient's immune system, enhancing their effectiveness and reducing the likelihood of side effects.

Cancer

Therapeutic vaccines for cancer aim to stimulate the immune system to recognize and destroy cancer cells. By targeting cancer-specific antigens and activating immune memory, these vaccines can potentially offer long-term protection against disease recurrence. The advantages include more precise targeting of cancer cells, reduced side effects, and personalized treatment approaches. Despite their promise, challenges such as tumor heterogeneity and immune suppression remain obstacles that need to be overcome.



Infectious diseases

Therapeutic vaccines designed for infectious diseases activate the immune system to target and eliminate specific pathogens. These vaccines are being developed to manage chronic infections such as HIV, hepatitis B, and hepatitis C by lowering viral loads and slowing disease progression. While they hold significant potential for global health, creating a strong and sustained immune response remains challenging, particularly due to the high mutation rates of some viruses.

Mechanisms of Therapeutic Vaccines for Infectious Diseases

- **Targeting specific antigens:** Identifies unique antigens or proteins from pathogens to stimulate a focused immune response.
- **Viral latency control:** Aims to reduce viral load and slow disease progression in chronic infections like HIV, hepatitis B, and hepatitis C.
- **Immune system activation:** Boosts the immune system's ability to recognize and neutralize viruses or bacteria already present in the body.

Potential Benefits of Therapeutic Vaccines for Infectious Diseases

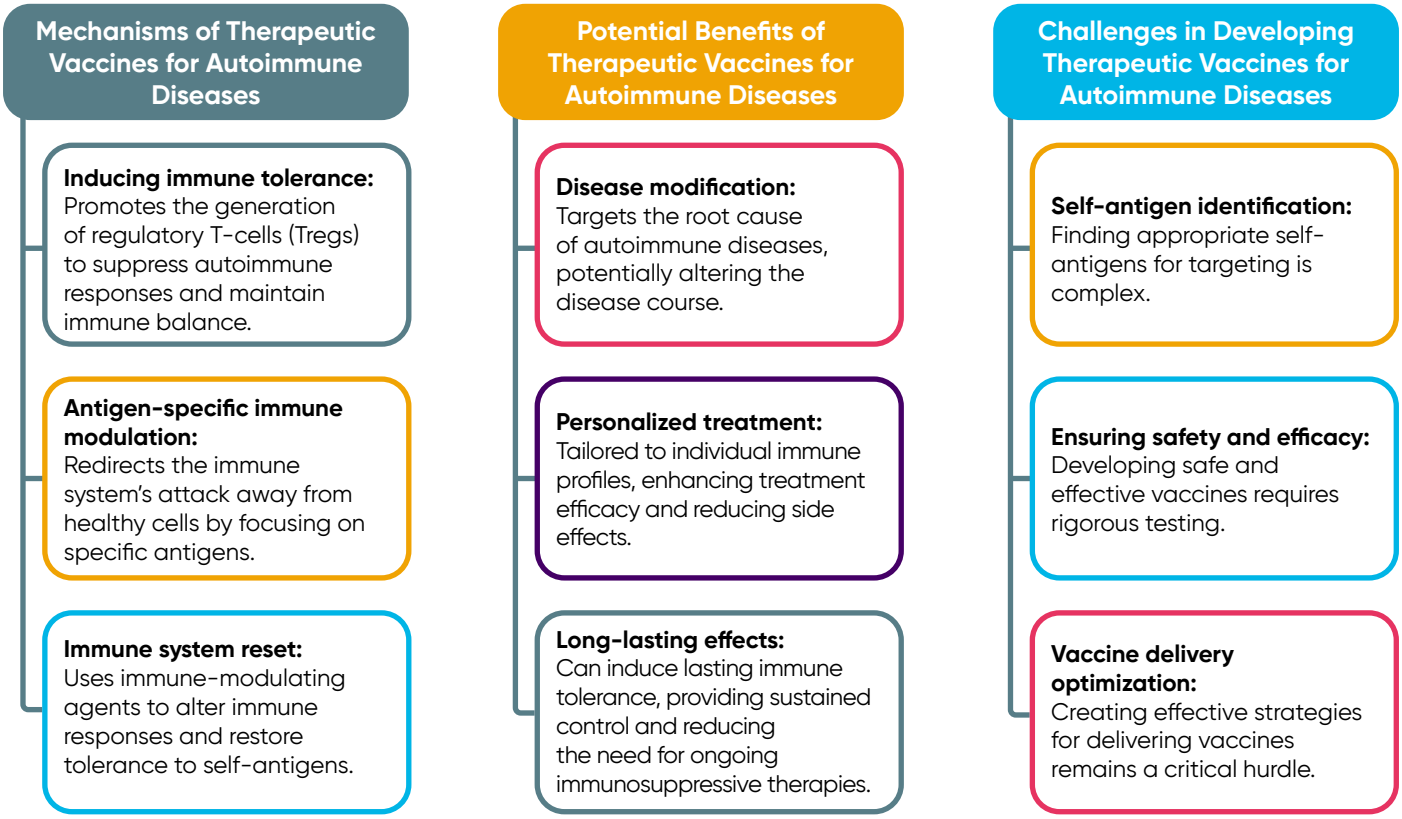
- **Chronic infection treatment:** Shows promise in treating HIV, hepatitis B, and C by controlling viral load and improving overall health.
- **Global health impact:** Offers potential breakthroughs in treating diseases like Tuberculosis by preventing relapses and addressing long-term consequences.
- **Combination therapy:** Can be used alongside other treatments to enhance effectiveness and improve patient outcomes.

Challenges in Developing Therapeutic Vaccines for Infectious Diseases

- **Weakened immune response:** Existing infections may compromise the immune system, making it harder to elicit a strong response.
- **High mutation rates:** Viruses like HIV mutate rapidly, complicating vaccine development.
- **Ongoing research:** Active clinical trials and technological advancements continue to improve the effectiveness and safety of these vaccines.

Autoimmune diseases

Therapeutic vaccines offer a promising new approach for autoimmune diseases by targeting self-antigens that cause immune system dysregulation. These vaccines aim to restore immune balance by promoting the activity of regulatory T-cells and modulating immune responses to prevent attacks on healthy tissues. Though they hold the promise of long-term control, challenges remain in identifying appropriate self-antigens and ensuring the safety of these therapies.



The therapeutic vaccine pipeline is robust, with over 300 candidates in various stages of development across the globe. Most therapeutic vaccines are in the early clinical trial phases, with 46% in Phase I and 45% in Phase II. A smaller proportion, 7%, has reached Phase III, indicating that many are still in the proof-of-concept stage, with few progressing toward later clinical trials. (Figure 25)

Coming to vaccine subtypes, subunit vaccines lead with 48%, followed by recombinant vector vaccines at 18%, and DNA vaccines at 16%. mRNA vaccines account for 10%, with smaller portions for conjugate (4%), inactivated (3%), and live attenuated vaccines (1%). Subunit and recombinant vector vaccines dominate due to their ability to focus on specific antigens or use vectors for targeted delivery. DNA and mRNA vaccines are gaining prominence for their adaptability, ease of production, ability to induce strong immune responses and for their potential in personalized therapies. (Figure 26)

Figure 25: Pipeline vaccines by phase

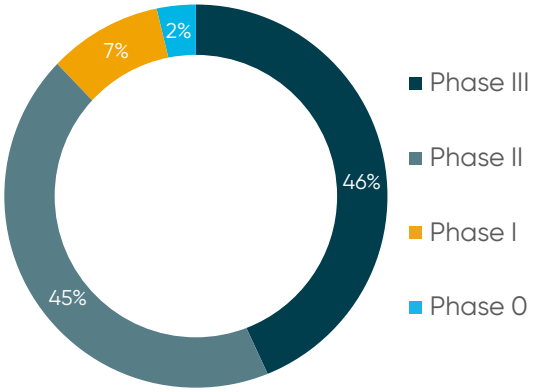
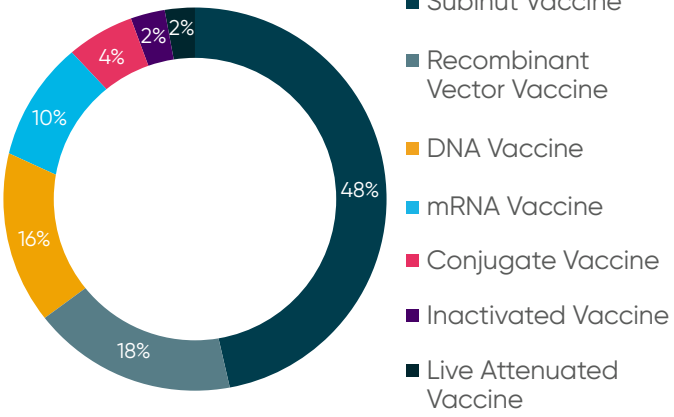


Figure 26: Pipeline vaccines by subtypes



Source: GlobalData October 2024

Innovative Vaccines on the Horizon: Transforming Global Health through Preventive Interventions

The past few years have shown the immense impact vaccines can have, from the rapid development of COVID-19 vaccines to the introduction of the first vaccines for malaria and chikungunya.

Currently, vaccines help prevent more than 20 life-threatening diseases, saving millions of lives each year. Despite these successes, there are still millions of children who miss routine vaccinations each year, and the need for continued investment in vaccine development remains critical.

In recognition of World Immunization Week 2024, GHTC (Global Health Technologies Coalition) is focusing on five vaccines (shown below) in development that have the potential to transform the fight against some of the world's most dangerous diseases, showing the promise of vaccines to save even more lives in the years to come.

Tuberculosis (TB) Vaccine

- The M72/AS01E vaccine, in Phase 3 trials, offers hop e for preventing latent TB from progressing to active pulmonary TB.
- If successful, it could become the second licensed TB vaccine, transforming global TB control efforts.

Zika Vaccine

- Valneva's VLA1601 and Moderna's mRNA-1893 vaccines are currently in Phase 1 and Phase 2 trials, respectively.
- These vaccines aim to prevent Zika infections, which can cause severe congenital conditions in newborns.

Lassa Fever Vaccine

- A Phase 2 trial led by IAVI and CEPI offers the most advanced effort yet to develop a vaccine for Lassa fever.
- This vaccine could help protect against viral outbreaks in West Africa, where the disease is endemic.

Nipah Virus Vaccine

- The ChAdOx1 NipahB vaccine, utilizing the same technology as the AstraZeneca COVID-19 vaccine, is in early human trials.
- It could provide much-needed protection against this zoonotic virus, which has a fatality rate of 40-75%.

Enterotoxigenic Escherichia coli (ETEC) Vaccine

- ETVAC, an oral vaccine candidate in Phase 2 trials, shows promise in reducing diarrheal disease in children and travelers.
- This vaccine could also play a significant role in combating antimicrobial resistance by reducing the need for antibiotics.

These five vaccine candidates represent critical advances in global health, targeting diseases with significant mortality and morbidity rates. Continued investment in vaccine research and development is essential to ensure these breakthroughs reach those who need them most, ultimately saving lives and protecting global health for future generations. Sustaining these efforts is key to pushing the boundaries of innovation and securing a healthier world [5].

4. EMERGING TRENDS IN VACCINE CLINICAL TRIAL DESIGNS

Clinical trial designs for vaccines are rapidly evolving to improve efficiency, safety, and success rates in both prophylactic and therapeutic contexts. Prophylactic vaccine trials, often large and randomized, focus on evaluating the prevention of infectious diseases. These trials increasingly adopt adaptive designs and interim analyses to accelerate timelines, particularly in pandemic situations, where rapid safety and efficacy assessments are critical.

Therapeutic vaccine trials, particularly in cancer and chronic disease treatments, tend to be more targeted and personalized. Basket and umbrella trials are becoming more common, allowing multiple treatments to be tested across different patient subgroups or diseases under a single protocol, making these designs especially useful for rare conditions and improving trial efficiency.

The following section discusses key emerging clinical trial design strategies for both prophylactic and therapeutic vaccines. It provides a detailed look at how large, randomized trials with adaptive designs are streamlining the development of vaccines to prevent infections, particularly during global health emergencies. Additionally, it explores how innovative designs like basket and umbrella trials are enhancing efficiency in therapeutic vaccine trials, especially for rare diseases and personalized cancer treatments.

Prophylactic Vaccines

Traditional Randomized, Double-Blind, Placebo-Controlled Trials

These trials involved large, randomized populations to evaluate the efficacy of preventing SARS-CoV-2 infections. For example, Pfizer's trial involved several thousands of participants, with a placebo group and a vaccine group to assess infection rates and immune responses. Example: COVID-19 Vaccines (Pfizer, Moderna, AstraZeneca) [7].

Adaptive Trials

Adaptive designs are becoming popular in seasonal flu vaccine trials, allowing interim analyses to adjust dosing regimens or trial populations based on ongoing results. For example, trials can adjust for changes in flu strains during a season, ensuring the trial remains relevant. Example: Influenza Vaccines [8,9].

Accelerated and Surrogate Endpoints

Ebola vaccine trials, such as the one for rVSV-ZEBOV, used accelerated approvals due to the high mortality rate of the disease. These trials often used surrogate endpoints like immunogenicity (neutralizing antibody levels) instead of waiting for clinical cases to emerge, expediting the process.Example: Ebola Vaccine Trials, Merck [7].

Cluster-Randomized Trials

In cluster-randomized trials for malaria vaccines (like the RTS, S/AS01 vaccine), groups of participants from specific areas are randomized to receive the vaccine or a control. This design helps assess the broader population-level impact in endemic areas, rather than focusing solely on individual outcomes. Example: Malaria Vaccines [8].

Open-Label and Dose-Optimization Studies

Sci-B-Vac, a prophylactic vaccine, is undergoing open-label trials to assess dose consistency and immune response across different population subsets. These trials aim to standardize dosing strategies and improve immunogenicity, particularly in harder-to-treat populations like diabetics. Example: Sci-B-Vac [10].

Therapeutic Vaccines

Randomized, Double-Blind, Placebo-Controlled Trials

In Phase IIb trials, bepirovirsen has shown potential for durable efficacy, with a key endpoint being the reduction of hepatitis B surface antigen (HBsAg) over time. These trials use multiple dosing arms to assess optimal treatment duration and dose, with functional cure (loss of HBsAg) being a major goal. Phase III trials are expected to further refine the dosing and duration. Example: GSK's Bepirovirsen [10].

Adaptive Trials

Adaptive designs are being employed to assess safety and efficacy at various stages. The ongoing trials for the novel therapeutic vaccine TherVacB utilize adaptive methodologies to adjust dosing based on real-time results, allowing faster progression through phases. Example: TherVacB [11].

Personalized Medicine Trials

Personalized mRNA cancer vaccines, such as those targeting neoantigens, are tested in small patient populations with specific tumor mutations. These trials often focus on individuals with melanoma or colorectal cancer, where vaccines are developed based on each patient's mutational profile, and immune responses are monitored over time. Example: Cancer Vaccines (mRNA-based) [9].

Basket and Umbrella Trials

Basket trials allow for testing of the same vaccine or therapy across multiple cancer types sharing a common biomarker. For example, HPV therapeutic vaccines are being evaluated in patients with head and neck cancers, cervical cancer, and other HPV-related malignancies under a single trial protocol. The flexibility in such designs helps expedite the evaluation process across various tumor types. Example: HPV and Cancer Therapeutic Vaccines [8].

Combination Therapy Trials

Trials combining vaccines with immune checkpoint inhibitors, such as pembrolizumab with a therapeutic HPV vaccine, focus on enhancing immune responses in cancers. These combination trials are typically smaller and use endpoints like progression-free survival (PFS) and overall response rates (ORR). Example: Checkpoint Inhibitors + Vaccines in Cancer [12].

Sequential Trials

In TB vaccine trials, a sequential design is used where patients first receive a therapeutic vaccine followed by an evaluation period to assess immune responses before moving to the next phase of treatment. These trials are particularly useful in slow-progressing infections like TB, where outcomes may take longer to manifest. Example: Tuberculosis (TB) Therapeutic Vaccines [13]

Innovative Trial Designs

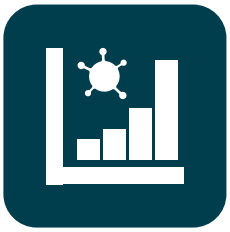
Challenge Trials

In these trials, participants are deliberately exposed to the virus after vaccination to evaluate the effectiveness of the vaccine in preventing infection. This controversial approach is used to speed up efficacy evaluations, such as in ongoing COVID-19 vaccine research. Example: COVID-19 Challenge Trials [7]

Platform Trials

The NIH's ACTIV initiative used a platform trial design to simultaneously evaluate multiple COVID-19 vaccines and treatments. This approach allows sharing of control groups and a more streamlined process for comparing multiple interventions in parallel. Example: ACTIV COVID-19 Vaccine Trials [7,9].

Key Takeaway



Prophylactic vaccines

Rely heavily on large population-based trials but are increasingly adopting adaptive and accelerated designs to meet urgent public health needs.

Therapeutic vaccines

Therapeutic areas especially in oncology, focus on personalized and combination therapies, with emerging designs like basket and umbrella trials enabling broader testing across cancer types.

Innovative approaches

Emerging approaches like challenge and platform trials are accelerating vaccine development, particularly for rapidly emerging infectious diseases like COVID-19.

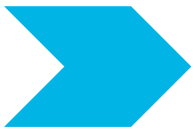
Emerging trial designs involving vaccine subcategories

DNA and RNA vaccines

Moving towards adaptive and platform trial designs to quickly assess efficacy and scale production.

Protein subunit and viral vector vaccines

Often utilize multi-center, randomized control trials but face challenges in adjuvant selection and pre-existing immunity.



Cellular vaccines

Focus on small, personalized trials but encounter production complexities.

Inactivated and live-attenuated vaccines

Remain reliable but face challenges in balancing safety with immune stimulation, especially in newer applications like COVID-19.

Enabling technologies that promote innovative clinical trial designs

Technologies like mRNA platforms are revolutionizing clinical trial designs by enabling rapid development and testing of vaccines, particularly for infectious diseases. The success of mRNA-based COVID-19 vaccines (Pfizer-BioNTech, Moderna) demonstrated the technology's ability to streamline the transition from preclinical to clinical phases. With their ability to be rapidly adapted to emerging variants, mRNA vaccines are influencing adaptive clinical trial designs, allowing for real-time modifications based on interim results. This flexibility reduces trial timelines and improves safety and efficacy assessments.

Other groundbreaking technologies include viral vectors, DNA vaccines, and protein subunit vaccines, which are improving immune responses and durability of protection. These platforms often employ innovative trial designs like platform trials, which test multiple vaccine candidates simultaneously, optimizing resources and speeding up comparisons

Furthermore, immunotherapies and therapeutic vaccines, such as those using dendritic cell technologies or personalized neoantigen vaccines, are shaping therapeutic vaccine trials. These technologies, especially in cancer therapies, encourage basket and umbrella trial designs, allowing for testing across different diseases and subpopulations in a single trial protocol.

Artificial Intelligence (AI) for its part is also transforming vaccine trials by improving participant selection, data analysis, and real-time monitoring. Companies like Pfizer and Moderna use AI-driven machine learning to streamline patient recruitment, reduce timelines, and enhance trial diversity. AI enables real-time adjustments in adaptive trials, optimizing safety and efficacy. Natural language processing (NLP) further aids in analyzing medical records for predicting outcomes and detecting adverse events. These capabilities significantly boost the precision and efficiency of large-scale global vaccine trials, such as those conducted during COVID-19.

In summary, advancements in technologies like mRNA, viral vectors, and AI are revolutionizing clinical trial designs, enabling more adaptive, efficient, and responsive frameworks. AI, in particular, enhances participant selection, real-time monitoring, and data analysis, contributing to faster, more precise trials. These innovations, by shortening timelines and improving trial flexibility, are critical in addressing global health crises and chronic diseases. The future of vaccine development will increasingly depend on these advanced technologies and trial designs, ensuring that vaccines therapies reach the market rapidly while maintaining high safety and efficacy standards [7,9,12].

5. VACCINES: STRATEGIC ANALYSIS AND OVERCOMING CHALLENGES

Strengths, Weaknesses, Opportunities, Threats (SWOT)

Vaccines are essential to maintaining global health, with prophylactic vaccines aimed at preventing infectious diseases, and therapeutic vaccines targeting the treatment of ongoing conditions like cancer and chronic viral infections. Recent advancements, primarily the use of mRNA technology seen during the COVID-19 pandemic, have driven rapid innovation in both vaccine types. This SWOT analysis explores the main strengths, weaknesses, opportunities, and threats for prophylactic and therapeutic vaccines, shedding light on current trends and market shifts.

Prophylactic and therapeutic vaccines each offer distinct benefits and face unique challenges in their development and commercialization. Prophylactic vaccines, driven by strong global demand and technological advancements, are the top priority in preventing widespread infectious diseases, but face issues like vaccine hesitancy and distribution disparities. On the other hand, therapeutic vaccines show great potential in areas such as oncology, yet they struggle due to slower patient recruitment and high development costs.

By capitalizing on opportunities like growing R&D investments and addressing existing threats such as regulatory hurdles, vaccine developers can continue to shape the future of global health and treatment outcomes [14,15].

Prophylactic Vaccines

Opportunities

- Strong market demand driven by the need for immunization against widespread diseases like COVID-19, influenza, and HPV.
- Technological advancements such as mRNA vaccines have proven highly effective, as seen in the COVID-19 pandemic, which boosts R&D interest and investment.
- Governmental support, subsidies, and global public health initiatives enhance distribution and access.

Weaknesses

- Complexity and long timelines in the development of new vaccines. The R&D process often takes years from discovery to approval.
- Vaccine hesitancy, fueled by misinformation or concerns about safety, especially in regions with lower trust in public health systems.

Opportunities

- Increasing mergers, acquisitions, and collaborations in the vaccine space enhance innovation and global market reach.
- Ongoing development of mRNA and other advanced vaccine platforms has expanded potential for rapid development of new prophylactic vaccines for emerging diseases.

Threats

- New viral mutations may render existing vaccines less effective, necessitating continuous updates and adaptability.
- Unequal global distribution and accessibility issues, particularly in low-income countries, create gaps in immunity and public health safety.

Therapeutic Vaccines

Opportunities

- Rapidly growing interest in immunotherapies, especially in oncology. Therapeutic vaccines hold promise for treating diseases like cancer, which currently lack curative solutions.
- Expansion of personalized medicine approaches, allowing vaccines to target specific genetic profiles of diseases.

Weaknesses

- Therapeutic vaccines tend to have smaller patient populations, leading to longer recruitment times and higher costs per clinical trial.
- Regulatory hurdles remain significant, with complex approval processes due to the innovative nature of therapeutic vaccines.

Opportunities

- The rise in cancer incidence and the continued demand for alternative therapies provide significant growth opportunities.
- Increased R&D investments in targeted therapies, especially for diseases like melanoma, non-small cell lung cancer, and others, as new immune checkpoint inhibitors show promise in clinical trials.

Threats

- High costs associated with developing and bringing therapeutic vaccines to market, especially for complex diseases like cancer.
- Competitive pressures from other immunotherapy approaches, such as CAR-T therapies, could limit market share for therapeutic vaccines.

Vaccine development and deployment face numerous challenges, including ongoing infections, pathogen evolution with high sequence variability, complex antigens, and emerging or re-emerging pathogens. Key barriers include a limited understanding of immunity, host and pathogen variability, vaccine safety concerns, and non-heritable factors.

These obstacles hinder the timely realization of full benefits of vaccines. Additional challenges include issues related to adjuvants, maintaining long-term efficacy, public adaptability, gaps in scientific knowledge, potential for virulence reversal, biological complexities, and flawed business models that hinder progress.

Moreover, vaccine access is limited in developing countries due to inadequate healthcare infrastructure, and safety concerns often discourage vaccination. Other hurdles include lengthy development timelines, genetic variability of pathogens (especially RNA viruses), reduced efficacy in older populations, and immune evasion by critical pathogens like HIV, malaria, and tuberculosis, making vaccine development for these diseases particularly challenging.

The below table summarizes approaches to address these challenges [6].

Approaches to address challenges

Scientific and Immunological Approaches

- Conduct systems biology studies.
- Identify non-humoral immune protection.
- Explore functions that aid quick recovery from infection.
- Ensure vaccines elicit both cellular and humoral responses.
- Use diagnostics to measure vaccine response regularly.
- Develop vaccines that produce broad neutralizing antibodies.
- Base vaccine production on genetic variability.

Vaccine Design and Production

- Launch multivalent vaccines.
- Develop novel subunit, protein-based, and peptide-based vaccines with new adjuvants.
- Implement dose-sparing methods.
- Consider aging impacts on vaccine efficacy.
- Accelerate vaccine development with innovative methods.

Public Health and Accessibility

- Population dynamics should be considered when producing and/or implementing vaccines.
- Access to the vaccines should be quick and unanimous for the public.
- Vaccine awareness should be equally prioritized with the same spirit by which the vaccine was produced, because anti-vaccine movements undo significant progress quickly.
- Herd immunity, in the case of pandemics, is an effective solution.

Safety and Efficacy

- Safety should be a top priority.
- Vaccines should produce a broad spectrum of neutralizing efficacies of antibodies.
- Vaccine response should be accurately measured with effective diagnostic tests.

Business and Policy

- Safety should be a top priority.
- Vaccines should produce a broad spectrum of neutralizing efficacies of antibodies.
- Vaccine response should be accurately measured with effective diagnostic tests.

Regulatory and Global Coordination

- Regulatory bodies should streamline approval processes for faster vaccine availability.
- Global cooperation in vaccine development and distribution should be strengthened to ensure uniform standards and accessibility.
- Policies to ensure equitable vaccine distribution across developed and developing countries.

6. INVESTMENT LANDSCAPE

Mergers and Acquisitions

From 2020 to 2023, M&A activity in vaccines R&D experienced fluctuations in both deal volume and value. In 2020, there were 27 deals worth $3.8 billion. By 2021, the number of deals rose slightly to 28, while the total value surged to $29.7 billion. Although the number of deals dropped to 24 in 2022, the value decreased to $6.1 billion. In 2023, activity reached its highest point with 33 deals valued at $51.4 billion. As of 2024 YTD, there have been 16 deals totalling $1.3 billion, suggesting a possible slowdown in the sector. (Figure 27)

M&A deals were also distributed across various therapeutic areas, with infectious diseases leading at $88.1 billion, followed by oncology ($78.9 billion) and respiratory illnesses ($71.4 billion). Immunology and gastrointestinal therapies also received large investments, while the central nervous system saw the lowest amount at $26.8 billion. The strong focus on infectious diseases aligns with the heightened focus on vaccine development during the global pandemic. (Figure 28)

Moving on to M&A deals by locations, most deals in vaccines R&D took place in the United States, making up 92% of the total. The United Kingdom, China, and France each accounted for 2-4%, highlighting the U.S.'s leading role in driving global vaccine research and development through mergers and acquisitions. (Figure 29)

With regards to strategic focus areas, a striking 95% of deals during this period aimed at increasing scale or business expansion, as companies looked to grow their capabilities and consolidate their market position. Only 3% of deals focused on expanding product offerings, and 2% were tied to geographic expansion, indicating that business growth and consolidation were the primary motivators for dealmaking in the vaccine R&D space. (Figure 30)

AstraZeneca's acquisition of Icosavax for USD1.1 Billion (2024), CanSino Biologics' acquisition of 10% Stake in Solution Group for USD1.85 Million (2023), Novartis's acquisition of Chinook Therapeutics for Approximately USD3.5 Billion (2023), Genexine's merger with EPD Biotherapeutics (2024), Aeterna's merger with Ceapro (2024), Renovaro Biosciences (Enochian Biosciences) merger with GEDi Cube Intl (2024) are some of the top M&A deals since 2023.

Figure 27: M&A deals and amount by year

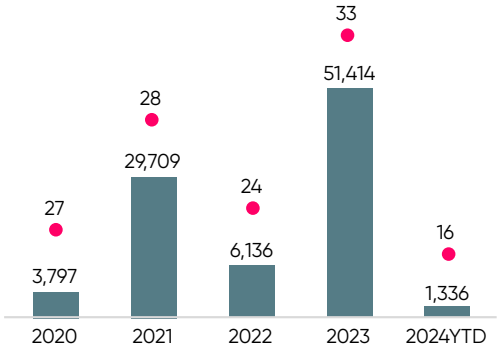


Figure 28: M&A deals (US$m) by top therapeutic area

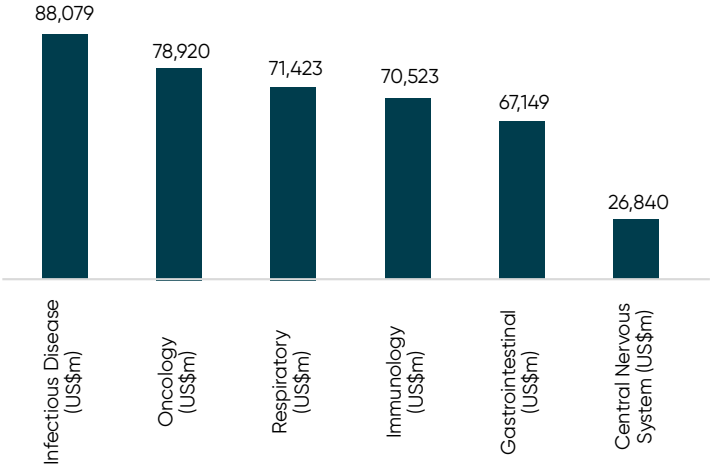


Figure 29: M&A deals % share by locations

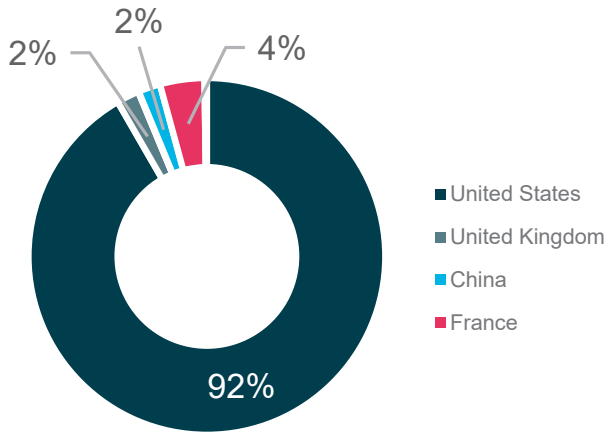
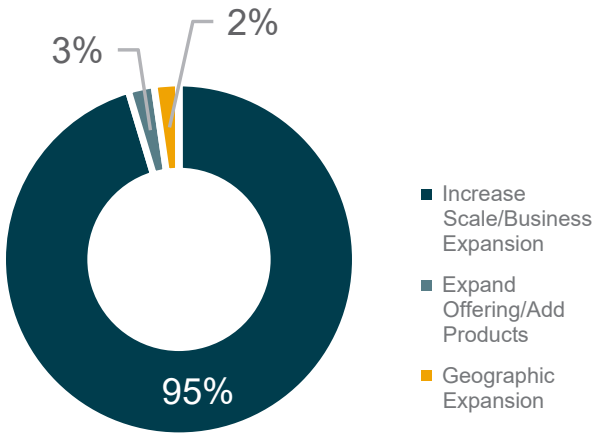


Figure 30: M&A delas % share by requirement category



Venture funding

Between 2019 and 2024 year-to-date (YTD), venture funding has fluctuated significantly in both deal volumes and values, reflecting the evolving landscape of vaccine development. The surge in venture funding in 2021 was driven by the global need for COVID-19 vaccines, with investors focusing on urgent vaccine innovations and delivery platforms. A decline in both deal volumes and values followed in 2022 and 2023, as the pandemic urgency receded. However, consistent funding in 2023 and 2024 YTD reflects ongoing interest in next-gen vaccines and therapeutic vaccines. (Figure 31)

Among the therapeutic areas, Infectious disease sector received the highest funding ($5.2 billion), largely due to the COVID-19 pandemic, while Oncology vaccines garnered $3.3 billion, driven by interest in cancer immunotherapies. (Figure 32)

Among the geographical locations, China and the United States led the venture funding, driven by their strong biotech ecosystems and leadership in vaccine development, with China attracting 50% and the U.S. receiving 33% share of venture funding, respectively. (Figure 33)

Moving on to the rounds of investment, Series B (35%) and Series C (38%) rounds dominated the funding, as investors focused on supporting early- to mid-stage companies that show promise in advancing innovative vaccine platforms. (Figure 34)

Sustained funding in 2023 and 2024, despite the post-pandemic decline, shows confidence in next-gen vaccine therapeutics. With China and the U.S. leading and Series B and C rounds attracting most interest, early- to mid-stage companies are key to driving vaccine innovation.

Suzhou Abogen Biosciences Co Ltd, Affinivax Inc, BioNTech SE, ReNAgade Therapeutics Inc and Clover Biopharmaceuticals Ltd were some of the top companies that received venture funding among others.

Figure 31: Venture funding deals and amount by year

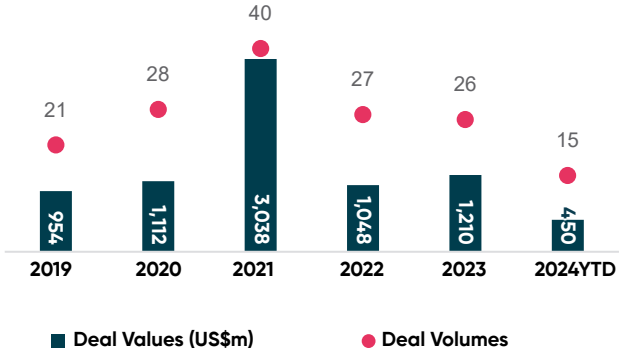


Figure 32: Venture funding (US$m) by top therapeutic area

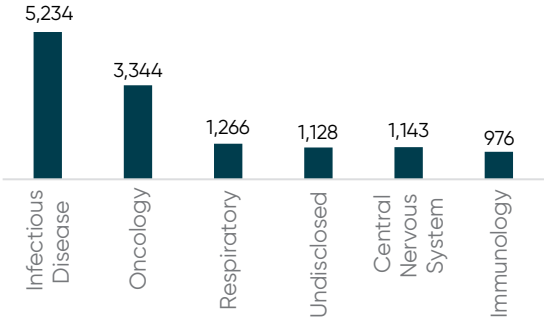


Figure 33: Venture funding % share by locations

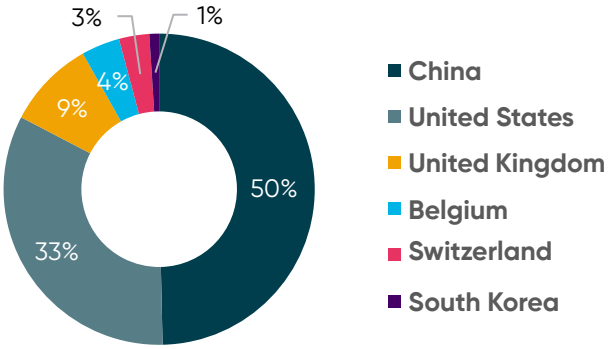
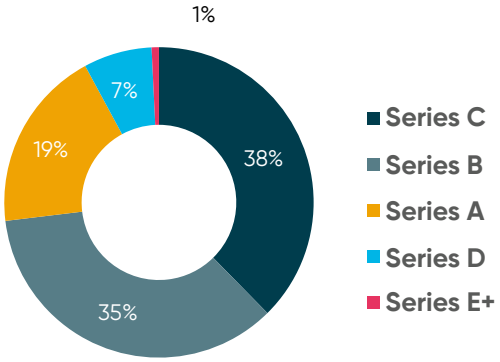


Figure 34: Venture funding by rounds of financing



Source: GlobalData October 2024

7. EMERGING GLOBAL HEALTH THREATS AND VACCINE RESPONSE

Emerging pathogens such as Mpox (Monkeypox), COVID-19, and other zoonotic viruses like RSV and Zika are reshaping the global vaccine development landscape, with urgent efforts underway to create effective preventive measures. Following the WHO's declaration of Mpox as a significant global health concern, numerous clinical trials have been initiated to develop vaccines targeting this threat.

Moderna's mRNA-1769 mpox vaccine, currently in early trials in the U.K. and U.S., is one of the key candidates leveraging mRNA technology for rapid immunogenic response. Similarly, Bavarian Nordic's MVA-BN (JYNNEOS), for Mpox, originally designed for smallpox, has shown strong post-exposure prophylaxis potential in Phase III trials, especially in regions like Africa and Europe. In addition to Mpox, other emerging pathogens, such as respiratory syncytial virus (RSV) and coronaviruses, are driving the development of next-generation vaccines.

Moderna's mRNA-1283 (COVID-19) and mRNA-1345 (RSV) vaccines are in late-stage Phase III trials, showing high efficacy, underscoring the versatility of mRNA platforms in responding to diverse pathogens. Furthermore, Moderna's mRNA-1083, a combination vaccine targeting both influenza and COVID-19, is also in Phase III, highlighting a trend towards simplifying immunization strategies to tackle multiple respiratory infections simultaneously.

These developments highlight the biotech industry's adaptability in combating future pandemic threats, utilizing advanced platforms and quick regulatory frameworks to address urgent global health needs [16,17,18,19].

Gavi Vaccine Roadmap: Introduction and Impact of VIS

Gavi, an international organization, unites public and private sectors to enhance equitable vaccine access. Its Vaccine Investment Strategy (VIS) evaluates vaccines every five years, prioritizing based on impact, cost, and relevance to low-income countries. Since 2001, VIS has expanded Gavi's vaccine portfolio from 6 to 19 vaccines, including Ebola, COVID-19, and malaria. As of June 2024, Gavi supports vaccines against 20 infectious diseases through 53 product presentations, continuing efforts to address global health challenges like tuberculosis, hepatitis and mpox by 2030.

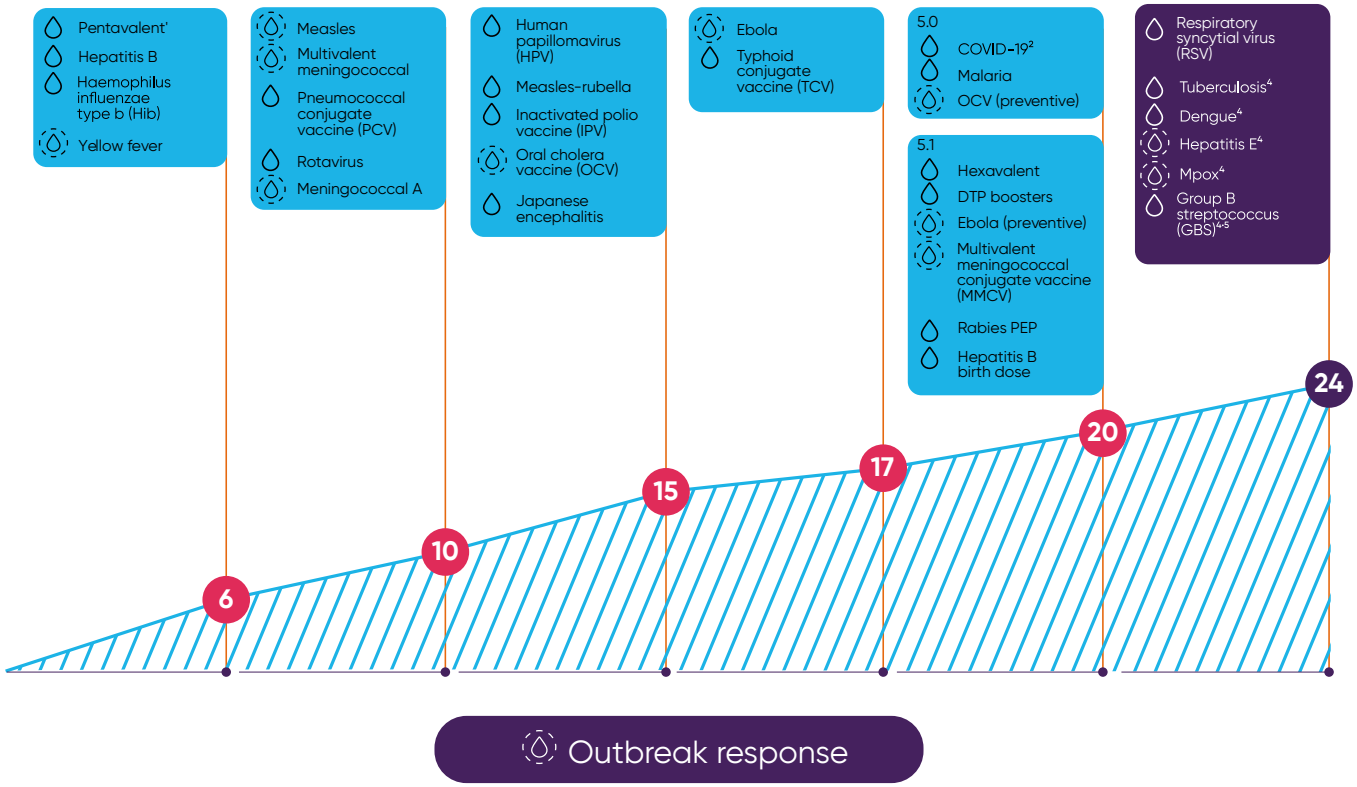
In June 2024, the Gavi Board approved VIS 2024, focusing on future vaccine programs for tuberculosis, Group B streptococcus, and dengue, as well as stockpiles for Mpox and Hepatitis E. Gavi will support learning agendas to accelerate vaccine access in low-income countries. Additionally, Gavi plans to sunset routine COVID-19 vaccination by the end of 2025, while maintaining emergency response mechanisms for potential future needs. Mpox response will be expanded in the Democratic Republic of Congo, leveraging COVID-19 experience for dose donations. The table below summarizes Gavi Board decisions for VIS 2024.

VIS 2024: decisions

Vaccine	Population	In principle investment	Learning agenda
Tuberculosis	Adolescents and adults	✓	✓
Group B streptococcus	Pregnant women	✓	✓
Dengue	2–16-year-olds	✓	✓
	Conditional on burden data in Africa		
Hepatitis E	High-risk populations in outbreak response	✓	✓ from Gavi 5.1
Mpox		✓	✓ from Gavi 5.1
Shigella	Infants	✗	✓
Chikungunya	Outbreak response	✗	✗
COVID-19	High-risk populations	No continued investment post-2025	

The figure 35 illustrates the growth of Gavi's vaccine portfolio from 2000 to 2030, highlighting key milestones across six phases (Gavi 1.0 to Gavi 6.0). Starting with six vaccines in 2000, Gavi has expanded to support 24 vaccines by 2030. Each phase introduced new vaccines, such as pneumococcal and HPV vaccines, with a focus on addressing critical diseases like Ebola, COVID-19, and respiratory syncytial virus (RSV). The timeline also includes an outbreak response segment for specific epidemics [20].

Figure 35: Gavi's vaccine portfolio (2000 to 2030)



Notes:

1. Diphtheria, tetanus, pertussis (DTP), hepatitis B, Haemophilus influenzae type b (Hib).
2. The Vaccine Investment Strategy (VIS) did not recommend continuing COVID-19 in Gavi's portfolio from 2026.
3. Respiratory syncytial virus (RSV) vaccine was approved in principle through the Vaccine Investment Strategy 2018.
4. Tuberculosis, dengue, hepatitis E, mpox, and Group B streptococcus (GBS) vaccines were approved in principle by the Gavi Board in June 2024 as outcomes of the Vaccine Investment Strategy 2024.
5. Estimated timeline for vaccine availability is Gavi 7.0 (2031–2035).

Source: www.gavi.org

8. REGULATORY LANDSCAPE

The regulatory landscape for vaccines, both prophylactic and therapeutic, involves multiple international and national health authorities working to ensure vaccine safety, efficacy, and quality. Key agencies like the FDA (U.S.), EMA (Europe), and WHO play pivotal roles in overseeing the development, approval, and post-market monitoring of vaccines. The processes differ across regions, but a shared focus on fast-tracking approvals during public health emergencies, ensuring equitable access, and postapproval surveillance is critical. Emerging trends emphasize collaboration between governments and private sectors to streamline approval pathways and enhance pandemic preparedness. The table below outlines how key regulatory bodies manage vaccine approvals and access across different regions [21, 22].

Region	Regulatory Agency	Pathway for Prophylactic Vaccines	Pathway for Therapeutic Vaccines	Key Features
Global	WHO (World Health Organization)	WHO Prequalification Programme (PQ) for global use, particularly in low- and middle-income countries	Provides guidelines but not direct approvals; focuses on safety, efficacy, and quality of both prophylactic and therapeutic vaccines	Harmonizes global vaccine regulations, ensures compliance with Good Clinical Practices (GCP).
United States	FDA (Food and Drug Administration)	Center for Biologics Evaluation and Research (CBER) through Investigational New Drug (IND) applications and Biologics License Application (BLA)	May also fall under Center for Drug Evaluation and Research (CDER) for therapeutic vaccines, especially in cases like cancer	Emergency Use Authorization (EUA) available for urgent cases (e.g., COVID-19); post-market monitoring through VAERS.
European Union	EMA (European Medicines Agency)	Centralized Marketing Authorization through Committee for Medicinal Products for Human Use (CHMP)	Advanced Therapy Medicinal Products (ATMPs) for innovative vaccines; Conditional Marketing Authorization for urgent needs	Centralized system for all EU member states, conditional approvals with strict post-market obligations.
Japan	PMDA (Pharmaceuticals and Medical Devices Agency)	Biologics registration pathway with comprehensive safety data	Therapeutic vaccines are emerging and treated under biologicals with stringent clinical requirements	PMDA offers fast-track approvals for emergency vaccines like COVID-19.
China	NMPA (National Medical Products Administration)	Vaccines undergo registration via comprehensive trials and pre-approval inspections	Accelerated pathways in emergencies; strict regulatory oversight for therapeutic vaccines	Fast approvals for critical vaccines, with robust surveillance systems.
India	CDSCO (Central Drugs Standard Control Organization)	New Drug and Clinical Trial Rules; fast-track for public health needs	Therapeutic vaccines follow similar expedited pathways; require clinical trials and WHO guidelines adherence	Rapid expansion of vaccine development capacity; aligned with WHO guidelines for global standards.
Africa	AMA (African Medicines Agency)	WHO Prequalification and regional bodies like the East African Community (EAC)	AMA coordinates regulatory framework for vaccine approvals across the continent	Harmonization efforts to accelerate access to vaccines for diseases like malaria and Ebola.
Australia	TGA (Therapeutic Goods Administration)	Follows the "Biologicals" pathway with post-market surveillance	Similar process as for biologicals, focusing on new therapeutic modalities	Aligns with international standards and emphasizes risk management post-approval.

9. STRATEGIES FOR VACCINE DEVELOPMENT AND ACCESS

The strategies table outlines key actions to enhance vaccine development, pandemic preparedness, and equitable global distribution. By focusing on increasing government funding, fostering public-private partnerships, and building global health security frameworks, these strategies aim to ensure timely vaccine access, especially during public health emergencies like mpox.

Enhancing post-market surveillance and capacity building in vulnerable regions further strengthens preparedness for future pandemics. These recommendations are designed to drive global collaboration and ensure a more resilient and equitable vaccine landscape. This approach ensures that vaccine innovation, accessibility, and response mechanisms are globally aligned for better health outcomes [23,24,25, 26,27,28].

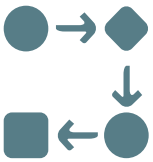
Area	Strategy	Rationale
Vaccine R&D Investment	Increase government funding in the development of both prophylactic and therapeutic vaccines. Focus should be on global health needs, targeting pandemic-prone diseases such as mpox, avian influenza, and Ebola.	Public funding is essential for mitigating risks in early-stage vaccine R&D. Government support, like the U.S. government's $1.9 billion investment in vaccine access and development, plays a critical role.
Pandemic Preparedness	Expand pandemic preparedness efforts by investing in vaccine stockpiles and scalable manufacturing capacities.	The WHO and Gavi, along with government funding, are working to build global vaccine stockpiles for diseases like mpox, ensuring rapid deployment in outbreaks.
Microarray Patches (MAPs) for Vaccine Delivery	MAPs offer a novel, needle-free approach for vaccine delivery, improving accessibility in low-resource settings. China has been investing in MAP technology for mass vaccine delivery, aiming to enhance its pandemic preparedness.	Investment in MAP technology is crucial to enhance vaccine delivery, particularly in regions with limited healthcare infrastructure. The technology may help drive large-scale and efficient vaccination campaigns globally.
Public-Private Partnerships	Expand public-private partnerships (PPP) to enhance funding for vaccine innovation. Collaborate with organizations like CEPI and WHO.	Partnerships between governments, CEPI, and the private sector enable larger-scale investments in vaccine research, manufacturing, and distribution.
Regional Manufacturing	Establish and scale regional vaccine manufacturing hubs with government incentives and financial support.	Government grants and incentives for local production facilities reduce dependency on foreign vaccine supplies, ensuring quicker response times.
Government Subsidies for Equity	Ensure equitable vaccine pricing through government subsidies, especially for low- and middle-income countries (LMICs).	Government funding for initiatives like COVAX helps secure lower prices and guarantees supply for LMICs. The U.S. has committed over $4 billion to COVAX to ensure equitable access.
Regulatory Harmonization	Increase international government collaboration to harmonize regulatory pathways and fast-track approvals.	Governments can work with multilateral organizations to align regulations across borders, which would accelerate vaccine availability during health emergencies.
Global Vaccine Distribution	Support government-led multilateral initiatives like Gavi's COVAX to ensure fair global distribution.	U.S. government funding for Gavi, exceeding $4 billion, ensures that vaccine doses reach countries in need, enhancing global pandemic preparedness.
Post-Market Monitoring	Enhance government-funded pharmacovigilance and post-market safety systems globally.	Governments should invest in monitoring programs to track vaccine safety and efficacy post-approval, protecting public health.
Capacity Building for Outbreaks	Direct government funding to capacity building in healthcare and research infrastructure, especially in LMICs.	Funding healthcare worker training and lab infrastructure ensures efficient vaccine deployment and public health system readiness.

10. FUTURE OUTLOOK

By 2024, the global vaccine market is expected to reach $74 billion, with continued expansion in the coming years. [29] The United States is anticipated to be the top contributor in terms of revenue. The increasing demand for vaccines is driven by public health campaigns promoting herd immunity and the need to address global health challenges.

The clinical trial landscape for vaccines is set for considerable growth, fueled by innovations in vaccine technology, the rising threat of global health crises, and a greater focus on strengthening public health systems.

Technological Innovations



mRNA Vaccines: The rapid success of mRNA vaccines during the COVID-19 pandemic has accelerated the development of this platform for other diseases. This technology offers fast production timelines, flexibility, and the potential to develop personalized vaccines.

Nanotechnology: Research is focusing on nanotechnology to enhance vaccine delivery, improve stability, and boost immunogenicity. Nanoparticles help present antigens more effectively to immune cells, potentially leading to stronger immune responses.

AI and Machine Learning: The integration of AI and machine learning into vaccine research is optimizing design, predicting immune responses, and speeding up clinical trial processes. These tools can help identify effective vaccine candidates more quickly, reducing both time and costs.

Emerging Global Health Threats

Pandemics and Epidemics: The COVID-19 pandemic highlighted the critical need for accelerated vaccine development to combat new infectious diseases. Future pandemics are expected to further prioritize investment and innovation in vaccine research and development.

Antimicrobial Resistance: With antibiotic resistance becoming a growing concern, efforts are underway to create vaccines targeting drug-resistant bacteria. These vaccines could play a crucial role in preventing infections that are increasingly difficult to treat with conventional antibiotics.

Non-communicable Diseases: Researchers are expanding the potential of vaccines to include non-communicable diseases like cancer and autoimmune disorders. This represents a breakthrough in preventative medicine, offering new possibilities for disease management.

Increased Emphasis on Public Health Preparedness

Global Health Security: Governments and international organizations are investing in building stronger public health systems and improving pandemic preparedness. This includes supporting vaccine research, development, and manufacturing capacity.

Vaccine Equity: Efforts are being made to ensure equitable access to vaccines, particularly in low- and middle-income countries. This includes initiatives to address vaccine hesitancy and improve vaccine supply chains.

Partnerships and Collaborations: Public-private partnerships and international collaborations are becoming increasingly important for vaccine development and deployment. These partnerships can accelerate innovation, share resources, and ensure global access to vaccines.

Challenges and Opportunities

Regulatory Complexities: The process of gaining regulatory approval for vaccines is often time-consuming and complicated. To speed up vaccine development and distribution, it is essential to simplify and streamline these regulatory pathways.

Manufacturing Constraints: Meeting the global demand for vaccines remains a significant challenge. To overcome this, substantial investment in manufacturing infrastructure is necessary to expand production capacity and ensure a reliable supply.

Vaccine Hesitancy: Overcoming vaccine hesitancy and addressing misinformation are critical for ensuring public confidence and widespread adoption of vaccines. Targeted public health initiatives and educational campaigns can help build trust and improve vaccine acceptance.

Looking ahead, the future of vaccine clinical trials appears promising. Innovations in technology, the emergence of new health challenges worldwide, and a heightened priority on public health preparedness are pushing vaccine development forward at an accelerated pace. By tackling current challenges and leveraging new opportunities, we can work towards a healthier and more resilient future globally [29,30,31,32].

APPENDIX

List of Marketed Vaccines

Brand Name	Indication	Molecule Type	Drug Descriptor
Comirnaty	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Spikevax	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Arexvy	Respiratory Syncytial Virus (RSV) Infections	Subunit Vaccine	Prophylactic Vaccine
COVID-19 Vaccine	Coronavirus Disease 2019 (COVID-19)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Jcovden	Coronavirus Disease 2019 (COVID-19)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Abrysvo	Respiratory Syncytial Virus (RSV) Infections	Subunit Vaccine	Prophylactic Vaccine
Vaxneuvance	Streptococcal Pneumonia	Conjugate Vaccine	Prophylactic Vaccine
Vaxneuvance	Otitis Media	Conjugate Vaccine	Prophylactic Vaccine
Covovax	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine
Nuvaxovid	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine
Qdenga	Dengue Fever	Live Attenuated Vaccine	Prophylactic Vaccine
Rabies Vaccine	Rabies	Inactivated Vaccine	Prophylactic Vaccine
Covishield	Coronavirus Disease 2019 (COVID-19)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Vaxzevria	Coronavirus Disease 2019 (COVID-19)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Gobik	Diphtheria; Haemophilus influenzae Type B Infections; Pertussis (Whooping Cough); Poliomyelitis; Tetanus	Inactivated Vaccine; Subunit Vaccine; Toxoid Vaccine	Prophylactic Vaccine
COVID-19 Vaccine	Coronavirus Disease 2019 (COVID-19)	Inactivated Vaccine	Prophylactic Vaccine
PreHevbrio	Hepatitis B	Subunit Vaccine	Prophylactic Vaccine
Sci-B-Vac	Hepatitis B	Subunit Vaccine	Prophylactic Vaccine
PreHevbri	Hepatitis B	Subunit Vaccine	Prophylactic Vaccine
Quintvac	Diphtheria; Haemophilus influenzae Type B Infections; Pertussis (Whooping Cough); Poliomyelitis; Tetanus	Inactivated Vaccine; Subunit Vaccine; Vaccine	Prophylactic Vaccine
DTP-Vaccine	Diphtheria; Pertussis (Whooping Cough); Tetanus	Inactivated Vaccine; Toxoid Vaccine	Prophylactic Vaccine
Pentavac PFS	Diphtheria; Haemophilus influenzae Type B Infections; Hepatitis B; Pertussis (Whooping Cough); Tetanus	Conjugate Vaccine	Prophylactic Vaccine
Quinserix	Diphtheria; Haemophilus influenzae Type B Infections; Pertussis (Whooping Cough); Tetanus	Conjugate Vaccine	Prophylactic Vaccine
Diphtheria Toxoid + Tetanus Toxoid	Diphtheria; Tetanus	Toxoid Vaccine	Prophylactic Vaccine
Mebella	Measles; Rubella (German Measles)	Live Attenuated Vaccine	Prophylactic Vaccine
Vaktrivir	Measles; Mumps; Rubella (German Measles)	Live Attenuated Vaccine	Prophylactic Vaccine
BCG-Vaccine	Non Muscle Invasive Bladder Cancer (NMIBC) (Superficial Bladder Cancer)	Live Attenuated Vaccine	Cancer Vaccine; Immuno-Oncology; Immunomodulatory Therapy; Therapeutic Vaccine
Ixchiq	Chikungunya Fever	Live Attenuated Vaccine	Prophylactic Vaccine
Shanchol	Cholera; Vibrio cholerae Infections	Inactivated Vaccine	Prophylactic Vaccine
Omicron KP.2-adapted monovalent COVID-19 vaccine	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Comirnaty KP.2	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
KoviVac	Coronavirus Disease 2019 (COVID-19)	Inactivated Vaccine	Prophylactic Vaccine
Spikevax KP.2	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based

Brand Name	Indication	Molecule Type	Drug Descriptor
Daichirona	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
CoronaVac	Coronavirus Disease 2019 (COVID-19)	Inactivated Vaccine	Prophylactic Vaccine
Kostaive	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	Prophylactic Vaccine; self-amplifying mRNA
Bimervax	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine
Gemcovac-19	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	Prophylactic Vaccine; self-amplifying mRNA
VidPrevtyn Beta	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine
COVID-19 Vaccine	Coronavirus Disease 2019 (COVID-19)	Inactivated Vaccine	Prophylactic Vaccine
Nuvaxovid XBB.1.5	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine
Covgoz	Coronavirus Disease 2019 (COVID-19)	Subunit Vaccine	Prophylactic Vaccine; Recombinant
Spikevax Omicron XBB.1.5	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Covaxin	Coronavirus Disease 2019 (COVID-19)	Inactivated Vaccine	Prophylactic Vaccine
Cyfendus	Anthrax	Subunit Vaccine	Prophylactic Vaccine
COVID-19 Bivalent Vaccine	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Spikevax Original/Omicron BA.4-5	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Spikevax Original/Omicron BA.4-5	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Spikevax	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
AD-M-toxoid	Diphtheria	Toxoid Vaccine	Prophylactic Vaccine
Equine Antidiphtheria Serum	Diphtheria	Toxoid Vaccine	Prophylactic Vaccine
Zabdeno	Ebolavirus Infections (Ebola Hemorrhagic Fever)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Mvabea	Ebolavirus Infections (Ebola Hemorrhagic Fever)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Ervebo	Ebolavirus Infections (Ebola Hemorrhagic Fever)	Live Attenuated Vaccine	Prophylactic Vaccine
Fluad Tetra	Influenza A Virus, H1N1 Subtype Infections; Influenza A Virus, H3N2 Subtype Infections; Influenzavirus B Infections	Inactivated Vaccine	Prophylactic Vaccine
Senwei	Herpes Zoster (Shingles)	Live Attenuated Vaccine	Prophylactic Vaccine
Cecolin	Cervical Intraepithelial Neoplasia (CIN)	Subunit Vaccine	Prophylactic Vaccine
Incellipan	Pandemic Influenza	Subunit Vaccine	Prophylactic Vaccine
Celldemic	Influenza A Virus, H5N1 Subtype Infections	Inactivated Vaccine	Prophylactic Vaccine
Panvax	Influenzavirus A Infections	Inactivated Vaccine	
QIV	Influenza A Virus, H1N1 Subtype Infections; Influenza A Virus, H3N2 Subtype Infections; Influenzavirus B Infections	Inactivated Vaccine	Prophylactic Vaccine
Flu-M Tetra	Seasonal Influenza	Inactivated Vaccine	Prophylactic Vaccine
AdimFlu-S (QIS)	Influenza A Virus, H1N1 Subtype Infections; Influenza A Virus, H3N2 Subtype Infections; Influenzavirus B Infections	Inactivated Vaccine	Prophylactic Vaccine
Ultriks	Influenza A Virus, H1N1 Subtype Infections; Influenza A Virus, H3N2 Subtype Infections; Influenzavirus B Infections	Inactivated Vaccine	Prophylactic Vaccine
Kostaive JN.1	Coronavirus Disease 2019 (COVID-19)	mRNA Vaccine	
Meas-Bio	Measles	Live Attenuated Vaccine	Prophylactic Vaccine
MenQuadfi	Neisseria meningitidis Infections	Conjugate Vaccine	Prophylactic Vaccine
Menphecia	Neisseria meningitidis Infections	Conjugate Vaccine	Prophylactic Vaccine
Penbraya	Neisseria meningitidis Infections	Conjugate Vaccine	Prophylactic Vaccine
Menhycia	Neisseria meningitidis Infections	Conjugate Vaccine	Prophylactic Vaccine

Brand Name	Indication	Molecule Type	Drug Descriptor
Monkeypox Vaccine	Monkeypox; Smallpox	Live Attenuated Vaccine	Prophylactic Vaccine
Mvabea + Zabdeno	Ebolavirus Infections (Ebola Hemorrhagic Fever)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Sepsivac	Bacterial Sepsis; Leprosy	Inactivated Vaccine	Immunomodulatory Therapy; Prophylactic Vaccine; Therapeutic Vaccine
Mycidac-C	Non-Small Cell Lung Cancer	Inactivated Vaccine	Immunomodulatory Therapy; Prophylactic Vaccine; Therapeutic Vaccine
Sepsivac	Non-Small Cell Lung Cancer	Inactivated Vaccine	Immunomodulatory Therapy; Prophylactic Vaccine; Therapeutic Vaccine
Pneumococcal Polysaccharide 13-valent Vaccine	Streptococcal Pneumonia	Conjugate Vaccine	Prophylactic Vaccine
Capvaxive	Streptococcal Pneumonia	Conjugate Vaccine	Prophylactic Vaccine
Prevnar 20	Streptococcal Pneumonia	Conjugate Vaccine	Prophylactic Vaccine
Sabin Inactivated Polio Vaccine	Poliomyelitis	Inactivated Vaccine	Prophylactic Vaccine
Picovax	Poliomyelitis	Inactivated Vaccine	Prophylactic Vaccine
Rabies Vaccine	Rabies	Inactivated Vaccine	Prophylactic Vaccine
Human Rabies Vaccine (Vero Cell)	Rabies	Inactivated Vaccine	Prophylactic Vaccine
Bivalent (Recombinant) Respiratory Syncytial Virus Vaccine	Respiratory Syncytial Virus (RSV) Infections	Recombinant Vector Vaccine; Subunit Vaccine	Prophylactic Vaccine; Recombinant
Mresvia	Respiratory Syncytial Virus (RSV) Infections	mRNA Vaccine	mRNA-Based; Prophylactic Vaccine
Rota Vaccine	Rotavirus Infections	Live Attenuated Vaccine	Prophylactic Vaccine
Sputnik V	Coronavirus Disease 2019 (COVID-19)	Recombinant Vector Vaccine	DNA-Based; Prophylactic Vaccine
Tetanus Toxoid	Tetanus	Toxoid Vaccine	Prophylactic Vaccine
Sentaibao	Tick Borne Encephalitis	Inactivated Vaccine	Prophylactic Vaccine
BCG M Vaccine	Tuberculosis	Vaccine	
Typhus Vaccine E Combined Live	Typhus Fever	Live Attenuated Vaccine	Prophylactic Vaccine
Barycela	Chicken Pox	Live Attenuated Vaccine	Prophylactic Vaccine
Provarix	Chicken Pox; Varicella Zoster (HHV-3) Infections	Live Attenuated Vaccine	Prophylactic Vaccine

Source: GlobalData: October 2024

Ongoing/Planned Phase III Oncology and Non-oncology - Therapeutic Vaccine Trials

Trial Identifier	Drug Name	Therapy Area	Indication	Status	Sponsor
NCT05593185	galinpepimut-S	Oncology	Myelodysplastic Syndrome	Ongoing	SELLAS Life Sciences Group Inc
GDC30019459	galinpepimut-S	Oncology	Acute Myelocytic Leukemia (AML, Acute Myeloblastic Leukemia)	Ongoing	SELLAS Life Sciences Group Inc
EudraCT-2018-003427-11	Beltavac	Respiratory	Asthma	Ongoing	Probelte Pharma SA
NCT04351685	VPM-1002	Infectious Disease	Tuberculosis	Ongoing	Serum Institute of India Pvt Ltd
CTRI/2022/10/046401	pneumococcal (15-valent) vaccine	Respiratory	Streptococcal Pneumonia	Ongoing	Tergene Biotech Ltd
NCT06538480	PRGN-2012	Infectious Disease	Recurrent Respiratory Papillomatosis (Juvenile Laryngeal Papilloma or Laryngeal Papilloma)	Ongoing	Precigen Inc
GDC30028764	(IO-102 + IO-103)	Oncology	Metastatic Melanoma	Ongoing	IO Biotech Inc
GDC30020451	Diamyd	Metabolic Disorders	Type 1 Diabetes (Juvenile Diabetes)	Ongoing	Diamyd Medical AB
GDC30032537	OSE-2101	Oncology	Non-Small Cell Lung Cancer	Ongoing	OSE Immunotherapeutics SA
NCT06077760	mRNA-4157; pembrolizumab	Oncology	Squamous Non-Small Cell Lung Cancer	Ongoing	Merck & Co Inc
CTR20201547	(bizalimogene ralaplasmid + mavilimogene ralaplasmid)	Women's Health	Cervical Intraepithelial Neoplasia (CIN)	Ongoing	Beijing Apollo Saturn Biomedical Technology Co Ltd
GDC30032976	mRNA-4157; pembrolizumab	Oncology	Melanoma	Ongoing	Merck & Co Inc
GDC20023687	GP-2	Oncology	Breast Cancer	Ongoing	Greenwich LifeSciences Inc
CTR20233873	tuberculosis vaccine 1	Oncology	Bladder Cancer	Ongoing	Chengdu Keen Biotechnology Co Ltd
GDC30002770	adagloxad simolenin	Oncology	Breast Cancer	Ongoing	OBI Pharma Inc
CTRI/2017/03/008266	VPM-1002	Infectious Disease	Pulmonary Tuberculosis	Ongoing	Serum Institute of India Pvt Ltd
NCT04741828	typhoid vaccine	Infectious Disease	Typhoid Fever	Ongoing	PT Bio Farma
GDC30027690	GRANITE-001	Oncology	Metastatic Colorectal Cancer	Ongoing	Gritstone Bio Inc
GDC50012443	BLSM-07	Women's Health	Cervical Intraepithelial Neoplasia (CIN)	Ongoing	MOA Life Plus Co Ltd
NCT01842360	MV-130	Respiratory	Chronic Obstructive Pulmonary Disease (COPD)	Ongoing	Inmunotek SL
GDC30034993	mRNA-4157; pembrolizumab	Oncology	Cutaneous Squamous Cell Carcinoma (cSCC)	Ongoing	Moderna Inc
GDC50011276 GDCT0445950	tertomotide	Central Nervous System	Alzheimer's Disease	Planned	Samsung Pharm Co Ltd
GDC30035381 GDCT0517763	GRANITE-001	Oncology	Colorectal Cancer	Planned	Gritstone Bio Inc

Source: GlobalData, 2024

Non-oncology indications of Phase I Ongoing/Planned Therapeutic Vaccine Trials

Trial Identifier	Drug Name	Therapy Area	Indication	Trial Status	Sponsor
ACTRN12623000841673; CLB-3000-1-001; GDCT0494415	CLB-3000	Infectious Disease	Hepatitis B	Ongoing	ClearB Therapeutics Inc
GDC30032152; NCT05770895; GS-US-642-5670; GDCT0476065	GS-6779	Infectious Disease	Hepatitis B	Ongoing	Gilead Sciences Inc
GDC30030052; NCT06430905; H-500-001; GDCT0449306	HB-500	Infectious Disease	Human Immunodeficiency Virus (HIV) Infections (AIDS)	Ongoing	Hookipa Pharma Inc
GDC30032520; 202300629; LEM-mR203-101; NCT06032000; GDCT0480124	LEM-mR203	Infectious Disease	Coronavirus Disease 2019 (COVID-19)	Ongoing	Lemonex Inc
GDC30028205; NCT06070051; 21-0200-101; GDCT0426365	elebsiran; tobevibart; VRON-0200	Infectious Disease	Hepatitis B	Ongoing	Virion Therapeutics LLC
GDC30031161; NCT05762276; VXX-401-101; GDCT0462822	VXX-401	Metabolic Disorders	Hypercholesterolemia	Ongoing	Vaxxinity Inc
GDC30011599; NCT05328115; ALZ-C-001; 2019-002277-62; GDCT0270141	ALZ-101	Central Nervous System	Alzheimer's Disease	Ongoing	Alzinova AB
GDC30011599; NCT05328115; ALZ-C-001; 2019-002277-62; GDCT0270141	ALZ-101	Central Nervous System	Mild Cognitive Impairment	Ongoing	Alzinova AB
GDC30011599; NCT05328115; ALZ-C-001; 2019-002277-62; GDCT0270141	ALZ-101	Central Nervous System	Dementia	Ongoing	Alzinova AB
GDC30035634; GDCT0521045	PPV-06	Immunology	Inflammation	Ongoing	Peptinov SAS
GDC30034093; GDCT0501138	Triplex	Infectious Disease	Human Immunodeficiency Virus (HIV) Infections (AIDS)	Planned	Helocyte Biosciences Inc
GDC30034729; GLU001; NCT06310291; GDCT0510093; AVALON	VTP-1000	Gastrointestinal	Celiac Disease	Ongoing	Barinthus Biotherapeutics Plc

Source: GlobalData: October 2024

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