# GLOBAL THERAPEUTIC VACCINES MARKET, 2022-2035

*Dissertation submitted in partial fulfillment of the requirement for the degree of*

**Master of Science in Biotechnology**


By

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UNDER THE SUPERVISION OF

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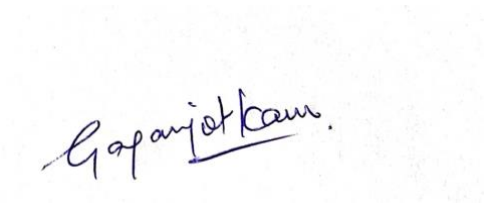
# CERTIFICATE

This is done to ensure that the work described in the M. Sc. Thesis titled '***Global Therapeutic Vaccines Market, 2022-2035'*** submitted by **Rupanshi Sharma** in partial fulfillment for the award of degree of M.Sc. Biotechnology from **Jaypee University of Information & Technology** has been carried out under my supervision. This report was not submitted to any other University or Institute in full or in part for the award of any other degree, certificate or other titles.



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# DECLARATION

I hence state that the work reported in the M. Sc Thesis entitled "**Global Therpeutics Vaccine Market, 2022-2035**" submitted at **Jaypee University of Information Technology, Waknaghat, Solan, Himachal Pradesh, India,** is a true record of my work completed under the guidance and direction of **Mr. Gaurav Chaudhary and Ms. Gaganjot Kaur.** Additionally, my 2nd semester research project work was carried out under the guidance of **Dr. Hemant Sood** at **Jaypee University of Information Technology, Waknaghat.** This work has not been submitted for any other degree or credential. The contents of my M. Sc Thesis are entirely my responsibility.

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# 1

# COMPANY PROFILE

Roots Analysis Pvt, Ltd. deals with market research and consulting, and was founded in 2013, and specializes in offering extensive business analysis as well as pharma industry consultancy services. The company focuses on providing an informed and impartial view of the industry's greatest issues, and other important elements. The study conducts a thorough investigation, seeking to cover all of the aspects mentioned in figure 1.1


**Figure 1.1 Primary Parameters for In-depth Analysis**

The firm also provides customized research and consulting services, all with the goal of providing the best possible service to clients. The major focus areas of the company are as follows:

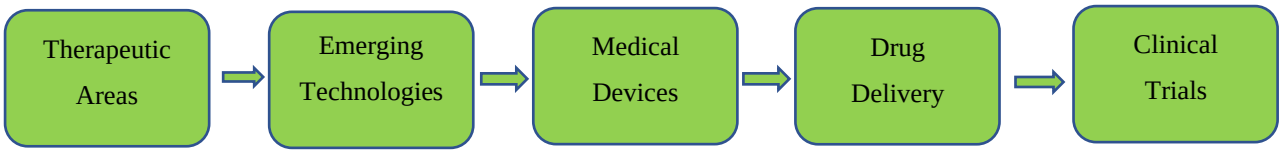



**Figure 1.2 Major Focus Areas for Reports**

# 2

# PROJECT APPROACH

The report *Global Therapeutic Vaccines Market, 2022-2035* has been synthesized using various secondary resources. Table 2.1 presents these in detail.

## Table 2.1 Report Sources and Market Insights

**Information Sources**

**Secondary Research**

| | | |
|---|---|---|
| Investor Presentations | Annual Reports | Press Releases |
| SEC Filings | Industry Databases | Other Analysts' Opinion Reports |

**Primary Research**

Interviews conducted with senior representatives of industry stakeholders

**Market Insights**

| | | | |
|---|---|---|---|
| Industry Landscape | Key Growth Drivers | Challenges | Future Trends / Scenarios |

**Data Triangulation**

| | | |
|---|---|---|
| In-house Experts | Industry Stakeholders (via Primary Research) | Client Feedback (on-going pre / post project release) |

# 3

# PREFACE

## 2.1. SCOPE OF THE REPORT

Unlike the prophylactic vaccines that are designed and administered as a precautionary measure to prevent the occurrence of a disease, researchers have developed therapeutic vaccines intended to alleviate the suffering of the patient already infected with disease.[1] Therapeutic vaccines that help the immune system in recognizing a foreign agent are primarily developed for viral infections. Individuals who are affected with chronic infections but cannot produce enough efficient antibodies can be administered with such vaccines. Currently, there are six therapeutic vaccines on the market, with more than 400 compounds in development for various illnesses. Imlygic®, Provenge®, and Tice® are three vaccinations that have lately been licenced for the treatment of melanoma, prostate cancer, and bladder cancer. The approval of these vaccines led to a major breakthrough, which has not only provided a new treatment modality for chronic disease management but also paved the way for rationally designing and optimizing future vaccines with improved efficacy.

Given the progressive increase in the global population and the burden of chronic disease indications, the application of therapeutic vaccines to these diseases is anticipated to increase significantly. These vaccines offer an attractive alternative owing to their potential safety, specificity, and long-lasting response. Presently, several drug developers are investigating therapeutic vaccines in areas of high unmet need, such as cancer and infectious diseases with the hope to achieve considerable success in the domain, however, these have not resulted to be as efficacious as the preventive vaccines. Significant progress has been achieved in enhancing the

general stability of these medicinal formulations in this aspect It is worth highlighting that, For the production of more diverse vaccine formulations, a number of adjuvants (substances having the natural ability to enhance an immune response) have been discovered. It is important to mention that despite being a relatively new domain, several pharmaceutical companies have selectively increased their investments in the space owing to the size of the development portfolio and the nature of the clinical benefits of these therapies.

The report "**Global Therapeutic Vaccines Market, 2022–2035**" provides an in-depth study of the existing market scenario, as well as an informed assessment of its anticipated evolution and future opportunities associated with the therapeutic vaccines market. The study underlines an in-depth analysis, highlighting the crucial determinants and the market dynamics in this rapidly changing sector of the pharmaceutical business. The report consists of the following:

- The current market landscape related to therapeutic vaccines, based on several relevant parameters, such as phase of development (*clinical and preclinical*) of lead candidates, type of vaccine (*antigen vaccine, dendritic vaccine, DNA vaccine and peptide vaccine*), type of vaccine by method of composition (*autologous vaccine and allogeneic vaccine*), type of therapy (*monotherapy and combination therapy*), target disease indication and route of administration (*intramuscular, intranasal, oral, intradermal, subcutaneous, intravenous and others*) and dosage frequency. Further, the chapter presents a list of players developing next generation complement therapeutics along with information on their year of establishment, company size and location of headquarters.
- Elaborate profiles of key players engaged in the establishment of therapeutic vaccines, based across North America, Europe and Asia Pacific. Each profile features a brief overview of the company, its financial information (*if available*), details on its clinical-stage vaccine candidates, recent developments and an informed future outlook.
- A comprehensive examination of finished, current, and upcoming clinical trials of therapeutic vaccines, based on important parameters, such as trial registration year, phase of development, trial recruitment status, study design, trial focus area, target disease indication(s), type of sponsor / collaborator, leading industry sponsors / collaborators (in terms of number of trials conducted), number of patients enrolled and and regional distribution.

- An in-depth analysis of grants that have been awarded to various research institutes for research related to therapeutic vaccines, during the period, 2016-2022, on the basis of different parameters, such as year of grant award, amount awarded, administering institute center, support period, type of grant application, purpose of grant award, activity code, focus area, study section involved, type of recipient organization and focus area. In addition, it
  It focuses on the geographic distribution of beneficiary organisations, well-known NIH departments, well-known programme officers, and well-known recipient organizations.
- One of the report's main goals was to assess the current market size and future growth potential of the therapeutic vaccines industry in the medium to long term.

## 2.2. QUESTIONS ADDRESSED

- The major competitors in the field of therapeutic vaccine development?
- The most important therapeutic areas where therapeutic vaccines are being explored or have been created?
- What are the current competitive landscape trends of therapeutic vaccines?
- What are the most active geographies for performing therapeutic vaccination clinical trials?
- What are the most well-known financing groups for therapeutic vaccines?
- What types of collaboration models do industry and non-industry stakeholders use most frequently?
- What have been the various steps taken by start-up players in the development of new therapeutic vaccines in recent times?
- What is the expected distribution of existing and future market potential across key industry sectors?

## 2.3. CHAPTER OUTLINES

**Chapter 2** gives a general summary of the company Roots Analysis and the various parameters that are considered for the in-depth analysis that is conducted on wide range of pharmaceuticals.

**Chapter 3** gives a brief introduction about the search reports and market insights that forms the backbone of the company. It consists of the information sources, market insights and data triangulations.

**Chapter 4** provides a general introduction to therapeutic vaccines, including information on their types, characterized by the method of composition and mechanism of action. Additionally, the chapter provides information on the various disease indications for which therapeutic vaccines are being investigated / developed. Further, the chapter has summarized the development and approval processes for vaccines and their future perspectives.

**Chapter 5** It features a comprehensive analysis of the pipeline molecules based on several relevant parameters, such as, phase of development (*clinical and preclinical*), type of vaccine (*antigen vaccine, dendritic vaccine, DNA vaccine, peptide vaccine*), type of vaccine by composition method (*autologous vaccine, allogeneic vaccine*), kind of therapy (*monotherapy and in combination*), dosage (*weekly, biweekly, monthly, bimonthly, triweekly*), target disease indication, route of administration and dosage frequency.

**Chapter 6** includes detailed profiles of key players and profile features a brief overview of the company, its financial information (*if available*), details on its clinical-stage vaccines candidates, recent trends and an informed future outlook, based in North America, Europe and Asia- Pacific.

**Chapter 7** summarizes the overall report, which provides information on current market trends and how the therapeutic vaccines industry is anticipated to evolve.

# INTRODUCTION

## 4.1 CHAPTER OVERVIEW

Initially developed as preventive formulations designed to augment the body's immunity against a particular pathogen, vaccines have garnered significant interest as a potential treatment option for several disease indications over the time. These are known as therapeutic vaccines and can be administered to alleviate the suffering of patients those already with disease.[2] It is worth mentioning that the first therapeutic vaccine was approved in 1990 and currently, XX therapeutic vaccines are commercially available for the purpose of treatment of melanoma, prostate cancer and bladder cancer. In addition, over XX vaccines are under development for various oncological, infectious, hepatological, neurological and autoimmune disorders.[3] Further, researchers are actively engaged in the development of therapeutic vaccines against some challenging and spurring conditions, such as cancer, HIV, hepatitis B and human papillomavirus.[4] In fact, a number of product development program focused on therapeutic vaccines have been initiated and, presently, many have progressed into late-stage trials.

Given the rate at which chronic diseases are growing among the population, The need for therapeutic vaccinations is expected to skyrocket in the coming years. Significant progress has been achieved in improving existing vaccine formulations, with the main focus being on stability enhancement. In the realm of biotechnology, the current technology trends have signalled the start of a new age in vaccine immunogen design. This has paved the way for rationally designing and optimizing future vaccines with improved efficacy.

This chapter presents a general introduction to therapeutic vaccines and numerous vaccine administration routes have been discussed in detail. It also includes a snapshot of the various classifications of therapeutic vaccines based on the method of composition and mechanism of action.

## 4.2 THERAPEUTIC VACCINES

A vaccine is a pharmaceutical formulation developed using either the microorganism(s) (weakened / inactivated) responsible for causing a disease(s) or representative antigenic components of pathogen(s) (structural proteins, inactivated toxins). These are intended to provide a lasting immune response against the disease(s).[5] There are broadly two types of vaccines, namely preventive (or prophylactic) vaccines and therapeutic vaccines. A preventive vaccine is designed to build immunity in a patient who is free of (the targeted) infection, whereas a therapeutic vaccine is designed to treat patients who are already suffering from the disease.[6] Figure 4.1 represents the major differences between preventive vaccine and therapeutic vaccine.

Figure 4.1 **Difference Between Preventive Vaccine and Therapeutic Vaccine**

| Parameters | Preventive Vaccine | Therapeutic Vaccine |
|---|---|---|
| Administration | Administered to a healthy individual before the onset of disease indication | Administered to an unhealthy individual after the occurrence of disease indication |
| Evaluation | Vaccine emphasizes on prevention and safety | Vaccine emphasizes on treatment |
| Clinical Outcome | Decrease microbial infection or transmission | Cures or delays the progression of disease |
| Regimen | Low dose regimen is followed | High dose regimen is followed |
| Dosage frequency | Episodic treatment is followed | Continual dose is essential usually like a drug |
| Public Expectation | Vaccine is sensitive to potential risks | Less concerns regarding the potential risks |
| Examples | MCV2 vaccine, AV7907 (NuThrax) | Provenge, Canvaxin |

Source: https://www.researchgate.net/figure/Design-of-a-peptide-based-vaccine-for-preventive-or-therapeutic-use_tbl2_262055695

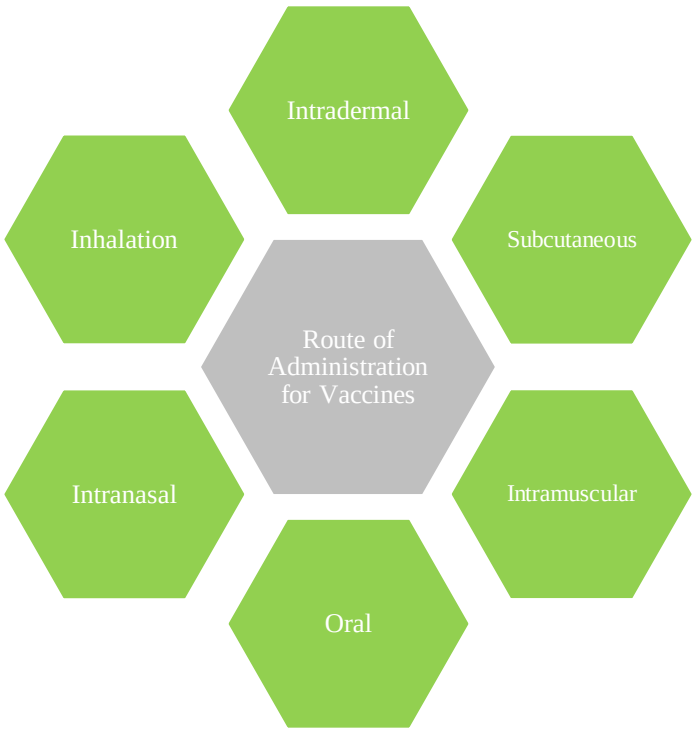
As indicated above, instead of immunizing the body against future diseases and infections, a therapeutic vaccination combats a present infection in the body. It is important to mention that in

some disease conditions, such as cancer and HIV, the immune system fails to elicit an adequate response. Additionally, a few infections and malignancies can be caused due to the failure of immune system's inability to recognize the invading cells. As a result, it overwhelms the immune response and prevent it to function effectively.

The therapeutic vaccines force the immune system to identify the virus and cancerous cells and combat against them. Moreover, the novel therapeutic vaccine stimulates the immune system to target the infected cells to retrain them from spreading in other parts of the body. Henceforth, majority of the ongoing research is focused on developing therapeutic vaccines for cancer, yet other researchers are making an attempt to develop them for HIV, human papillomavirus and other potentially fatal diseases.[7]

In terms of their route of administration, vaccines can be administered through various routes, including oral, nasal, intramuscular, subcutaneous, and intradermal. It is worth highlighting that majority of the commercially available vaccines are delivered via intramuscular and subcutaneous routes, using the conventional injection system comprised of a syringe and needle.[8] Figure 4.2 depicts the numerous vaccine administration routes employed in the pharmaceutical industry.

Figure 4.2 **Vaccine Delivery Methods**




Source: Roots Analysis

### 4.2.1 CLASSIFICATION OF VACCINE BY METHOD OF COMPOSITION

Based on the method of composition, therapeutic vaccines may be broadly classified as:

- Autologous Vaccine
- Allogeneic Vaccine

#### 4.2.1.1 AUTOLOGOUS VACCINE

This is a personalized therapeutic intervention which is created by using the person's own body cells (such as immune cells or tumor cells). The cells are isolated from patient's infected organ or tumor and then a formulation of vaccine is processed processed *in vitro*. Notably, A number of phase II and phase III trials of autologous cancer cell vaccines are currently underway or have just concluded; one such example includes *Vaccine 1*, a FDA approved autologous vaccine for the treatment of prostate cancer. However, it is important to highlight that the production of these vaccines is a complicated and highly time-consuming process, as a result they are not preferred for advanced stage illness.[9]

#### 4.2.1.2 ALLOGENEIC VACCINE

This form of vaccine is developed by using the cells of one patient, engineering them in the laboratories and then administering to another patient to stimulate an immune response. It is important to note that allogeneic vaccine eliminates all the drawbacks pertaining to the autologous vaccine. Unlike the autologous vaccines, these vaccines are relatively less complicated and cheaper to produce. These predominantly find their application in the treatment of cancer such as pancreatic cancer, leukemia, and non-small cell lung cancer.[10] Notably, several allogeneic vaccines are being evaluated in early stages of development, such as Canvaxin, which is in the process of being developed for the treatment of invasive bladder cancer.[11] However, it is worth highlighting that the lack of required antigens which are necessary for the treatment of the disease in this type of vaccine, limits its manufacturing and standardization.

### 4.3 CLASSIFICATION OF VACCINE BY MECHANISM OF ACTION

Based on the mechanism of action, therapeutic vaccines may be broadly categorized as:

- Antigen Vaccine
- Dendritic Vaccine
- DNA Vaccine
- Peptide Vaccine

#### 4.3.1 ANTIGEN VACCINE

These vaccines employ antigens, which are the entities that induce a distinct antibody response and are used in the development of antigen vaccine. The antigens can be in various forms such as weakened (live attenuated) pathogen, inactivated pathogen, a chemical produced by the pathogen or even a subunit of the pathogen.[12] When these antigens are ingested, they trigger the immune system to generate antibodies to fight the disease.

#### 4.3.2 DENDRITIC VACCINE

Dendritic vaccine involves dendritic cells (a WBC type), which are a part of innate immune system. These are the top-notch cells which attack the pathogen prior to the action of immune

system. Dendritic cells are extracted from a person's body, loaded with dead tumor or virus cells and further, reinjected into the person. Furthermore, dendritic cells that are being trained to recognise invading cells may cause the immune system to respond by attacking them.[13] It is worth mentioning that the dendritic cells can act as memory cells and recognize the tumors or viral infections and attack aggressively in future.[14]

### 4.3.3 DNA VACCINE

This is a distinct approach of developing therapeutic vaccine using genes (nucleic acids) encoding the antigenic component of the disease-causing microorganism. The genes are introduced into the body of a host in such a manner that they are taken up and incorporated within the cell's genome. The transformed cell then manufactures the antigen molecules. These antigens are displayed on the cell's surface (via the major histocompatibility complex), which stimulates a cell mediated immune response. DNA vaccines are relatively less complicated and cheaper to develop.[15] Owing to the advantages offered by these vaccines, DNA vaccines are being tested for therapy of diseases such as breast cancer, prostate cancer, and melanoma in a number of studies and human trials.

### 4.3.4 PEPTIDE VACCINE

As mentioned earlier, therapeutic vaccines are either made from immune cells or tumor cells. However, certain vaccines can also be produced from proteins or their subunits, called peptides. These proteins or peptides can either be administered as standalone or can be offered in integrated with either virus or with immune-stimulating molecules.

## 4.4 APPLICATIONS OF THERAPEUTIC VACCINES

Although not many therapeutic vaccines have been approved by the US FDA, yet this domain is flourishing rapidly with promising results. Additionally, this novel vaccine technology has the ability to treat all sorts of serious ailments, including, cancer, HIV, HPV and herpes.

### 4.4.1 CANCER

Most considerable and significant advancements in therapeutic vaccine research have been made in the treatment of cancer. To begin with, vaccines do not target the tumor cells or their microenvironment directly, rather, they activate the immune system to fight the tumour.[16] On the surface of cancer cells, cancer-specific antigens are frequently present that are absent in healthy cells. Therapeutic vaccines work by stimulating the immune system to recognize and eliminate cancer cells that contain these antigens. Therapeutic vaccines act with the agenda of inducing tumor regression, eradicating minimal residual disease, establishing lasting antitumor memory and avoiding non-specific or adverse reactions.[17] Table 4.1 lists the approved therapeutic vaccines for cancer treatment.

Table 4.1 **Vaccines for Cancer Treatment**

| S. No. | Vaccine | Indication | Phase of Development |
|---|---|---|---|
| 1 | A | Bladder Cancer | Marketed |
| 2 | B | Prostate Cancer | Marketed |
| 3 | C | Skin Cancer | Marketed |

Source: https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276

### 4.4.2 HIV

Significant research activities are taking place in the domain of therapeutic vaccines targeting HIV treatment. Majority of these studies are focused on a subset of people called, long-term non progressors, who despite being infected with HIV, are able to withstand its progression.[18] It is important to mention that scientists and researchers anticipate replicating this effect with therapeutic vaccines, establishing an effective cure for the patients with infection but without any symptoms or progression. One such approach is to inject dendritic cells combined with AIDS virus into the patient's body, provoking an effective immune response. As a result, in 2004, it was observed that amongst the 18 people injected with vaccine, the virus concentration descended by 80%.[19] Table 4.2 lists vaccines for HIV treatment which are under investigation.

Table 4.2 **Vaccines for HIV Treatment**

| S. No. | Vaccine | Indication | Phase of Development |
|---|---|---|---|
| 1 | Vaccine 1 | HIV Infection | Phase I |
| 2 | Vaccine 2 | HIV Infection | Phase II |

| S. No. | Vaccine | Indication | Phase of Development |
|---|---|---|---|
| 3 | Vaccine 3 | HIV Infection | Phase I / II |

Source: Roots Analysis

### 4.4.3 HPV

Human papillomavirus is capable of clearing out of the body itself, however, in some cases it may persist and lead to some threatening ailments such as cervical cancer and anal cancer.[20] Therefore, researchers are working towards destroying the virus after the infection has occurred. Notably, there are a few vaccinations to protect from HPV infection, there are none to cure it after it has happened. Table 4.3 lists some vaccines which are under investigation for HPV.[21]

Table 4.3 **Vaccines for HPV Treatment**

| S. No. | Vaccine | Indication | Phase of Development |
|---|---|---|---|
| 1 | D | Tumors caused by HPV 16 | Phase I |
| 2 | E | Cancer | Phase II |
| 3 | F | Pre-malignant tumor | Phase I / II |

Source: https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276

### 4.4.4 HERPES

Herpes Simplex Virus (HSV) is another domain wherein the application of therapeutic vaccines is being evaluated. These vaccines are considered to lower the rising concentration of virus in tissues and body fluids. This process of increased level of virus in the body, called virus shedding, can augment during acute herpes outbreak and moreover, multiply its transmission. It is worth mentioning that several vaccines, namely, HSV529, Delta gD-2 and GSK4108771A, have known to depict some promising results in reducing the HSV shedding and lesions in an early stage of research.[22] Table 4.4 lists therapeutic vaccines for Herpes Simplex Virus that are under development

Table 4.4 **Vaccines for Herpes Treatment**

| S. No. | Vaccine | Indication | Status of Development |
|---|---|---|---|
| 1 | G | Herpes Simplex Virus 2 | Phase I |
| 2 | H | HSV-1 / HSV-2 | Phase I |
| 3 | I | Herpes Simplex Virus | Phase I |

Source: https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276

## 4.5 CLINICAL DEVELOPMENT AND APPROVAL OF VACCINES

Each novel vaccine candidate undergoes an elaborate development process and testing, across multiple phases, which evaluate the safety, immunogenicity, and protective efficacy in humans, before it is licensed for use. Clinical trials for vaccines in humans are conducted in four phases of development, for several years. Phase I and phase II trials are usually small-scale trials that involve around 10-100 and 100-1,000 healthy individuals, respectively.[23] These studies are conducted to assess the safety and the appropriate dose of the vaccine candidate for clinical use. Overall, these trials are conducted to determine whether the vaccine is safe for human use and whether it evokes the desired immune response. Phase II trials are conducted at a slightly larger scale than phase I and are aimed to assess the effectiveness of the vaccine in artificially induced and / or clinical disease.[24, 25] Phase III trials are carried out in large groups ranging from 1,000 to 10,000 healthy individuals, across multiple sites, to evaluate a heterogeneous population. These studies are intended to validate the efficacy of the vaccine under natural disease conditions. Additional information regarding the safety of the product and its associated side effects are also gathered to evaluate the overall risk-benefit profile of the candidate vaccine. Typically, these studies take three to five years to complete. The parameters assessed in phase III trials are intended to provide an adequate basis for marketing approval.[26, 27] Finally, phase IV is a post-marketing surveillance study, which is carried out after the product has been launched. This stage is aimed to assess long term efficiency and to detect rare adverse effects associated with the product.[28]

Vaccine development is subject to strict licensing requirements; developers are required to meet the regulatory standards of various regulatory bodies across the globe. In the US, the FDA conducts thorough reviews of the manufacturing process and the manufacturing sites for the production of vaccines. The FDA audits demand that the developers need to standardize and document each step of the manufacturing process and demonstrate a *state of control* for the process. This means that each step should have proper written instructions and must be recorded with close attention to detail. In case of an error, the FDA does not specify the correctness of each and every step, however, ensures that the process is safe and completely documented.[29]

During pandemics, when an urgent need for vaccines arises, vaccine developers do not have enough time to complete all phases of clinical testing. In order to address the urgent need during such circumstances, the regulatory bodies, across different regions of the world, have developed specialized protocols for expediting the review of pandemic vaccines, as done by Health Sciences Authority, Singapore.

## 4.6 CONCLUDING REMARKS

Diseases like cancer, HIV and many more are a prevalent concern across the globe, and therapeutic vaccines could be an effective strategy to treat these ailments. In the past decades, significant advancements have been made in this technology, resulting in the increasing interest among various researchers. Additionally, the outbreak of Covid-19 compelled the scientific experts to find solution to various unresolved questions. Hence, potential therapeutic strategies and vaccinations started gaining importance. It is worth mentioning that inactivated vaccines, nucleic acid-based vaccines, and vector-based vaccinations have all entered phase III studies, over the past few years.[30] Driven by encouraging clinical trial results, increasing adoption of therapeutic vaccines for treating various clinical conditions and investment in R&D. The therapeutic vaccines market is expected to expand significantly in the near future.

# 5

# MARKET LANDSCAPE

## 5.1 CHAPTER OVERVIEW

The chapter presents the current landscape of the market of therapeutic vaccines that have either been marketed or are being developed for the treatment of different disease indications. It also includes a thorough analysis of the vaccines built on a set of pertinent parameters, such as phase of development (*phase I, phase II, Phase III, BLA Filing and Marketed),* vaccine type (*antigen vaccine, DNA vaccine, peptide vaccine and dendritic vaccine*), Vaccine preparation method (*autologous and* allogeneic), therapy type (*monotherapy and in combination*), target disease indication, route of administration (*subcutaneous, intradermal, intramuscular, intratumoral, intravenous, oral, intranodal, intra-articular and* others) and dosage.

## 5.2 THERAPEUTIC VACCINES: LIST OF VACCINES

During our research, we were able to identify XX marketed drugs and XXX clinical stage drugs and 42 early drug development programs for the treatment of various oncological and non-oncological inidcations. Table 5.1 contains information about these therapeutic vaccines, including the type of vaccine, the developer, the status of development, the target disease indication, the therapeutic area, the method of vaccine composition, the type of therapy, the route of administration, and the dosage frequency. Kindly note that data presented in the table is based on detailed secondary research conducted on a *best-effort* basis.

Table 5.1 **Therapeutic Vaccines: List of Vaccines**[31, 32]

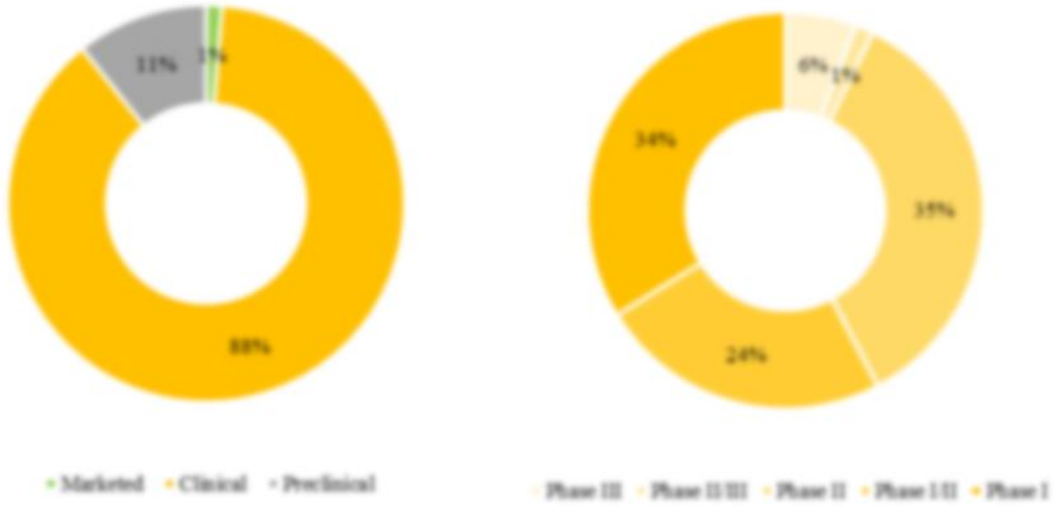
| S. No. | Therapeutic Vaccine Name | Developer | PoD | TDI | Therapeutic Area | Type of Vaccine | Type of Vaccine Composition | Type of Therapy | RoA | Dosage |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| 1 | Provenge | Dendreon Pharma-ceuticals | Marketed (US:2010) | Prostate Cancer | Oncological Disorders | Dendritic | Autologous | NA | Intravenous | Biweekly |
| 2 | Provenge | Dendreon Pharm-aceuticals | Marketed (US:2010) | Prostate Cancer | Oncological Disorders | Dendritic | Autologous | Combination | Intravenous | Biweekly |
| 3 | Copaxone | Teva Pharm-aceuticals | Marketed (US:2014) | Multiple Sclerosis | Autoimmune Disorders | Peptide | Allogeneic | Monotherapy | NA | Thrice weekly |
| 4 | RIAVAX | Kael-GemVax | Marketed (Korea:2015) | Pancreatic Cancer | Oncological Disorders | Peptide | NA | Monotherapy | NA | NA |
| 5 | Imylgic | Amgen | Marketed (US:2015, Europe:2015) | Melanoma | Oncological Disorders | NA | Allogeneic | NA | Subcutaneous / Cutaneous / Nodal Lesions | Multiple |

Abbreviations: PoD: Phase of Development, TDI: Target Disease Indication, RoA: Route of Administration,

### 5.2.1 STATUS OF DEVELOPMENT ANALYSIS

Figure 5.1 depicts the distribution of therapeutic vaccines based on their current development status.

Fig. 5.1 **Therapeutic Vaccines: Distribution based on developmental stage**




It is worth highlighting that XX molecules, namely Copaxone (Teva Pharmaceuticals), Provenge (Dendreon Phgarmaceuticals) and RIAVAX (Kael-GemVax) have been commercialized till date; this constitutes only X% of the total number of therapies, which suggests that the therapeutic vaccines market is set to expand rapidly in the coming years. Further, around XX% molecules are in clinical stages of development; of these close to 150 molecules are in advanced phases (*phase*

*II and above*). For instance, Neuronata-R (developed by Corestem), which is being evaluated in phase III clinical trials for the treatment of Amyotrophic Lateral Sclerosis. Similarly, Hepcortespenlisimut-L (developed by Immunitor) is being investigated for Hepatocellular Carcinoma. The relatively high number of candidates in preclinical and early clinical stages demonstrate the growing interest of several stakeholders in this field.

As can be observed in the figure, most of the therapeutic vaccines (XX%) have already been developed and marketed, followed by those that have been developed, although not yet commercialized (XX%).

### 5.2.2 TYPE OF THERAPY ANALYSIS

Figure 5.2 depicts the type of therapy distribution.

Fig. 5.2 **Therapeutic Vaccine: Therapy Type Distribution**

As can be observed from the figure, maximum number of (XX%) therapeutic vaccine candidates are predominantly being evaluated as monotherapies. In addition, XX% of the Furthermore, XX% of therapies are being tested in combination with other therapeutic agents, such as antibodies. Examples of molecules being evaluated as combination therapy (*in alphabetical order*) include

ABX196 (developed by Abivax), BNT-113 (developed by BioNTech) and BRII-835 (developed by Brii Biosciences).

## 5.3 THERAPEUTIC VACCINES: LIST OF DEVELOPERS

| S. No | Company Name | YoE | Headquarters | Company Size |
|---|---|---|---|---|
| 1 | ABC | 2013 | France | Small |
| 2 | DEF | 2003 | Switzerland | Mid-sized |
| 3 | GHI | 2019 | US | Mid-sized |
| 4 | JKL | 2003 | Austria | Small |
| 5 | MNO | 1997 | US | Mid-sized |

Abbreviations: YoE: Year of Establishment

# 6

# COMPANY PROFILES

## 6.1 CHAPTER OVERVIEW

Several companies have undertaken initiatives to develop therapeutic vaccines, either as a monotherapy or in combination with existing immunotherapies / drug classes for prostate cancer, hepatocellular carcinoma, HIV infection, hepatitis, melanoma, lung cancer, head and neck cancer and many more. This chapter includes detailed profiles of the companies that have XX therapeutic vaccines (either marketed or under clinical evaluation) in their product portfolio. Every profile includes a company snapshot , its monetary details (*if available*), its product portfolio information, current trends and future perspectives.

Table 6.1 presents the list of companies (*in alphabetical order*) that have been profiled in this chapter.

Table 6.1 **Global Therapeutic Vaccines: List of Companies Profiled**

| S. No. | Company Name | Year of Establishment | Headquarters |
|---|---|---|---|
| 1 | AgelessRx | 2019 | Michigan, US |
| 2 | XY | Sample Data Text | Text Sample |
| 3 | XZ | Sample Data Text | Text Sample |
| 4 | AB | Sample Data Text | Text Sample |
| 5 | BC | Sample Data Text | Text Sample |
| 6 | CD | Sample Data Text | Text Sample |
| 7 | EF | Sample Data Text | Text Sample |
| 8 | GH | Sample Data Text | Text Sample |
| 9 | HI | Sample Data Text | Text Sample |
| 10 | Rejuvenate Bio | 2017 | California, US |

## 6.2. COMPANY A

### 6.2.1. COMPANY OVERVIEW

Company A is a pharmaceutical company, which specializes in manufacturing and commercialization of novel pharmaceuticals intended for the treatment of indications across several therapeutic areas, involving, immunology, nephrology and urology, etc. The company has a global presence and operates through its subsidiaries based in the US, Europe and certain Asian countries. Table 6.2 gives a snapshot of the company.

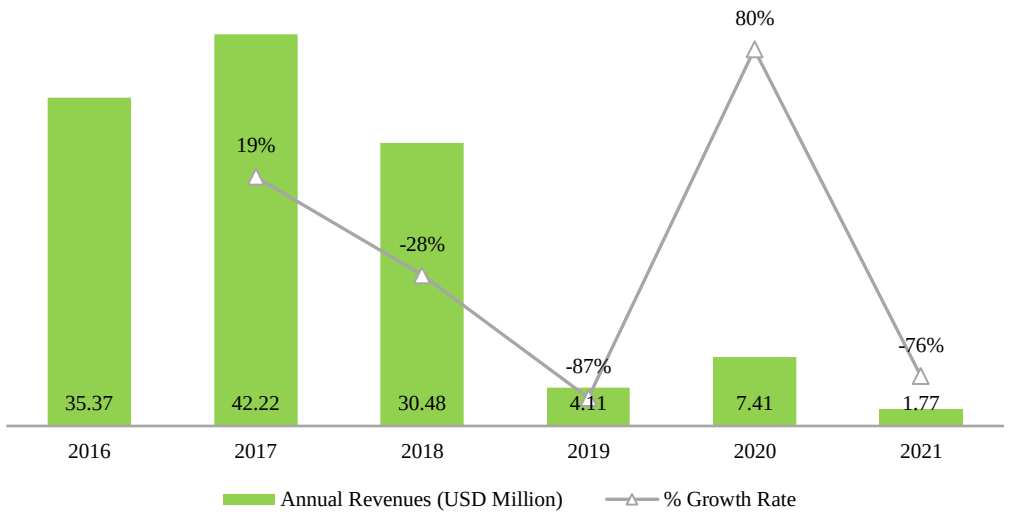
Table 6.2 **Company A: Company Snapshot**

| Particulars | Specifications |
|---|---|
| **Headquarters** | US |
| **Establishment Year** | 1978 |
| **Employee Count** | 201-500 |
| **Executive Team Members** | ▪ **Candidate A:** Sample Text Data<br>▪ **Candidate B:** Sample Text Data<br>▪ **Candidate C:** Sample Text Data<br>▪ **Candidate D:** Sample Text Data<br>▪ **Candidate E:** Sample Text Data<br>▪ **Candidate F:** Sample Text Data |

#### 6.2.1.1 FINANCIAL INFORMATION

The financial year of Company A spans from January to December. In 2021, the company generated revenues worth USD 1.77 million, registering a decrease of 76% as compared to the revenues of previous year (USD 7.41 Million). Figure XX presents the annual revenues of Company A in the last 5 years.

Figure 6.4 presents the annual revenues of the company generated between the time period between 2016 and 2021.




### 6.2.1.2. CURRENT TRENDS AND FUTURE PERSPECTIVES

Table 6.3 presents details on various recent developments and strategies, that we believe, the company is likely to undertake in order to drive future growth.

Table 6.3 **Company A: Current Trends and Future Perspectives**

| Strategic Initiatives | Recent / Past Trend(s) | Future Outlook |
|---|---|---|
| Making Strategic Acquisitions to Expand Product Portfolio | ▪ **July 2017: Sample Text** | Sample Text |
| Participating in Conferences and Other Events to Enhance Company Visibility | **October 2020:** The company hosted a webinar, "DNA Medicines: From COVID-19 to Cancer". | Sample Text |
| Making Key Appointments to Strengthen Management Team | **March 2021:** The company appointed XXX as the Chief Commercial Officer<br><br>**July 2021:** Sample Text | Sample Text |
| Strategic Initiative 4 | **2019-2021: Sample Text** | Sample Text |

### 6.1.1 PRODUCT PORTFOLIO

The company has eight therapeutic vaccines (*which are being evaluated alone or in combination with other therapeutics*) in its clinical pipeline. Details on the products offered by the company are provided in the subsequent sections.

#### 6.1.1.1 XXX

Table 6.4 provides information on the company's drug candidate, XXX.

Table 6.4 **Vaccine Profile: XXX**

| Parameters | | Details |
|---|---|---|
| Name of the Drug | | XXX |
| Other Name(s) | | xxxx |
| Type of Vaccine | | DNA Vaccine |
| Vaccine by Composition Method | | Allogeneic |
| Target Disease Indication(s) | | Anal cancer, cervical cancer, vulvar cancer, head and neck cancer, papillomavirus infections |
| Type of therapy | | • Monotherapy<br>• Combination therapy with imiquimod |
| Current Development Status | **Phase III** | Cervical cancer |
| | **Phase II** | • Anal cancer<br>• Vulvar cancer (*monotherapy and in combination with* imiquimod) |
| | **Phase I / II** | Head and neck cancer |
| | **Phase I** | Papillomavirus infections |

#### 6.1.1.2 YYY

Table 6.5 provides information on the company's drug candidate, YYY.

Table 6.5 **Vaccine Profile: YYY**

| Parameters | Details |
|---|---|
| Name of the Drug | YYY |

| Parameters | | Details |
|---|---|---|
| Type of Vaccine | | DNA Vaccine |
| Type of Vaccine (by method of composition) | | Allogeneic |
| Target Disease Indication | | Papillomavirus Infection |
| Type of therapy | | Monotherapy |
| Current Status of Development | **Phase I / II** | Papillomavirus Infection |

### 6.1.1.3 ZZZ

Table 6.6 provides information on the company's drug candidate, ZZZ.

Table 6.6 **Vaccine Profile: ZZZ**

| Parameters | | Details |
|---|---|---|
| Name of the Drug | | ZZZ |
| Type of Vaccine | | DNA Vaccine |
| Type of Vaccine (by method of composition) | | Allogeneic |
| Target Disease Indication | | Glioblastoma, urothelial cancer, BRCA 1/2 Mutation |
| Therapy Type | | • Monotherapy<br>• In Combination |
| Current Development Status | **Phase I / II** | • Glioblastoma (*in combination)*<br>• Urothelial cancer (*in combination)* |
| | **Phase I** | BRCA 1/2 mutation (*monotherapy or in combination)* |

## 6.2 COMPANY B

### 6.2.1 COMPANY OVERVIEW

Company B is a biotechnology company that specializes in the discovery and development of novel therapies for diverse infectious diseases. The comprehensive platform developed by the company is optimized for diverse modes of action, high precision targeting, mRNA therapeutics development, engineered cell therapies, antibodies, and immunomodulators. It is worth noting that

the company's XY product candidate, BNT111 is being evaluated in the phase II trial (for advanced melanoma) and has reported promising results. Table 6.7 provides a company snapshot.

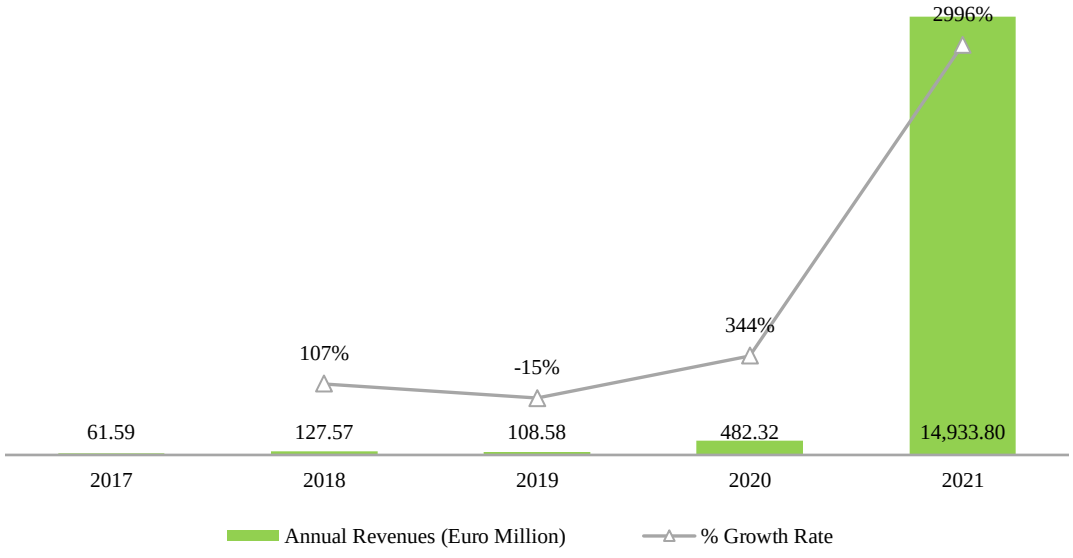
Table 6.7 **Company B: Company Snapshot**

| Company Parameters | Details |
|---|---|
| Establishment Year | 2008 |
| Headquarters Location | Germany |
| Employee Count | 1,001-5,000 |

### 6.2.2 FINANCIAL INFORMATION

Company B's financial year spans from January to December. In 2021, the company reported total revenues worth EUR 14,933 million, depicting a surge of over 2000% as compared to the previous year (EUR 482 million). The significant increase in finances was primarily attributed to the high demand of company's COVID-19 vaccine and revenues generated from the collaboration agreements with PCompany C and Company D.[33] Figure 6.2 presents the annual revenues of the company generated between the time period between 2017 and 2021.

Figure 6.2 **Company B: Annual Revenues, 2017-2021 (EUR Million)**



### 6.2.3 PRODUCT PORTFOLIO

The company has 10 therapeutic vaccines (*which are being evaluated alone or in combination with other therapeutics*) in its clinical pipeline. Details on the products offered by the company are provided in the subsequent sections.

#### 6.2.3.1 AAA

Table 6.8 provides information on the company's drug candidate, AAA.

Table 6.8 **Vaccine Profile: AAA**

| Parameters | | Details |
|---|---|---|
| Name of the Drug | | AAA |
| Type of Vaccine | | Antigen Vaccine |
| Vaccine by Composition Method | | Autologous |
| Disease Indication | | Melanoma |
| Therapy Type | | • Monotherapy<br>• In Combination |
| Current Status of Development | **Phase II** | Melanoma (*monotherapy and in combination)* |

Source: Roots Analysis

#### 6.2.3.2 BBB

Table 6.9 provides information on the company's drug candidate, BBB.

Table 6.9 **Vaccine Profile: BBB**

| Parameters | | Details |
|---|---|---|
| Name of the Drug | | BBB |
| Vaccine Type | | Antigen Vaccine |
| Type of Vaccine (by composition method) | | Autologous |
| Target Disease Indication | | Head and Neck Cancer |
| Type of therapy | | Combination therapy with pembrolizumab |
| Current Status of Development | **Phase II** | Head and Neck Cancer (*in combination)* |

# 7

# CONCLUDING REMARKS

## 7.1 CHAPTER OVERVIEW

The chapter describes the overall report, presenting the most important facts and figures about the current industry landscape. Furthermore, it identifies the important evolutionary trends identified during the study that might impact therapeutic vaccines market in future.

Figure 7.1 presents the summary of the overall market landscape of therapeutic vaccines, which described in detail in chapter 4 of the report.

Fig. 7.1 **Concluding Remarks: Overall Market Landscape of Therapeutic Vaccines**

**Global Therapeutic Vaccines**
*Distribution by Phase of Development*

**Global Therapeutic Vaccines**
*Distribution by Type of Therapy*

**Global Therapeutic Vaccines**
*Distribution by Therapeutic Area*

Source: Roots Analysis

Figure 7.2 presents the summary of the clinical trial analysis, which is described in detail in chapter 6 of the report.

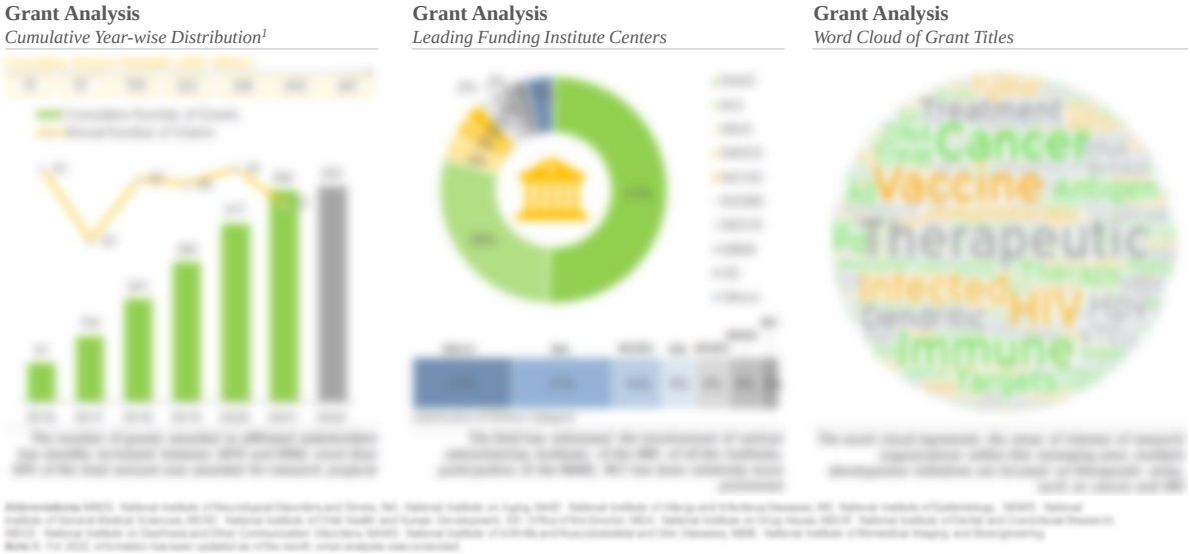
## Figure 7.2 **Concluding Remarks: Clinical Trial Analysis**

**Global Therapeutic Vaccines**
*Geographical Distribution of Clinical Research Landscape*[1,2]


Source: Roots Analysis

Figure 7.3 presents the summary of grant analysis, which is described in detail in chapter 7 of the report.

## Figure 7.3 **Concluding Remarks: Grant Analysis**




Source: Roots Analysis

Figure 7.4 presents the summary of partnerships and collaborations analysis, which is described in detail in chapter 8 of the report.

## Fig. 7.4 **Concluding Remarks: Partnerships and Collaborations**


Source: Roots Analysis

Figure 7.5 presents the summary of therapeutic vaccines market forecast analysis, which is described in detail in chapter 10 of the report.

## Fig. 7.5 **Concluding Remarks: Therapeutic Vaccines Market Forecast**

**Global Therapeutic Vaccines Market**
*Distribution by Disease Indication*[1, 2]

**Global Therapeutic Vaccines Market**
*Distribution by Vaccine Composition*[1, 3]

**Global Therapeutic Vaccines Market**
*Distribution by Geography*[1, 4]

Source: Roots Analysis

# REFERENCES


1. https://www.rootsanalysis.com/
2. https://www.linkedin.com/
3. https://www.crunchbase.com
4. https://clinicaltrials.gov/
5. https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276
6. https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276
7. https://www.webmd.com/vaccines/features/treating-disease-with-vaccines
8. https://europe.vaccineconferences.com/events-list/human-preventive-therapeutic-vaccines
9. https://www.cancerresearch.org/en-us/immunotherapy/treatment-types/cancer-vaccines
10. https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276
11. https://www.nature.com/articles/s41568-021-00346-0
12. https://www.webmd.com/children/vaccines/what-to-know-dna-vaccines
13. https://www.drugs.com/drug-class/therapeutic-vaccines.html
14. https://www.britannica.com/science/vaccine
15. https://europe.vaccineconferences.com/events-list/human-preventive-therapeutic-vaccines
16. https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276
17. https://innovareacademics.in/journal/ijap/Vol1Issue1/102.pdf
18. https://www.historyofvaccines.org/content/articles/cancer-vaccines-and-immunotherapy

19. https://www.historyofvaccines.org/content/articles/cancer-vaccines-and-immunotherapy

20. https://www.verywellhealth.com/what-is-a-therapeutic-vaccine-3133276

21. https://vaccine-safety-training.org/pre-licensure-vaccine-safety.html

22. http://www.euvaccine.eu/vaccines-diseases/vaccines/stages-development

23. https://investors.biontech.de/static-files/63dfd984-c1ce-46df-b543-2b3b037503e4