

Vaccines Industry The race for COVID-19 vaccine



How do Vaccines work?

What is a Vaccine?

A vaccine contains dead or weakened bacteria or viruses (they are not capable of causing a disease) that are administered to individuals to encourage the immune system to recognize them and to consequently produce antibodies that can identify the germ early on. This allows the individual to fight the germ if it encounters it again, therefore preventing disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.

Types of Vaccine



Source: Ministry of Health-Saudi Arabia, Mostagbal.ae

vaccines after actually contracting the disease. They are used to treat infections after their occurrence, in addition to being used in the treatment of other diseases such as cancers.

> Curative vaccine

History of Vaccination – Key Events

1796 Edward Jenner invented a method to protect against smallpox

1948

1st combination vaccine for Diphtheria, Tetanus and Pertussis

1977 - 1979

90% of vaccine developers move out of the market due to several lawsuits related to side effects caused by vaccines on candidates.

2000

Prevnar becomes first vaccine to generated USD 1 billion in sales

2010 1st therapeutic vaccine developed for Prostate cancer

1885

Louis Pasteur develops 1st live attenuated vaccine for Rabies

1974

MMR vaccine linked to Autism in Children. Creates controversy; Vaccination rate declines

1981

1st recombinant antigen vaccine developed for Hepatitis B

2003

Bill and Melinda Gates foundation launched to improve healthcare and aid in development of affordable vaccines.



Meningococcus B vaccine developed through reverse vaccinology

Vaccines have played a key role in eradication of several diseases Pre-vaccine and post-vaccine disease reduction in U.S.A.



Vaccine Market Overview

Vaccination market is expected to expand rapidly in the next five years due to renewed focus and inflow of investments



Source: Statista, Marketandmarkets, Lansdowne & Company, Bio Process International

High Income countries driving vaccine procurement by values whilst Middle-income countries continue to drive volume

Global Vaccine Market Volumes by region in 2018 (billion doses)



Source: World Health Organization

Few large players dominate the global vaccination market

Top pharma companies based on global vaccine revenues in 2019 (USD billions)



Top global vaccine products based on revenue

Vaccine Name	Company	Condition/Disease treated	Sales in USD billion (2019)
Prevnar 13	Pfizer	Pneumococcal Pneumonia	5.95
Gardasil 9	MERCK	HPV	3.73
Pentacel	Sanofi	Diphtheria/Tetanus	2.29*
Fluzone	Sanofi	Influenza	2.23*

Source: Statista, Company Website; Note: * - includes sales of group products, figures converted from EUR to USD at the rate 1 EUR = 1.18 USD

Stage of vaccine development

Vaccine Development Process is meticulous and is scrutinized at every stage to ensure safety

Vaccine Development stages



toxins, or other substances derived from pathogens





Challenges in developing vaccines

Every vaccine that has successfully passed preclinical stage has less than 20% chance of passing clinical trials and approval

Success ratio of Vaccines from development to approval





Types of Vaccines and their working mechanism

Live

Attenuated

Rubella, Measles

and Mumps

Inactivated

Approved Vaccines by WHO

Polio

Source: CDC, NIAID and FDA

Examples

Source: The Wall Street Journal *predicted

Subunit	Viral vector	DNA & RNA
Uses the surface of the virus to provoke immune response	Uses harmless virus to deliver viral genes and build immunity	Uses DNA or RNA molecules to teach immune system to target viral proteins
Triggers immune response without causing infection	As the virus is live, it triggers a stronger immune response	Easy and quick to design
May not be strong. Could require a boost for long-term immunity	An immune response to the viral vector could make the vaccine less effective	Successful vaccine has never been developed before
Hepatitis B, Human Papillomavirus	Ebola	-
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New gen vaccine

Vaccine development is a high-risk process with several challenges

Challenges in Vaccine development

Commercial Challenges

Costs	Vaccine development and manufacturing is a high cost and high-risk business that requires sizeable investments. Success rate of a vaccine being approved is also low.
Pricing	Pricing of vaccines needs to be accessible and at the same time profitable. Visibility on the willingness of governments and non-governmental organization to subsidize prices is a key factor for considering commercialization
Market Size	The size of the population at risk determines the market size. A very small market for a non-fatal disease sometimes discourages heavy investments into the project.
Market Access	Presence of commercial channels of distribution needs to be evaluated as it is a key determinant of profitability
Time to market	Research, Development, Approval and Manufacturing of Vaccines take several years. Time for the product to reach the market is very high and therefore realization of costs take time.

Technical Challenges

Research	Complexity of disease causing pathogens makes research and development a time-consuming process with high chances for failure.
Efficacy	The developed vaccine needs to trigger antibody response in patients with varied profiles (Age, climate, medical history etc.). Efficacy needs to be high to be considered successful.
Mutation	The disease causing pathogen could mutate, rendering the vaccine ineffective over time.
Longevity	The Vaccine's effect needs work for a long duration. Some cases require revaccination or adjuvants to boost the effectiveness.
Safety	The vaccine needs to be safe and must not cause undesirable effects in the individual over time.
Manufacturing complexity	Due to the complex nature of vaccine development, manufacturing processes also become complex, thereby increasing failure rates.

Regulatory Challenges

Ethics	Certain practices like the Human challenger trials are considered unethical and prohibited by certain regulators.
Time	Vaccine approvals tend to take a long time due to high regulatory scrutiny.
Quality control	Companies in certain cases need to perform 500 + different quality control tests on a routine basis to satisfy regulations, thereby increasing costs. Certain regulations also mandate that the samples collected during clinical tests to be preserved for up to seven years, requiring large storage facilities.
Weak regulatory capability	Regulatory bodies of Low and Middle income group countries sometimes lack the resources to reliably evaluate vaccines.

Source: Marmore Research

The race for COVID-19 vaccine

Vaccine development efforts for COVID-19 at full swing

Status of COVID-19 vaccines



Source: Biocentury

Sputnik V – The first COVID-19 vaccine to be approved for use

Vaccine Name: Sputnik V (earlier called Gam-COVID-Vac)

Developer: Gamaleya Research Institute, part of Russia's Ministry of Health

Vaccine Type: Viral vector vaccine

Clinical Trial launch date: June 17, 2020

Approval date: August 11, 2020

Key Points

- The vaccine has not completed phase 3 trials yet. After worldwide scepticism, Russia later walked back the announcement, saying that the approval was a "conditional registration certificate," which would depend on positive results from Phase 3 trials.
- Russian Direct Investment Fund (RDIF), Russia's Sovereign Wealth fund finances the production of and Binnopharm
- According to Russia, at least 20 countries had expressed interest in obtaining the Sputnik V, including Saudi Arabia, UAE, Indonesia, Philippines, Brazil, Mexico and India.
- RDIF and Brazil's Bahia state agree to supply up to 50 million doses of Sputnik V to Brazil; RDIF and Dr. Reddy's to cooperate on clinical trials and supply of 100 million doses of Sputnik V vaccine to India; RDIF and Landsteiner Scientific agree to supply 32 million doses of Sputnik V vaccine to Mexico.



the Sputnik V in Russia on the basis of production capacities of its portfolio companies, R-Pharm

Unconventional RNA and DNA vaccines are viewed as the best options for a quick COVID-19 vaccine

Classification of vaccine candidates by technique used



Source: Biocentury

How did developers shorten the COVID-19 vaccine timeline to 12-18 months?

Using Novel vaccine technologies - Novel DNA & RNA vaccine technology, which were not previously used, are being used to shorten development timeline. Vaccine developers are also using 'plug and play' platforms, which require much lesser time to develop vaccines compared to traditional approaches where the whole virus or its proteins must be grown and inactivated.

Combining and overlapping phases - Several vaccine developers are combining phase I and II or phase II and III clinical trials and running them parallel to each other to save time. Manufacturers have also been asked to start producing large quantities of promising vaccine candidates, much before their clinical trials are completed for immediate distribution on approval.

Repurposing research from similar diseases - Existing and ongoing research on severe acute respiratory syndrome (SARS), and the Middle East respiratory syndrome (MERS), that are caused by coronaviruses that belong to the same family as COVID-19 are being used by researchers to accelerate development.

Emergency use authorization - Emergency use authorization has been provided by regulatory bodies across the world for conducting clinical tests on a temporary basis to reduce the time taken from getting a formal approval that involves procedures that are more stringent.

Vaccine makers focusing efforts on shortening development timeline

Development timeline of COVID-19 vaccines that are approved for clinical testing

COVID-19 Vaccine developer/manufacturer	Country	Mar	Apr	May	Jun
University of Oxford/ AstraZeneca Sinovac	England				
Sinovac	China				
Wuhan Institute of Biological Products/Sinopharm	China				
Beijing Institute of Biological Products/Sinopharm	China				
Moderna/NIAID	U.S.A.				
BioNTech/Fosun Pharma/Pfizer	U.S.A./ Germany				
CanSino Biological Inc./Beijing Institute of Biotechnology	China				
Curevac	Germany				
Institute of Medical Biology, Chinese Academy of Medical Sciences	China				
Inovio Pharmaceuticals/ International Vaccine Institute	U.S.A.				
Osaka University/ AnGes/ Takara Bio	Japan				
Cadila Healthcare Limited	India				
Genexine Consortium	South Korea				
Bharat Biotech	India				
Janssen Pharmaceutical Companies	U.S.A.				
Novavax	U.S.A.				
Arcturus/Duke-NUS	Singapore				
Gamaleya Research Institute	Russia				
Vaxine Pty Ltd/Medytox	Australia				
University of Queensland/CSL/ Seqirus	Australia				
Instituto Finlay de Vacunas, Cuba	Cuba				
Medicago Inc.	Canada				

Source: The New York Times, McKinsey, World Health Organization, Marmore Research; The above list is not exhaustive







Under the spotlight: Prokarium contribution in the race for COVID-19 vaccine

Prokarium is one of the companies specialized in developing vaccination solutions based on synthetic biology that stimulates broad protective immune response applicable to a wide range of diseases. Prokarium's vision is to provide oral protein vaccines as well as reducing the costs and time to manufacture vaccines.

Key Company Highlights

Prokarium is one among Riyadh Valley Company's investment portfolio companies

Headquarters: London, England

Founded: 2012

Source: Prokarium, LinkedIn

Vaccines under development

		Indication	Current stage				
	Program		Drug Discovery	Preclinical	Early Clinical Development	Late Clinical Development	
Therapeutic	Bladder Cancer	Non Muscle Invasive Bladder Cancer		_			
	Solid Tumours	Undisclosed	_				
Prophylactic	Entervax	Enteric Fever S. Typhi and Paratyphi A					
	COVID-19	SARS-CoV-2					

Source: Prokarium

Prokarium's efforts in developing COVID-19 vaccine

- Prokarium is assessing the possibility of using the Vaxonella platform for active immunization against COVID-19.
- Prokarium's COVID-19 vaccine project will leverage insights from its Entervax clinical trial application granted November 2019. Due to the history of the platform, it is anticipated that regulatory approvals for the COVID-19 vaccine can be expedited.

Prokarium's pre-clinical development plan for COVID-19 vaccine

Querre	2020			
Stage	Q1	Q2	Q3	
Antigen Design		-		
Strain Engineering				
Strain Characterisation		-		
Chemistry, Manufacturing and Controls				
Toxicology				
Phase I/II adaptive clinical study				
Immunogenicity				
Challenge Model(s)				
Source: Prokarium				





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Saudi Arabia's role and effort in developing COVID-19 vaccine

Saudi Arabia's efforts in COVID-19 vaccine research

CanSino Vaccine

- Saudi Arabia's Ministry of Health announced that the third phase clinical trial for the COVID-19 vaccine developed by the Chinese company 'CanSino' will be conducted in Saudi Arabia.
- The first and second-phase trials were carried out in China. Third-phase trials to be performed in Saudi Arabia will be on a minimum of 5,000 healthy participants above the age of 18 years, divided into two groups.
- One group will be given a low dose of the vaccine and the other will be a control group who will be given a placebo. The trials will take place in Riyadh, Dammam, and Makkah in four health clusters.

Research efforts

· King Saud University had its participation in 40 scientific papers on COVID-19, becoming the most prominent contributor to the KSA's achievement of the first place in the Arab world and the 25th globally in terms of scientific research production related to the pandemic.

Source: Ministry of Health, Arab News, KAIMRC, KAUST, King Saud University



- King Abdullah International Medical Research Centre (KAIMRC) is searching for ways to repurpose existing drugs after isolating and sequencing the COVID-19 virus.
- Earlier in December 2019, KAIMRC launched their first 'first-in-human' (FIH) clinical trial centre at Riyadh. First phase clinical trial is now underway in the facility to test a novel Middle East Respiratory Syndrome (MERS-CoV) vaccine on healthy volunteers. KAIMRC developed the vaccine in collaboration with the University of Oxford.
- King Abdullah University of Science and Technology (KAUST) has also shifted their capabilities to develop solutions to the COVID-19 in collaboration with Saudi Centres for Disease Control and Ministry of Health.
- KAUST has become a signatory to both the AUTM COVID-19 Licensing Guidelines and adopted the COVID-19 Technology Development Framework, initiated by Massachusetts Institute of Technology, Stanford and Harvard. Both frameworks ensure that KAUST intellectual property will allow for royalty-free, time-limited, non-exclusive licenses during the pandemic and for a period after it ends.



Riyadh Valley Company

Riyadh Valley Company established in 2010 by Royal Decree No.116 dated 13/4/1431 AH to be the investment arm of King Saud University in the fields of Knowledge Economy and the university strategic projects.

Investment Sectors:

Knowledge Investments



To be the regional leader in knowledge-based investment and technology.



Mission

Riyadh Valley Company is a strategic investor, focused on leveraging the local capabilities, investing locally and globally in growth - stage businesses to create financial and strategic returns that will support the future of economic development in the Kingdom.





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Information & Communication technology

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Innovation and R&D Projects



Educational Projects

Healthcare Projects



Healthcare investment

Renewable energy& sustainable recourses



Commercial Projects

Residential Projects

Mixed-use Projects





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Real Estates Investment portfolio



SPC کے SPC للندویت

Sudair Pharma Company Project

Research center and company offices for Sudair Pharma Company



ELM Information Security Company Project

Innovation Center project for Elm information security company



Al-sorooh Al-Mubarakah Company **Project**

Mixed-use project contains office complex, Mall, Restaurants, cafes, and walkway for visitors



FOUR DIRECTIONS الاتحاضات الارتيعية **Four Directions**

Company Project Commercial and office project contains office buildings and multi-use halls



RC **Retail Real Estate Company Project**

Social-Entertaining and sports project



(DRM) عیادات دیرما Derma Clinic

Derma Clinic Company Project

Medical-Commercial project contains several medical clinics, medical products stores, and pharmacies



(DRM) عیادات دیرما Derma Clinic

Derma Clinic Company Project (Residential) Residential project for Derma Medical Clinics



City Lights Real Estate Company Project

مجموعة كيان)

Entertainment-Commercial project contains screens on the building and architectural blocks, in addition to areas for live shows



Hamad Bin Mohammed **Bin Saedan & Partners Investment Company** Project





Arrowad For Higher Education Company Project

Educational complex, Arrowad colleges University campus in Riyadh



Unified Real Estate Development Project

Cultural-Entertainment project that includes Luxury restaurants, Cafes, Cinemas and green spaces



SM/

NMR Real Estate Company Project

Mixed-use project includes a hotel, restaurants and cafes



The project serves King Saud University Campus residents. It includes large areas where events that reflect Saudi culture are held







Obeikan Company Project

Commercial project contains various stores near the Common First Year building





Dur Alkuttab Company Project

Educational project for **Primary Schools**





Omnia Real Estate Development Company Project

Commercial project contains various shops





University Boulevard

Commercial-Entertainment project gives visitors a different experience, and it includes Restaurants and cafes



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