

# Frequently Asked Questions about COVID-19 Candidate Vaccines and Access Mechanisms

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# **Progress in the Development of COVID-19 Vaccines**

## 1. Is there a vaccine against COVID-19?

As of January 6<sup>th</sup>, 2021, there are some COVID-19 vaccines for which certain national regulatory authorities have authorized the use. The World Health Organization (WHO) has also granted Emergency Use Listing (EUL) authorization to the Pfizer/BioNTech vaccine<sup>3</sup>.

The following vaccines have received national regulatory authorization<sup>3,4</sup>:

- Moderna/ NIAID/ Lonza/ Catalent/ Rovi/ Medidata/ BIOQUAL: Authorized for "emergency use" in the United States (U.S.).
- **BioNTech/ Pfizer/ Fosun Pharma/ Rentschler Biopharma**: Authorized for use by the European Commission and in the U.S., Mexico, Saudi Arabia, Canada, Bahrain, and the United Kingdom (U.K.).
- Gamaleya Research Institute: as a "registered" vaccine by the Russian Ministry of Health
- **CanSino Biologics/ Beijing Institute of Biotechnology/ Petrovax**: for "the military" by China's Central Military Commission.
- Wuhan Institute of Biological Products/ Sinopharm: for "emergency use" in China and the United Arab Emirates.
- Sinovac/ Instituto Butantan/ Bio Farma: for "emergency use" in China.
- **Beijing Institute of Biological Products/ Sinopharm**: for "emergency use" in China and the United Arab Emirates.

As of January 6<sup>th,</sup> 2021, there are 63 candidate vaccines in clinical evaluation in humans, and 172 candidate vaccines in the preclinical phase<sup>5</sup>.

Pan American Health Organization. Frequently Asked Questions (FAQs) about COVID-19 Candidate Vaccines and Access Mechanisms [Internet]. PAHO; 2020. Available at: <u>https://iris.paho.org/handle/10665.2/52629</u> <sup>3</sup> World Health Organization. WHO Recommendation COVID-19 mRNA vaccine (nucleoside modified)-COMIRNATY® [Internet]. WHO; 2021. Available at: <u>https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty%C2%AE</u>



<sup>&</sup>lt;sup>1</sup> Document subject to revision as new evidence and information become available.

<sup>&</sup>lt;sup>2</sup> A previous version of the document was published on 27 August 2020:

<sup>&</sup>lt;sup>4</sup> The Milken Institute. COVID-19 Vaccine Tracker [Internet]. The Milken Institute; 2020. Available at: <u>https://www.covid-19vaccinetracker.org/</u>

<sup>&</sup>lt;sup>5</sup> The draft landscape of COVID-19 vaccines is updated on a regular basis by the WHO <u>here.</u>

# 2. Will all the COVID-19 candidate vaccines be successful?

Only a portion of candidate vaccines will be successful. A study about vaccines targeting human infectious diseases showed that candidate vaccines in preclinical evaluation have an estimated marked entry probability of 7%, and once they have entered clinical evaluation of 17%. Over time, it is likely that COVID-19 vaccines will gradually become available.

## 3. Will COVID-19 vaccines be safe?

COVID-19 vaccines are novel vaccines that have never been used in humans on a large scale, therefore close safety monitoring post-authorization should be carefully conducted to continue to assess the safety profile of each vaccine. Currently, most available information has been provided by vaccine manufacturers during clinical trials. Dossiers containing safety data that are submitted to national regulatory authorities should be carefully assessed before the vaccine is approved (authorized) for use in a country or region. The summary of product characteristics of vaccines authorized for use by the WHO prequalification process are accessible on the WHO Prequalified Vaccines. Preparedness and basic training of staff to follow national guidelines or protocols for AEFI surveillance and, therefore, strengthen local capacity, should be planned.

Furthermore, COVID-19 vaccines will not be approved or rolled out for use in the general population until the safety data has been thoroughly reviewed by regulatory agencies and WHO.

## 4. What are the different phases a vaccine must go through to be approved?

The evaluation of a vaccine candidate undergoes different phases (preclinical and clinical) until a vaccine receives regulatory approval. The objective of this entire process is to ensure a safe and efficacious vaccine (as well as to answer other questions like dose number and timing)<sup>67</sup>.

- **Preclinical phase**: focuses on testing vaccine safety and its ability to produce an immune response in animals. The clinical evaluation in humans includes:
- Phase 1: trials are held on a small number of humans usually under 100 adults to evaluate the vaccine's safety and its ability to generate an immune response (immunogenicity). This phase could include studies to determine the number of doses needed and the methods of administering the vaccine. If the vaccine proves to be safe during phase 1, it will advance to phase 2<sup>8</sup>.
- Phase 2: the number of humans the vaccine is tested on increases to usually between 200 and 500. The vaccine is given to people who present characteristics (such as age and physical health) like those for whom the new vaccine is intended. During this phase, scientists will continue assessing its safety and capacity to generate an immune response.





<sup>&</sup>lt;sup>6</sup> A previous version of the document was published on 03 April 2020:

Pan American Health Organization. Summary on Advances in the Development of Vaccines against COVID-19 [Internet]. PAHO; 2020. Available at: <u>https://iris.paho.org/handle/10665.2/52273</u>

<sup>&</sup>lt;sup>7</sup> Pan American Health Organization. COVID-19 Fases de desarrollo de una vacuna [Internet]. PAHO; 2020. Available at: <u>https://www.paho.org/es/documentos/covid-19-fases-desarrollo-vacuna</u>

<sup>&</sup>lt;sup>8</sup> Pronker ES, Weenen TC, Commandeur H, Claassen EH, Osterhaus AD. Risk in vaccine research and development quantified. PLoS One. 2013;8(3): e57755. Available at: <u>https://doi.org/10.1371/journal.pone.0057755</u>



- Phase 3: the candidate vaccine is tested on several thousands of people. Phase 3 trials focus on assessing efficacy, are randomized and double-blind (meaning those participating in the studies do not know if they receive the real vaccine or a placebo) and can include single and multi-country studies. This phase is usually the last step before the vaccine receives the regulatory approval for vaccination of the population.
- **Phase 4:** After the vaccine is approved, it is also submitted to strict and continuous monitoring. The countries rely on surveillance systems to monitor adverse events. Additionally, many vaccines go through to assess effectiveness and monitor rare adverse events that may occur on an extremely rare basis, e.g. one in 2-3 million doses.

#### 5. What are the candidate vaccines in Phase 2/3 and Phase 3?

As of 28th December 2020, there are 16 COVID-19 candidate vaccines in Phase 2/3 and Phase 3 (details are provided in Table 1). There is no direct correlation between the trial phase of a vaccine and its superiority or future success. A vaccine reaching phase 3 would not necessarily indicate that it is better than a vaccine in phase 1 or phase 2. At the same time, it is important to consider that not all vaccine manufacturers with products in clinical studies have the capacity to scale up their production and distribution to respond to global demand.

Phase 💌	Vaccine 🗾	Platform 🔽	N	🕶 🛛 Age (years) 💌	N dose	Location 🔽	Trial number 🛛 💌
Phase III	Janssen Ad26.COV2.S	Non-replicating viral vector	60000	≥18	1	USA, Argentina, Brazil, others	NCT04505722
Phase III	WIBP/BIBP vaccines	Inactivated	45000	≥18	2	Bahrain, Jordan, Egypt, UAE	NCT04510207
Phase III	Cansino Ad5-nCoV	Non-replicating viral vector	40000	≥18	1	Argentina, Chile, Mexico, others	NCT04526990
Phase III	Gamaleya Gam-COVID-Vac/Sputnik V	Non-replicating viral vector	40000	≥18	2	Russia	NCT04530396
Phase III	Oxford ChAdOx1-S	Non-replicating viral vector	40000	≥18	2	USA, Argentina, Chile, others	NCT04516746
Phase III	CAMS vaccine	Inactivated	34020	≥18	2	Brazil, Malaysia	NCT04659239
Phase III	Janssen Ad26.COV2.S	Non-replicating viral vector	30000	≥18	2	USA, Belgium, Colombia, others	NCT04614948
Phase III	Moderna mRNA-1273	RNA	30000	≥18	2	USA	NCT04470427
Phase III	Novavax NVX-CoV2373	Protein subunit	30000	≥18	2	USA, Mexico, Puerto Rico	NCT04611802
Phase III	AZLB ZF2001	Protein subunit	29000	≥18	Unclear	China, others TBC	NCT04646590
Phase III	Bharat Covaxin	Inactivated	25800	≥18	2	India	NCT04641481
Phase III	Novavax NVX-CoV2373	Protein subunit	15000	18-84	2	UK	NCT04583995
Phase III	Sinovac CoronaVac	Inactivated	13060	≥18	2	Brazil	NCT04456595
Phase III	Sinovac CoronaVac	Inactivated	13000	18–59	2	Turkey	NCT04582344
Phase III	Oxford ChAdOx1-S	Non-replicating viral vector	10300	≥18	1 or 2	Brazil	NCT04536051
Phase III	WIBP/BIBP vaccines	Inactivated	6000	18-60	2	Peru	NCT04612972
Phase III	BIBP BBIBP-CorV	Inactivated	3000	18-85	2	Argentina	NCT04560881
Phase III	RIBSP QAZCOVID-IN	Inactivated	3000	≥18	2	Kazakhstan	NCT04691908
Phase III	CureVac CVnCoV	RNA	2520	≥18	2	Germany	NCT04674189
Phase III	Sinovac CoronaVac	Inactivated	2300	≥18	2	Chile	NCT04651790
Phase III	Gamaleya Gam-COVID-Vac/Sputnik V	Non-replicating viral vector	2000	≥18	2	Venezuala	NCT04642339
Phase III	Sinovac CoronaVac	Inactivated	1620	18–59	2	Indonesia	NCT04508075
Phase III	Sinovac CoronaVac	Inactivated	1040	≥18	2	China	NCT04617483
Phase III	Gamaleya Gam-COVID-Vac/Sputnik V	Non-replicating viral vector	1000	≥18	2	UAE	NCT04656613
Phase III	WIBP vaccine	Inactivated	600	≥18	2	Morocco	ChiCTR2000039000
Phase III	Cansino Ad5-nCoV	Non-replicating viral vector	500	18-85	1	Russia	NCT04540419
Phase III	Gamaleya Gam-COVID-Vac/Sputnik V	Non-replicating viral vector	100	18–60	2	Belarus	NCT04564716
Phase III	Oxford ChAdOx1-S	Non-replicating viral vector	100	≥18	2	Russia	NCT04540393
Phase II/III	BioNTech BNT162 (b1/b2)	RNA	43998	≥12	2	USA, Argentina, Brazil, others	NCT04368728
Phase II/III	CureVac CVnCoV	RNA	36500	≥18	2	Germany	NCT04652102
Phase II/III	Clover SCB-2019	Protein subunit	34000	≥18	2	Pending	NCT04672395
Phase II/III	Medicago CoVLP	Virus-like particle	30612	≥18	2	Canada, others TBC	NCT04636697
Phase II/III	Oxford ChAdOx1-S	Non-replicating viral vector	12390	≥5	1 or 2	UK	NCT04400838
Phase II/III	Covaxx UB-612	Protein subunit	7320	≥18	2	Pending	NCT04683224
Phase II/III	Inovio INO-4800	DNA	6578	≥18	2	USA	NCT04642638
Phase II/III	Moderna mRNA-1273	RNA	3000	12–17	2	USA	NCT04649151
Phase II/III	Gamaleya Gam-COVID-Vac/Sputnik V	Non-replicating viral vector	1600	≥18	2	India	NCT04640233
Phase II/III	Oxford ChAdOx1-S	Non-replicating viral vector	1600	≥18	2	India	CTRI/2020/08/027170
Phase II/III	AnGes AG0302-COVID19	DNA	500	≥18	2	Japan	NCT04655625

#### Table 1: Main characteristic of COVID-19 candidate vaccines in Phase 2/3 and Phase 3

*Source*: London School of Hygiene and Tropical Medicine. COVID-19 vaccine tracker [Internet]. LSHTM; 2020. Accessed on 01/06/2021. Available at: <u>https://vac-lshtm.shinyapps.io/ncov\_vaccine\_landscape/</u>



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#### 6. How have COVID-19 vaccines been developed so quickly?

The development of a novel vaccine is a complex and lengthy process that on average takes 10 years. However, COVID-19 vaccines are the culmination of years of research in new technologies and have been built on lessons learned from work on SARS and MERS vaccines in development, as well as the developed Ebola vaccines.

Given the current COVID-19 pandemic, institutions, commercial developers, and researchers around the world are working at an unprecedented speed and scale targeting for safe and effective COVID-19 vaccine(s) in approximately 12-18 months.



Figure 1: COVID-19 vaccine accelerated development

*Source*: World Health Organization. EPI-WIN updates: COVID-19 Vaccine Development. WHO; 2020. Available at: <a href="https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update45-vaccines-development.pdf?sfvrsn=13098bfc\_5">https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update45-vaccines-development.pdf?sfvrsn=13098bfc\_5</a>

#### 7. Where are these COVID-19 candidate vaccines being developed?

Most of the companies and institutions developing vaccines against COVID-19 are in countries such as the United States of America, United Kingdom, and China. Some of the vaccine clinical trials will take place in clinical sites in countries in Latin America (Argentina, Brazil, Colombia, Chile, Mexico, Peru, and Venezuela).





# 8. What types of COVID-19 vaccines are being developed?

Various technologies and platforms are being used such as:

- Nucleic acids (DNA, RNA) vaccines: vaccines that use one or more of the coronavirus's own genes to provoke an immune response.
- Viral vector vaccines: vaccines that use a virus non-replicating or replicating vector to deliver coronavirus genes into cells and provoke an immune response.
- Protein-based vaccines: vaccines that use a coronavirus protein or a protein fragment (protein sub-unit) to provoke an immune response.
- Whole-virus vaccines: vaccines that use a weakened (attenuated) or inactivated version of the coronavirus to provoke an immune response.

The table below shows the distribution of the different platforms of the vaccine candidates in development and the main characteristics of the candidate vaccines in Phase II and III.

Platform		Candidate vaccine	Candidate vaccines (no. and %)		
PS	Protein subunit	19	30%		
VVnr	Viral Vector (non-replicating)	10	16%		
DNA	DNA	8	13%		
IV	Inactivated Virus	9	14%		
RNA	RNA	7	11%		
VVr	Viral Vector (replicating)	4	6%		
VLP	Virus Like Particle	2	3%		
VVr + APC	VVr + Antigen Presenting Cell	2	3%		
LAV	Live Attenuated Virus	1	2%		
VVnr + APC	VVnr + Antigen Presenting Cell	1	2%		
		63			

Table 2: COVID-19 vaccine candidates development platforms

*Source:* World Health Organization. Draft landscape of COVID-19 candidate vaccines [Internet]. WHO; 2021. Accessed on 01/06/2021. Available at: <u>https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines</u>

# 9. Are mRNA new vaccines?

They are new but not unknown. Researchers have been studying and working with them for decades. Interest has grown in these vaccines because they can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods of making vaccines. mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV)<sup>9</sup>.



<sup>&</sup>lt;sup>9</sup> Centers for Disease Control and Prevention. Understanding mRNA vaccines [Internet]. CDC; 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

#### 10. How many doses of the vaccines will be needed?

This information is not completely known. Most of the ongoing COVID-19 vaccine candidate clinical trials are considering one or two. When the schedule considers two doses, there is an interval of 14, 21 or 28 days between the first and second dose.

#### 11. What could be the cold chain requirements of COVID-19 vaccines?

While most of the COVID-19 candidate vaccines are expected to present similar cold chain requirements as existing vaccines (between 2-8°C), some developed might using nucleic acids (DNA or RNA) might require lower temperatures such as -70°C or -80°C.

## 12. What could be the administration routes of COVID-19 vaccines?

The COVID-19 candidate vaccines in preclinical and clinical evaluations are using different administration routes. The specified WHO Target Product Profile (TPP) describes the preferred and minimally acceptable profiles for human COVID-19 vaccines, and indicates that any route of administration is acceptable, including intramuscular or subcutaneous injection, oral or intranasal.<sup>10</sup>

13. Will it be possible to co-administer COVID-19 vaccines with other existing vaccines against other pathogens?

This information is still unknown. Future studies will assess it.

14. What are the recommendations from SAGE and TAG to prioritize population groups to receive COVID-19 vaccination first?

WHO's Strategic Advisory Group of Experts on Immunization (SAGE) has endorsed the Values Framework which offers guidance on the allocation of COVID-19 vaccines between countries and national prioritization of groups for vaccination within countries while supply is limited<sup>11</sup>.

The Prioritization Roadmap considers 3 epidemiologic scenarios: community transmission, sporadic cases or clusters of cases, and no cases, but risk of importation. Different vaccine supply scenarios are applied: very limited, limited, and moderate availability (1–10%, 11–20% and 21–50% of population, respectively). Target populations were identified against various combinations of these scenarios in accordance with the general principles and objectives as laid out in the Values Framework<sup>12</sup>. PAHO's Technical Advisory Group (TAG) on Immunizations supports the adoption of the WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination and the Roadmap for Prioritizing Population Groups for Vaccines against COVID-19 and urges their use to guide country planning and decision-making.

Available at: https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines

<sup>11</sup> The complete framework can be accessed: World Health Organization. WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination [Internet]. WHO; 2020. Available at: https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE Framework-

Allocation and prioritization-2020.1-eng.pdf?ua=1

<sup>&</sup>lt;sup>12</sup> World Health Organization. Weekly epidemiological record [Internet]. WHO; 2020. Available at: https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf?ua=1







<sup>&</sup>lt;sup>10</sup> World Health Organization. WHO Target Product Profiles for COVID-19 Vaccines [Internet]. WHO; 2020.

#### 15. What will be the best vaccine delivery strategy?

Countries should plan for different vaccine strategies to reach the targeted groups. It will be also important for countries to assess their cold chain capacities and sort out their inventory of equipment and training needs. Lessons learned from the delivery of the H1N1 pandemic vaccine and other new vaccine introductions could be leveraged.

#### 16. What is herd immunity?

When most of a population is immune to an infectious disease, this provides indirect protection or herd immunity (also called herd protection)—to those who are not immune to the disease. For example, if 80% of a population is immune to a virus, four out of every five people who encounter someone with the disease won't get sick (and won't spread the disease any further). In this way, the spread of infectious diseases is kept under control. Depending on how contagious an infection is, usually, 50% to 90% of a population needs immunity to achieve herd immunity<sup>13</sup>.

#### 17. What will it take to achieve herd immunity with SARS-CoV-2?

As with any other infection, there are two ways to achieve herd immunity: A large proportion of the population either gets infected or gets a protective vaccine.

In the worst case (for example, if we do not practice physical distancing or enact other measures to slow the spread of SARS-CoV-2), the virus can infect this many people in a matter of a few months. This would overwhelm our hospitals and lead to high death rates.

In the best case, we maintain current levels of infection—or even reduce these levels—until a vaccine becomes available for use in the general population. This will take a concerted effort on the part of the entire population, with some level of continued physical distancing for an extended period, likely a year or longer, before a highly effective vaccine can be developed, tested, and mass- produced.

The most likely case is somewhere in the middle, where infection rates rise and fall over time; we may relax social physical distancing measures when numbers of infections fall, and then may need to re-implement these measures as numbers increase again. Prolonged efforts will be required to prevent major outbreaks until even after a vaccine is developed and first introduced. Even then, SARS-CoV-2 could still infect children before they can be vaccinated or adults after their immunity wanes. But it is unlikely in the long term to have the explosive spread that we are seeing right now because much of the population will be immune in the future<sup>14</sup>.

#### 18. What's the difference between vaccine efficacy and vaccine effectiveness?

These two terms are often used interchangeably in the context of the performance of COVID-19 vaccines in clinical trials. But there's a key difference: Efficacy refers specifically to how a vaccine is performing in the trials. This is an ideal performance of the vaccine, as it is in a trial environment that can be more tightly controlled than everyday life. Effectiveness refers more broadly to how





<sup>&</sup>lt;sup>13</sup> Johns Hopkins Bloomberg School of Public Health. What is Herd Immunity and How Can We Achieve It With COVID-19? [Internet]. JHSPH; 2020. Available at: <u>https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html</u>



the vaccine meets standards of success in the "real world," after it has been released for consumer use. This gives a more realistic performance of a vaccine, and takes into account that in the real world, the vaccine may be offered in a range of primary care settings, and offered to a broader population of people, including those who may have health conditions or other factors which could affect how well the vaccine protects against disease<sup>15</sup>.

# PAHO's Revolving Fund and COVAX Facility

## 19. What will be the price of COVID-19 vaccines?

This information is still unknown and will be based on numerous different complicated factors like market dynamics, manufacturers' pricing strategy, engagement with any advance market commitment mechanisms, cost of research and development, cost of scaling manufacturing capacities, reliability of demand and risk sharing approaches, etc. Based on initial available information, while some manufacturers are committing to minimal returns (no profit approach) on their pipeline products, other manufacturers indicate their pricing approach to be tiering countries based on income classifications (differentiated prices).

#### 20. What is PAHO's Revolving Fund?

PAHO's Revolving Fund for Access to Vaccines is a technical cooperation mechanism that supports PAHO Member States to plan for their annual vaccine needs, consolidates forecasted vaccine demand and leverages economies of scale to achieve lower prices and contribute this way to the sustainability of the National Immunization Programs. For more than 40 years, the Revolving Fund has facilitated access to high-quality life-saving vaccines and related products at the most affordable price for countries in the Americas. Currently, 42 Member States and 7 territories benefit from services offered by the Revolving Fund<sup>16</sup>.

#### 21. What is the ACT-Accelerator?

The Access to COVID-19 Tools (ACT) Accelerator is a mechanism that brings together numerous partners under one global effort to support equal access to the four pillars related to COVID-19: diagnostics, treatments, vaccines and health system strengthening,

The vaccine pillar includes three components: development and manufacturing, coordinated by the Coalition for Epidemic Preparedness Innovations (CEPI); policy and allocation, coordinated by WHO; and procurement and delivery at a global scale, coordinated by Gavi with participation from other partners, including WHO<sup>17</sup>.

#### 22. What would be the benefit of a global access mechanism for COVID-19 vaccines?

The benefit of a global access mechanism would be to facilitate equitable access to COVID-19 vaccines<sup>17</sup>.

<sup>&</sup>lt;sup>17</sup> To get more information, visit <u>WHO: ACT Accelerator.</u>





www.paho.org/coronavirus

<sup>&</sup>lt;sup>15</sup> Singal, Amit G MD, MS<sup>1,2</sup>; Higgins, Peter D R MD, PhD<sup>3</sup>; Waljee, Akbar K MD, MS<sup>3,4</sup> A Primer on Effectiveness and Efficacy Trials, Clinical and Translational Gastroenterology: January 2014 - Volume 5 - Issue 1 - p e45. Available at: doi:10.1038/ctg.2013.13

<sup>&</sup>lt;sup>16</sup> For more information, visit the Revolving Fund website.



The following potential situations might arise for a country to consider accessing COVID-19 vaccines through the ACT Accelerator:

- National access mechanism countries negotiate agreements directly with manufacturers: There is a risk of concentrating the resources in a few potentially unsuccessful COVID-19 vaccine candidates.
- Grouped access mechanism countries from regional groups or blocs negotiate supply agreements with manufacturers: There is also a risk of concentrating the resources in a few potentially unsuccessful COVID-19 vaccine candidates.
- Global access mechanism countries participate in a global mechanism to procure and access COVID-19 vaccines.

Participating in a globally coordinated mechanism, countries will be able to hedge the risk and increase chances for success by contributing to a large and diverse portfolio of COVID-19 vaccines. At the same time, through such a global mechanism, governments with limited or no ability to finance their own bilateral procurement can be assured access to life-saving vaccines that would otherwise have been beyond their reach.

#### 23. What is the COVAX Facility?

The COVID-19 Vaccine Global Access (COVAX) Facility is the vaccine pillar of the ACT Accelerator and the globally coordinated mechanism to provide equitable access, risk pooling, and affordable options for all participating countries. COVAX is co-led by Gavi (The Vaccine Alliance), the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO). Gavi is the COVAX Facility administrator and, as such, is responsible for making investments across a broad portfolio of promising vaccine candidates<sup>18</sup>.

To date, nine vaccines are part of the COVAX portfolio, and 172 countries have expressed interest in participating in the COVAX mechanism<sup>19</sup>.

#### 24. What is the Gavi COVAX Advance Market Commitment (AMC)?

Within the COVAX Facility, there are two groupings of countries. The first grouping is composed of the self-financing countries: self-financing (95) and countries that meet the requirements to receive COVAX Advanced Market Commitment (AMC) support. The latest is composed by 92 countries. In the Americas, they are: Bolivia, Dominica, El Salvador, Grenada, Guyana, Haiti, Honduras, Nicaragua, St. Lucia, and St. Vincent and the Grenadines<sup>2021</sup>.

#### 25. How is PAHO's Revolving Fund engaged with the COVAX Facility?

Since the design and initiation of the COVAX Facility, PAHO has taken an active role in advocating for PAHO Member States' needs, including the proposed use of existing mechanisms like the PAHO Revolving Fund for Access to Vaccines (the Revolving Fund) as a platform to ensure access to vaccines in the Region. In addition, as the largest pooled procurement mechanism in the world

<sup>&</sup>lt;sup>21</sup> For more information, visit <u>Gavi: COVAX AMC.</u>



<sup>&</sup>lt;sup>18</sup> For more information, visit <u>Gavi: COVAX Facility.</u>

<sup>&</sup>lt;sup>19</sup> World Health Organization. 172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility [Internet]. WHO; 2020. Available at: <u>https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility</u>

<sup>&</sup>lt;sup>20</sup> For a complete list of countries, visit Gavi: COVAX AMC countries.



for self-financing countries, the Revolving Fund has made important contributions to the design and implementation of the COVAX Facility, based on its 40-year experience of working side to side with national immunization programs of the Americas.

#### 26. How will the COVID-19 vaccines be allocated among countries?

A methodology is required to fairly allocate a COVID-19 vaccine, and it will need to prioritize vaccine supply to reduce the impact of the virus as quickly as possible. Global partners are working together to set up the framework and mechanism required to ensure fair allocation through the WHO Fair Allocation Framework and the COVAX Facility. These vaccines will be delivered to all participating countries, in a manner that is proportional to their populations and in a way that they are initially provided to 3% of the population and later expanding to cover up to 20%. Further doses will then be made available based on country need, vulnerability, and COVID-19 threat.

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