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New public-private collaboration mechanisms for COVID-19 vaccine development and access: A grounded theory perspective

Nuevos mecanismos de colaboración público-privada para el desarrollo y acceso a la vacuna COVID-19: una perspectiva desde la teoría fundamentada

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Abstract

The aim of this work is to identify and characterize how in the facing of a global high-impact event, such as a pandemic, new forms of collaboration and competition among agents (companies, public research centers and universities, governments) emerge to accelerate the development of the vaccine to mitigate the pandemic of coronavirus disease 2019 (COVID-19). This text analyses the vaccine production process to face the SARS-CoV-2 coronavirus from the vaccine candidates that are in the most advanced phases of the clinical studies stages by considering the characteristics of the agents, the countries to which they belong, the financing profile and the regulation features. The contribution of the work is to point out that in the development of the COVID-19 vaccine, new patterns of public-private collaboration have been promoted at the national and international level in multiple areas such as the scientific-technological, financial and regulatory. These patterns frame a new collaboration logic that could be an experience to solve global problems such as pandemics, with greater flexibility and speed.

JEL Code: F50, I 15, L65, O10, O30
Keywords: COVID-19 vaccine; public-private collaboration; coronavirus; vaccine development and access; grounded theory

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Resumen

El objetivo de este texto es identificar y caracterizar cómo ante un hecho global de alto impacto, como puede ser una pandemia, se crean nuevas formas de colaboración y competencia entre los agentes (empresas, centros públicos de investigación y universidades, gobiernos), para acelerar el desarrollo de la vacuna para mitigar la pandemia de la enfermedad por coronavirus 2019 (COVID-19). El texto analiza el proceso de producción de vacunas para enfrentar al coronavirus SARS-CoV-2 a partir de las candidatas que se encuentran en la etapa de estudios clínicos de las fases más avanzadas, considerando las características de los agentes, los países a los que pertenecen, el perfil del financiamiento y los rasgos de la regulación. La aportación del trabajo es la de señalar que en el desarrollo de la vacuna de la COVID-19 se han impulsado nuevos patrones de colaboración público-privado a nivel nacional e internacional en múltiples ámbitos como son el científico-tecnológico, el financiero y el regulatorio. Estos patrones enmarcan una nueva lógica de colaboración que pudiera ser una experiencia para resolver problemas globales como son las pandemias, con una mayor flexibilidad y velocidad.

Código JEL: F50, I 15, L65, O10, O30
Palabras clave: vacuna COVID-19; colaboración público-privada; coronavirus; desarrollo y acceso de la vacuna COVID-19; teoría fundamentada

Introduction

Since the emergence of a new virus of the coronavirus family identified in China in November 2019, a pandemic of the disease known as COVID-19 has come into existence. The contagion levels have reached practically all countries, with morbidity and mortality rates raising the alarm in the face of a new global public health problem. In recent years, humankind has been affected by diseases associated with the circulation of new and old virus serotypes and prototypes. That is, emerging viruses appear in places where they had never been diagnosed or re-emerging viruses appear where they had already been controlled. Among the factors favoring this circulation are urban sprawl, deforestation, and the invasion of wild or unpopulated ecological areas.

Moreover, the increased mobility of people, animals and goods is spreading infectious agents faster than ever. Recent viral threats derive from strains such as avian H5N1, or Ebola, Marburg, Lassa, and other viruses that cause contagious viral hemorrhagic fevers. The families of coronaviruses in humans date back at least eight centuries (HCoVNL63) up to the most recent SARS-CoV-1 and 2 and MERS-CoV types, which have only been identified in the present century. It is not possible to know how many viruses capable of infecting humans, animals and plants remain to be discovered, nor how many will be detectable with new diagnostic techniques (Reina *et al*., 2014). The high level of aggressiveness of SARS-CoV-2 contrasts with the known species of this family. The SARS virus family is characterized by its mutability, which makes epidemiological forecasting and possible vaccine development difficult. The

coronavirus family is widespread in the animal kingdom and is one of humans' most frequent causes of colds.

To date (November 21, 2020), no reliable treatment has been developed that can predictably halt the progression of COVID-19, which is characterized as a disease that can be mild, moderate, severe and even life-threatening. This global public health problem has increased the urgency of developing vaccines against the SARS-CoV-2 virus, to which several countries and institutions such as the WHO have been committed. Vaccine candidates to prevent COVID-19 rely on strategies to induce immune responses, including the generation of neutralizing antibodies directed against the SARS-CoV-2 spike protein. With the COVID19 pandemic considered a global emergency, there is a broad global consensus that innovative ways must be devised to accelerate the development of promising and effective vaccine candidates in the shortest time (WHO, 2020c). This paper explores complementary mechanisms to the market that have been created to accelerate their development (production) and access (distribution).

This work uses a grounded methodology. Glaser & Strauss (1967) proposed Grounded Theory (GT) as an alternative way of approaching social reality. Contrary to hypothetico-deductive approaches, GT is an inductive approach to research that privileges the context or phenomenon over the theory from the data (Walsh *et al*., 2015). Thus, by changing the usual order of literature review and data collection, GT seeks to adapt previous findings to the specific characteristics of the phenomenon under study (Hirschman and Thompson, 1997). It all started from the question: To what extent is the development of pandemic vaccines likely to be accelerated by greater international public-private coordination and collaboration in the scientific-technological, financial and regulatory domains? The main argument is that the development of the COVID-19 vaccine and the speed at which it can be used is being made possible due to the knowledge accumulated by companies and CPI-universities and to the institutional and coordinating capacities among countries and agents that have formed new public-private collaboration schemes. This is reflected in greater intensity in scientific-technological collaboration, in the generation of coordination mechanisms and public-private financing to reduce the risk of vaccine investment, as well as in the flexibility and acceleration of regulations at the national and international levels. Regarding scientific-technological capabilities, it is considered that the development of a vaccine requires that countries, companies, CPIs and universities have scientific-technological capabilities that cover the spectrum from R&D to commercialization activities, as well as specialized scientific and technical personnel. These capabilities require public and private financing and mechanisms to coordinate and integrate the knowledge and skills of each developing agent by interacting or collaborating with other public and private agents, including regulatory agencies, thus achieving new or recombined capabilities.

This work analyzed the COVID-19 vaccine projects identified by the World Health Organization that were in the most advanced stages (phase 1, 2, 1-2 and 3 clinical studies) as of October

15, 2020. The analysis of the vaccine candidates considers their characteristics, such as the technological platform used, the number of vaccines, the degree of progress, the type and intensity of the links between the various agents, traits of the agent either regarding sharing knowledge or receiving funding, the type of public or private funding, the nationality of the agent, and the nature of the links. The data analysis, concepts, and extensive documentary information identified various behavior patterns of the development and access to the COVID-19 vaccine following the GT method (Walsh *et al*., 2015).

The text consists of six sections. In the first one, which is this introduction, the problem is posed, and the methodology to be used is described in general. The second section presents the theoretical framework. In the third to fifth sections, the results are presented and discussed. Finally, the sixth section presents the conclusions.

Vaccine development and production: The market and global public health

The development and production of vaccines take place in the context of a specific industrial structure, with highly complex, risky, and costly innovation processes, and with the participation of companies, Public Research Centers (PRC, including hospitals) and universities that are permeated by the market and regulation, and therefore by public-private dynamics.

Innovation and scientific-technological collaboration

Innovation is collective, cumulative and uncertain. In the case of vaccines, this process is quite clear. It is a collective process that involves a set of actors and productive and organizational resources, the integration of a diversity of knowledge, and of people with different training and skills, which functions as a network of agents, knowledge and institutions. The cumulative characterization refers to the basic and technological knowledge on which new knowledge and technological solutions are built, giving rise to improvements in products and processes or radical innovations. Previous knowledge is the basis for the advances in knowledge that are made today. The search for a vaccine against SARS-CoV-2 is based on the scientific and technological advances accumulated in universities, public research centers, laboratories, and R&D centers of companies and governmental and international institutions and organizations. In the development of new discoveries, such as vaccines, there is no guarantee that the research process will bear fruit quickly and with certainty, i.e., uncertainty is important, and someone must bear the cost. The discussion leads to a reflection on the participation of different actors to achieve a solution. Given the expected risks and benefits, who is willing to invest? It is assumed that the State must play a fundamental role in situations of high risk and high social impact, such as the development of

vaccines. In this regard, Jacobs & Mazzucato (2016) point out that the State should play a role as a "creator of opportunities," investing in higher risk stages of the process and playing the role of the market shaper, either by generating the conditions for a sector to develop, or by intervening in a public-private scheme for the creation of specific markets, and not only participating as an actor that corrects its failures.

In the vaccine industry, the process of discovery and commercial production has shifted from "random techniques" to "directed techniques," whereby the high degree of concentration of production in a small group of large multinational companies has been complemented by the entry of small biotechnology companies, starting with the revolution in this sector that began in the 1980s. These biotech companies play an important role in the early stages of the drug discovery process, while the large firms are in charge of the development stages, clinical trials, regulatory review, and marketing activities (Demirel & Mazzucato, 2010). However, the sector's market structure is still dominated by a few large multinational companies, which in many cases have absorbed small biotech companies. Four companies control 80% of it - Glaxo Smith Kline, Merck Sharp & Dohme, Sanofi and Pfizer, which totaled $24.87 billion in 2017 (Evaluate Pharma, 2017). Venture capital, typical of financial markets, was used in biotechnology once the state had financed the riskier and more capital-intensive stages in the development of this technology, which occurred 20 years later. Today, health biotechnology is one of the sectors most supported by the State in countries such as the USA, China, Germany, and Denmark.

The state and public-private coordination and financing mechanisms in public health care

There is a debate about the participation of these actors, their objectives and the interests that can be manifested in a process as complex as public health and science and technology. The State has played a fundamental role. From the perspective of orthodox economic theory, the participation of the State is justified when there are market failures, that is, when the price system is not capable of allocating resources efficiently in order to achieve the supply of all goods and services in an economy. In the health sector, a case in point is the production and supply of so-called orphan drugs for rare diseases, which do not allow the recovery of the capital invested in the research required to find the active molecule. Companies generally seek profitability and entering the market when obtaining returns is more certain. It is then that public investment covers these market failures; vaccines can be a typical case due to the high R&D costs they require, the component of uncertainty that accompanies the innovation process, and the complexity of the knowledge they are built on. From the perspective of this study, the State can assume other roles. In this respect, Polanyi (1944) argued that the State could be considered not only as an entity existing alongside markets in which public policy only aims at shaping them through regulations and

incentives. That is, the state must be deeply involved in creating markets since they are embedded in political and social institutions. Thus, the role of the State would be not to support the actions that are already being taken, but to carry out those that are not being taken, so that public policy appears as a creator of new scenarios. In the development of the vaccine against COVID-19, it is proposed that new participation schemes for public-private cooperation be designed. State participation in science through public support is not limited to the financing of basic and applied research but also includes financing early stages of innovation in companies, which are considered too risky by the private financial sector. In the last 50 years, the participation of the entrepreneurial State through public support for science and new technologies such as the Internet or nanotechnology has been very important (Jacobs & Mazzucato, 2016). In the pharmaceutical industry in the USA, it is estimated that 75% of the most innovative drugs owe much of their financing to funding from the National Institutes of Health. Vaccine development is the first link in the chain of a solution to the pandemic problem, including scale-up, manufacturing, distribution, and application in the population.

From the perspective of innovation studies and the idea of agents or actors, cooperation includes universities, public research centers, governments, and companies (Etzkowitz & Leydesdorff, 2000). The industry producing drugs and vaccines has a strong basis in the generation and application of knowledge, often produced in public research centers and linked to pharmaceutical companies, which receive public resources to finance R&D. The development of vaccines and other immunization innovations must undergo increasingly complex regulatory and manufacturing processes that are guided by the public sector. The participation of the State is decisive for vaccine licensing and the possible support of public and other agents and institutions in manufacturing, distribution systems and logistics that require coordination, as in the case of COVID-19 vaccines.

COVID-19 vaccine development

The need for a vaccine and its development phases

By November 2020, global infections were just over 60 million people, and deaths had exceeded 1.5 million. The speed of infections and deaths reflected the fact that mitigation of the pandemic had not been achieved, which is expected to occur once there are new effective treatments, especially with the development of a vaccine (Figure 1).

The process of developing a vaccine must pass a series of regulatory requirements in each country that are standardized at the international level and must be subject to scientific verification. Vaccines usually require years of research and testing before reaching the market, especially for those

infectious diseases that tend to be less lethal, often endemic infections that are not considered PHEIC [Public Health Emergency of International Concern], and for which there are currently no licensed vaccines. This process follows two testing stages: preclinical studies consisting of laboratory and animal testing, and the clinical studies stage, which are human trials comprising phases 1, 2 and 3. The first phase 1 trials in dozens of people primarily focus on safety. Data indicating clinical acceptability and immunogenicity in Phase 1 lead to Phase 2 trials, which often compare different immunization schedules or vaccine formulations and may be conducted in several different age groups. In phase 3, the number of individuals is expanded, and safety and efficacy are verified (WHO, 2020d). In the case of the COVID-19 vaccine and therefore of a pandemic, the PHEIC has been activated, which implies accelerating its development, approval and mass use (AVAC, 2020).

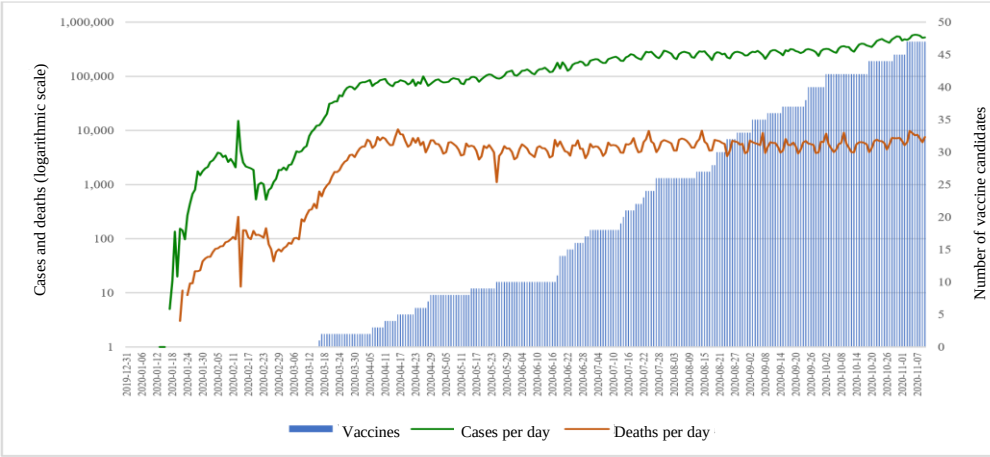


Figure 1. The COVID-19 pandemic worldwide
Cases of infection, deaths, and vaccine candidates in the clinical trials stage, as of November 12, 2020 (number and logarithmic scale)
Source: prepared by the authors based on CDC (2020), WHO (2020a).

COVID-19 vaccine candidates at the clinical trial stage

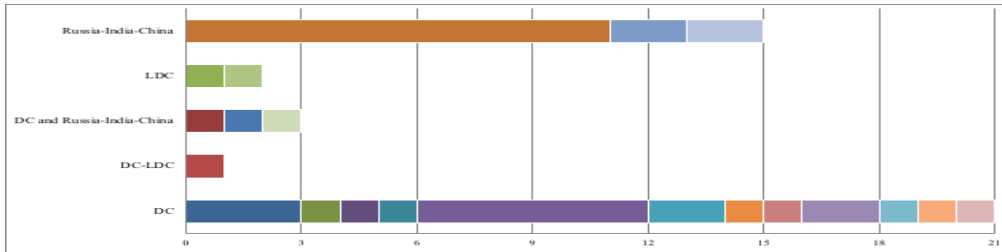
Development of the SARS-CoV-2 vaccine began in January 2020 with the virus genome sequencing. Phase 1 clinical studies began in March, and the first Phase 3 trials were in July of the same year. The process of developing the vaccine has been very fast compared to previous processes. Only 3.1 months later, the first study in humans was registered in a clinical trial that has been achieved in record time compared to other advances to address previous pandemics such as those caused by a virus of the same type (SARS coronavirus) or influenza A, in which the time to initiate clinical trials has been reduced by

almost seven times (Callaway 2020; WHO 2020b; WHO 2020c). As of October 15, 2020, there were 198 registered vaccine candidates, of which 27% are in clinical trials, and the remaining 73% are in early preclinical studies. The sample set includes vaccine candidates in the clinical trial stage (phases 1, 1 and 2, 2 and 3), which represent 27% and are comprised of 42 vaccine candidates. Of this population, 43% are in phase 1, 26% in phases 1 and 2, 10% in phase 2 and the remaining 21% in phase 3.

General characteristics of COVID-19 vaccine candidates

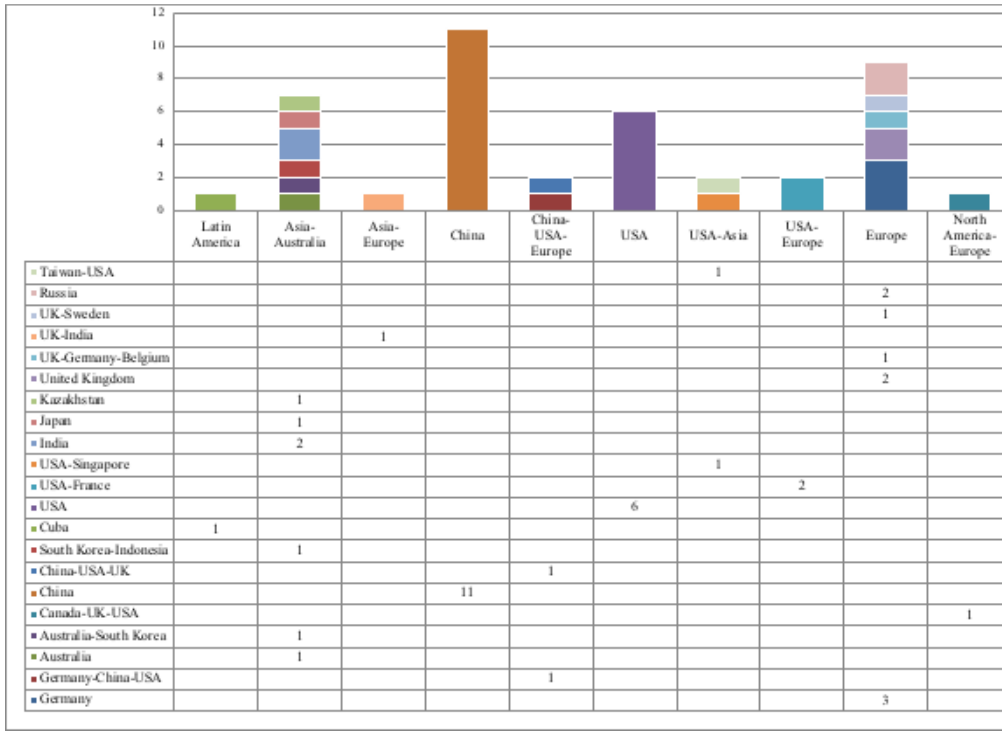
Characteristics by region and country of origin of the vaccine

Countries in Asia, Europe and the USA account for 98% and the remaining 2% are in Latin America. Only 19 countries are developing vaccines at the clinical trial stage, reflecting the concentration of efforts and the greater likelihood of access to approved vaccines. Developed countries (DC) are in the lead with 22 initiatives, followed by Russia-India-China (RIC) with 15 (Figures 2 and 3). It is worth noting the presence of less developed countries (LDC) (Kazakhstan, Indonesia and Cuba) and the absence of DC with known capabilities, such as Israel, Switzerland or the Netherlands, and of LDC such as Brazil or Mexico. There are companies from Italy and Austria that a British company recently acquired and another from the USA, which are in the race for the vaccine.



	DC	DC-LDC	DC and Russia-India-China	LDC	Russia-India-China
Germany	3				
Germany-China-USA			1		
Australia	1				
Australia-South Korea	1				
Canada-UK-USA	1				
China					11
China-USA-UK			1		
South Korea-Indonesia		1			
Cuba				1	
USA	6				
USA-France	2				
USA-Singapore	1				
India					2
Japan	1				
Kazakhstan				1	
United Kingdom	2				
UK-Germany-Belgium	1				
UK-Sweden	1				
Russia					2
Taiwan-USA	1				
UK-India			1		

Figure 2. COVID-19 vaccine projects by country group, 2020 (number as of October 15, 2020, n=42).
Source: created by the authors based on WHO (2020a).



	Latin America	Asia-Australia	Asia-Europe	China	China-USA-Europe	USA	USA-Asia	USA-Europe	Europe	North America-Europe
Taiwan-USA							1			
Russia									2	
UK-Sweden									1	
UK-India			1							
UK-Germany-Belgium									1	
United Kingdom									2	
Kazakhstan		1								
Japan		1								
India		2								
USA-Singapore							1			
USA-France								2		
USA						6				
Cuba	1									
South Korea-Indonesia		1								
China-USA-UK					1					
China				11						
Canada-UK-USA										1
Australia-South Korea		1								
Australia		1								
Germany-China-USA					1					
Germany									3	

Figure 3. COVID-19 vaccine projects by region, 2020 (number as of October 15, 2020, n=42).
Source: created by the authors based on WHO (2020a).

The USA and China are the leaders with 14 and 13 initiatives at the country level, respectively. The United Kingdom has seven projects, and Germany has five. These four countries account for more than half of the vaccine development efforts. In a third group are India with three initiatives and Korea, Australia, France and Russia with two. Finally, with one vaccine are Japan, Indonesia, Taiwan, Singapore, Sweden, Belgium, Kazakhstan, Canada and Cuba (Figures 2 and 3).

Type of vaccines by technology platform and stage of development

Vaccine development is carried out with a wide range of approaches using both conventional and more innovative technology platforms that seek to elicit an immune response. There are different classifications that helped arrange the 42 vaccine candidates into four types (Callaway, 2020; AVAC, 2020): protein-based (36%), genetic (24%), viral vector (24%) and inactivated virus (16%). Protein-based vaccines use a coronavirus protein or protein fragment. This platform is the new generation with the largest number of candidates and the most diversified as it appears in companies, PRC and universities, although none has

yet reached phase 3, which is the most advanced. In this platform, there was a Latin American presence with the vaccine from Cuba. Genetic vaccines use one or more of the coronavirus' genes to elicit an immune response and are being developed in most of the 19 participating countries. In this type of vaccine, the technological platform is highly complex; by using synthetic processes and not requiring culture or fermentation, they offer much faster development and manufacture. Viral vector vaccines use other viruses to introduce the coronavirus RNA into the cell. These vaccines are being developed in China, Asia and Australia, as well as in Europe and the USA (Table 1).

Table 1
COVID-19 vaccine development agents by type of collaboration, 2020 (number of vaccine candidates as of October 15, 2020, n=42).

Type of developer-agent/vaccine attributes	Vaccine type	Type of mechanism	Phases			
			1	1and2	2	3
a. Companies (10)			4	2	2	2
Beijing Minhai Biotechnology Co., Ltd. **	Inactivated viruses	-	1			
Sinovac **	Inactivated viruses	-				1
Zydus Cadila Healthcare Limited **	Genetics	-		1		
Novavax	Proteins	COVAX-OWS			1	
CureVac	Genetics	COVAX			1	
J&J-Janssen Pharmaceutical *	Viral vector	OWS				1
COVAXX-United Biomedical	Proteins	-	1			
Kentucky Bioprocessing (British American Tobacco Plc)	Proteins	-		1		
Medicago Inc.	Proteins	-	1			
Vaxart	Viral vector	-	1			
b. Companies (alliance) (6)			3	2		1
BioNTech/ Pfizer */ Fosun Pharma	Genetics	OWS				1
Clover Biopharmaceuticals Inc./GSK */ Dynavax	Proteins	COVAX	1			
Sanofi Pasteur */ GSK *	Proteins	OWS		1		
Arcturus Therapeutics/ Duke	Genetics	-		1		
ReiThera-GSK*/ Leukocare/ Univercells	Viral vector	-	1			
Vaxine Pty Ltd/Medytox	Proteins	-	1			
c. PRC/ University (11)			6	3	1	1
Bharat Biotech **	Inactivated viruses	-		1		
Chinese Academy of Medical Sciences, (Institute of Medical Biology) **	Inactivated viruses	-		1		

Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China **	Viral vector	-	1			
Imperial College London	Genetics	COVAX	1			
University Hospital Tuebingen	Proteins	COVAX	1			
FBRI SRC UK Vector, Rospotrebnadzor, Koltsovo	Proteins	-	1			
Gamaleya Research Institute	Viral vector	-				1
Instituto Finlay de Vacunas	Proteins	-	1			
Ludwig Maximilian University of Munich	Viral vector	-			1	
Research Institute for Biological Safety Problems, Rep. of Kazakhstan	Inactivated viruses	-		1		
West China Hospital of Sichuan University	Proteins	-	1			
d. Company with PRC/ University (15)			5	4	1	5
	Proteins	-	1			
Medigen Vaccine Biologics Corporation/ NIAID/ Dynavax **						
SpyBiotech/Serum Institute of India **	Proteins	-		1		
Walvax Biotech/People's Liberation Army (PLA) Academy of Military Sciences **	Genetics	-	1			
AstraZeneca* / University of Oxford	Viral vector	COVAX-OWS				1
Inovio Pharmaceuticals/ International Vaccine Institute	Genetics	COVAX-OWS		1		
Merck Sharp & Dohme*-Themis / Institute Pasteur/Univ. Pittsburg	Viral vector	COVAX-OWS	1			
CVR						
Moderna Therapeutics* / NIAID	Genetics	COVAX-OWS				1
CanSino Biological Inc./ Beijing Institute of Biotechnology	Viral vector	COVAX				1
University of Queensland/ CSL-Seqirus	Proteins	COVAX	1			
Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences	Proteins	-			1	
Beijing Wantai Biological Pharmacy/ Xiamen University	Viral vector	-	1			
Genexine Consortium	Genetics	-		1		
Osaka University/ AnGes/ Takara Bio	Genetics	-		1		
Sinopharm/ Beijing Institute of Biological Products	Inactivated viruses	-				1
Sinopharm/ Wuhan Institute of Biological Products	Inactivated viruses	-				1
Overall total (42)			18	11	4	9

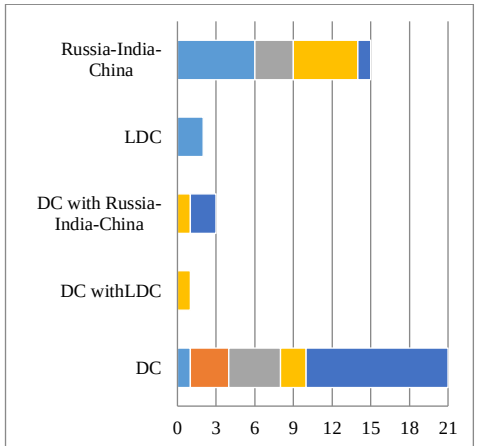
Notes: * world leading companies (Big Pharma)
** members of the Developing Countries Vaccine Manufactures Network (DCVMN)
Source: created by the authors based on WHO (2020a), Thanh *et al*. (2020a), Pagliusi *et al*. (2020) and AVAC (2020).

Finally, inactivated or attenuated virus vaccines use a weakened or inactivated version of the coronavirus; this technology predominates in Asia and Australia and is one of the most common in Chinese companies. It is the most conventional technology and is among the safest and most widely used to date. In phase 3, the most advanced, 21% of the vaccines are to be found, of which 14% are being

developed with more complex technologies (viral vector and genetic) and the remaining 7% with more conventional technologies, where there is more experience and safety in the process (inactivated viruses) (Table 1).

Nature and mechanisms of scientific collaboration and funding

There is a collaborative effort among agents either in the same country or at the international level. The collaboration includes alliances between companies (six cases, three with COVAX and OWS funding) and the PRC-university links with companies (15 cases, six with COVAX and OWS funding). In contrast, agents that do not collaborate include companies (10 cases, three with COVAX and OWS funding) and PRC-universities (11 cases, two with COVAX). There is significant collaboration among Developed Countries (DC) with 21 initiatives, three more with RICs, and one with a LDC, representing 60% of the vaccine candidates. Among these 25 projects, 11 are international collaborations of the COVAX initiative and the OWS program, two are PRC-university collaborations with companies (USA and Japan), three are alliances between companies, and only two are independent companies (USA, Canada and Germany). This composition shows the greater collaborative diversification with respect to the other types of countries and gives them an advantage in terms of access to scientific knowledge, risk sharing, and financial leverage. In a second group are the RIC countries with 18 vaccine candidates, of which three are with DC. Thirty-seven percent are from PRC and universities, 10% are from companies, and the remaining 53% are collaborative. Only 16% is with COVAX or OWS funding. The lower rate of collaboration with DC reflects their reluctance to link up, in addition to their relative institutional self-sufficiency. A third group of countries comprises LDC with only two initiatives. One is from a PRC in Cuba, and the other is from a PRC in Indonesia in partnership with a Korean company. This reflects their weak institutional and coordinating capacities (Table 1 and Figures 4 and 5).



	DC	DC withLDC	DC with Russia-India-China	LDC	Russia-India-China
PRC/ University	1			2	6
Company (alliance)	3				
Company (self financing)	4				3
Company with PRC/University	2	1	1		5
COVAX internacional public; OWS nacional	11		2		1

Figure 4. Covid-19 vaccine candidates by types of countries and agents (number as of October 15, 2020, n=42).

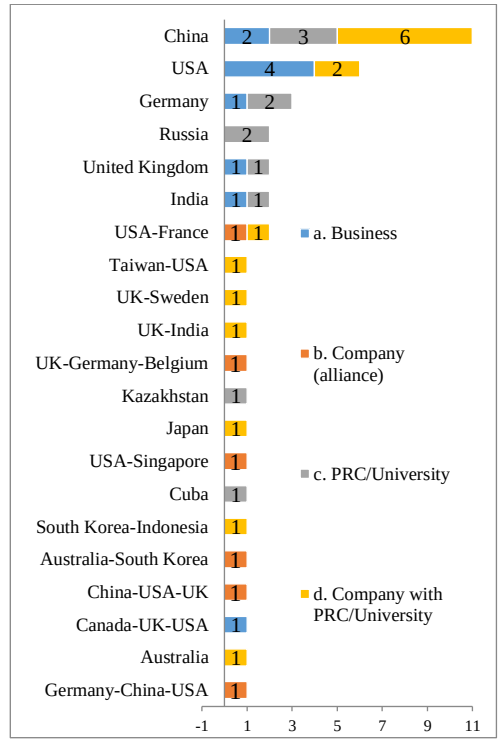


Figure 5. Covid-19 vaccine candidates by country and agent (number as of October 15, 2020, n=42).

Source: created by the authors based on WHO (2020a), Thanh *et al*. (2020a) and AVAC (2020).

By type of agent, as is the case at the country level, there is a high presence of companies (74%), either independently or in collaboration, among which are the Big Pharma world pharmaceutical leaders, like Astra Zeneca, Johnson & Johnson, Moderna, GSK, Sanofi, Merck Sharp & Dohme, or Pfizer and the recently acquired biotechnology companies RiuTher and Themis. In China, government participation in companies is significant, as in the cases of Sinopharm and Sinovac. The PRCs and universities have a participation of 62% (26% without collaborating and 36% collaborating with companies). In these PRC, the role of the State is decisive, as is the case in Russia, China, India and LDC such as Indonesia and Cuba. Although it is not surprising that companies lead the effort to develop vaccines, the participation of PRC and universities is very important, either independently or in collaboration with companies (62%), in networks of scientists together with companies or hospitals, or even following an independent path, especially in the PRC of emerging countries such as Cuba (Finlay Vaccine Institute) and Indonesia (Genexine Consortium) and the Serum Institute of India. The most significant funding (86%) is from the

multilateral COVAX initiative and the OWS program, mainly from European countries and the USA. Collaborative initiatives are higher in Asian countries, which participate in 100% of university initiatives with PRC and universities and 66% of alliances between companies (Table 1 and Figure 5).

Routes and processes for developing and distributing the COVID-19 vaccine

Based on concepts, data, and information collected and starting from the phenomenon, a GT-based (Walsh *et al*., 2015) argument was presented concerning the dynamics of vaccine development, identifying diverse collaboration patterns.

The pandemic and the complexity of rapidly developing an effective vaccine

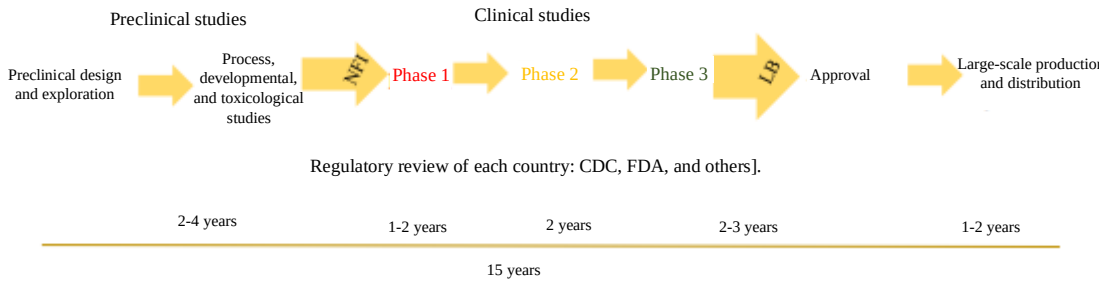
In developing and producing the COVID-19 vaccine, a new process is being constructed, more accelerated than the traditional one. In the traditional process, creating a new vaccine usually takes 12 to 20 years from its invention to its application and use, market incentives predominate, and Big Pharma companies lead it. The traditional process begins with a lengthy discovery phase in which vaccines are designed, and exploratory preclinical experiments and more formal toxicology studies are conducted. During this process, an "Investigational New Drug" (IND) application is submitted, followed by Phase 1, 2, and 3 trials. Once the results of the Phase 3 trials satisfy the evaluation criteria, a "Biologics License" (BL) application is submitted to the regulatory agencies that ultimately license the vaccine and the next stages of production, large-scale distribution, and sale are initiated (Figure 6).

The new process aims to develop a safe and effective vaccine as soon as possible. The WHO proposes a three-phase roadmap. In the first phase, research and funding will be coordinated globally with robust research protocols and tools and the rapid exchange of data and samples. In the second phase, there is rapid access to promising experimental programs, Randomized Controlled Trials (RCTs), and the use of generic/central protocols for accumulating robust evidence. Phase 3 refers to cost-effective technological and cost-effective scale-up, consideration of innovations with real potential for scale-up, and independent economic evaluation of markets and access (WHO, 2020b). This pathway encompasses three actions. The results of tests applied in the preclinical and clinical stages have been shared in the scientific area. In the regulatory area, flexibility mechanisms have been activated to allow the combination of phases by skipping the discovery phase, taking advantage of the knowledge acquired with the SARS-CoV-1 and MERS-CoV vaccine, and adopting existing processes and initiating phase 1/2 trials. Phase 3 trials were initiated after an interim analysis of Phase 1/2 results with several stages of clinical trials in parallel. They were done in the area of manufacturing and access through early manufacturing schemes

in which public and private entities fund the production of large quantities of the most promising candidate vaccines (AVAC, 2020) (Figure 6).

In the meantime, vaccine producers began a large-scale "Good Manufacturing Practices" production at risk. The licensing pathway or mechanism is still unclear, although Moderna has announced it will license patents related to its COVID-19 vaccine as long as the pandemic continues (Loftus, 2020). The proposal reflects greater public-private collaboration in multiple areas: in inter-institutional and corporate investment; in scientific research; in regional manufacturing agreements; in knowledge and data sharing; and in the activation of formal and informal groups among scientists and even the presence of PRC from LDC as development agents. In addition, regulatory agencies such as the FDA have promoted unprecedented flexibility and speed for laboratories and manufacturers to develop and offer COVID19 testing for the development and availability of medical products and equipment for use by patients, physicians and health systems. The generation of solutions to emerging problems such as the one faced with COVID-19 is not based on scientific knowledge alone, although this is crucial, but on the coordination of scientific, technological, financial, and institutional resources and capabilities (Figure 6).

I. The traditional route: market acceleration



II. The COVID-19 vaccine pathway: global public-private concerted acceleration

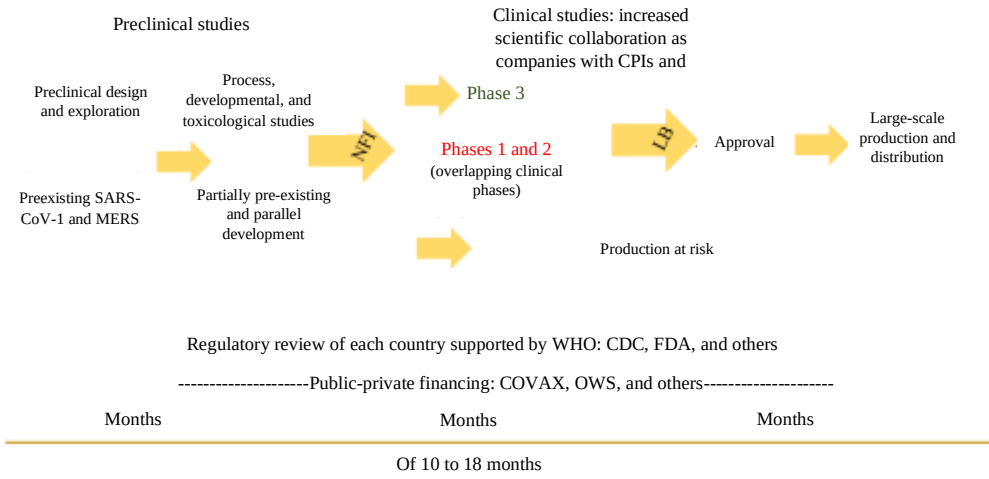


Figure 6. Routes to develop traditional and COVID-19 vaccines
Source: created by the authors based on Krammer (2020).

International COVAX initiatives and the Operation Warp Speed (OWS) program

The COVID-19 challenge is unprecedented and can only be faced with cooperation between PRC and universities, developers and manufacturers, governments, and multilateral partners.

The COVAX initiative

The COVAX initiative was created in April 2020 to drive the development, production, and fair and equitable access to the COVID-19 vaccine, framed within the WHO COVID-19 Vaccine Accelerator (ACT) strategy (COVAX, 2020a). COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI)—an innovative partnership between public, private, philanthropic, and civil organizations launched in Davos in 2017 to develop vaccines to stop future epidemics—, the Global Alliance for Vaccines and Immunization (GAVI)—a public-private partnership created in 2000, helping to vaccinate children around the world against some of the world's deadliest diseases—, and the WHO, created in 1948 as a UN institution. COVAX's goal is to develop at least three safe and effective vaccines, which are estimated to cost $2.1 billion dollars (CEPI, 2020). The initiative guarantees access through upfront contributions as a guarantee of a defined share from member countries, mutualizing the associated risks. This includes the commitment to "Advance Market Commitment" (AMC), where the public sector and philanthropic donors negotiate a price and plan the purchase and distribution of vaccines before the

vaccine testing process is completed (COVAX, 2020a). The initiative aims to produce two billion vaccine doses and distribute them in all 172 member countries (WHO, 2020c). As of September 2020, $1.255 billion dollars had been allocated (COVAX, 2020b). This initiative registers nine vaccine projects, of which two, Astra Zeneca-Oxford University and Novavax, account for 90.4% of the allocated funding. The initiative has a global scale and significant public-private collaboration (Figure 7).

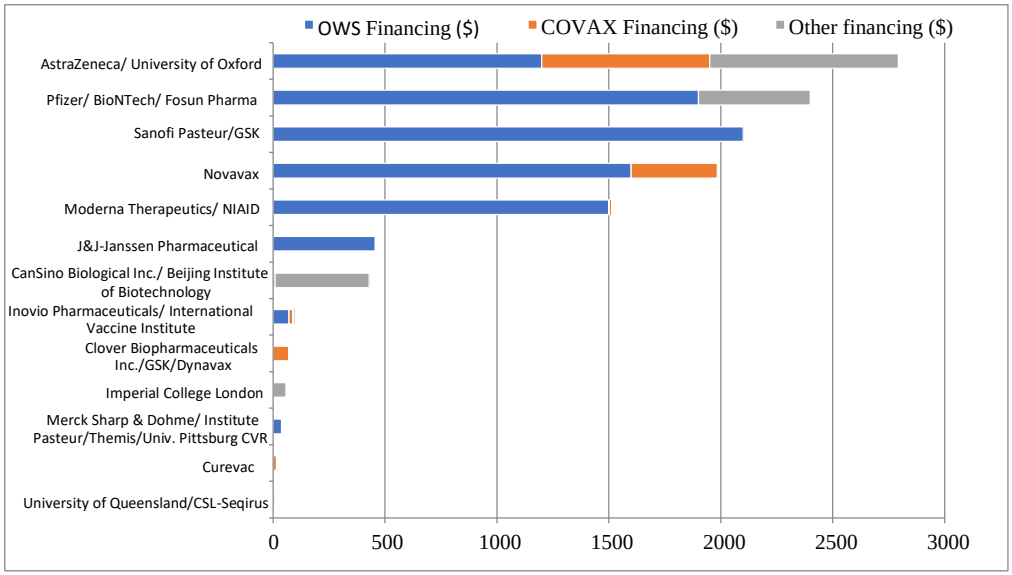


Figure 7. Companies with international COVAX, OWS program and corporate financing, as of September 17, 2020 (millions dollars).
Source: created by the authors with data from CEPI (2020), COVAX (2020b), AVAC (2020), Thanh *et al*. (2020a), and company reports.

The Operation Warp Speed program

This program comes from the U.S. government through a partnership of the Department of Health and Human Services (HHS), the Department of Defense, and the private sector, announced on May 15, 2020 (Slaoui & Hepburn, 2020). The goal is to rapidly control the COVID-19 pandemic through the advanced development, manufacture, and distribution of vaccines and diagnostic tests. The program envisages producing and managing 300 million doses by January 2021. This initiative is based on the experience of by the U.S. National Institutes of Health (NIH) in combating the Zika virus. In this scheme, companies will execute the clinical and development and manufacturing processes, while the OWS program seeks to leverage the capacity of the US government to ensure that there are no technical, logistical, or financial

burdens that limit the development and deployment of vaccines (Reina et al., 2014). Candidates must have the potential to enter Phase 3 between July and November 2020 and be on technology platforms that enable rapid and effective vaccine manufacturing, demonstrate industrial scale-up of the process, and demonstrate that more than 100 million doses can be produced by mid-2021. This program has the largest resources ($8,865 million), five times those of the COVAX initiative (COVAX, 2020a and b).

There are eight vaccine projects in this program, mainly involving US companies such as Novavax, J&J, GSK, Pfizer, Moderna, Inovio, and Merck, either independently or in collaboration with US universities or PRCs, such as the National Institute of Allergy and Infectious Diseases, the International Vaccine Institute, and the University of Pittsburgh. The only non-US project is Astra Zeneca's British vaccine with the University of Oxford. This group includes the world's leading Big Pharma vaccine developers, which account for 80% of the global vaccine market (Table 1 and Figure 7). The program is framed within the process described by Jacobs and Mazzucato (2016), from which it assumes entrepreneurial functions in the production process and especially when there is high risk or uncertainty, as is the case of the health crisis, and which are combined with the electoral periods of the financing country. This initiative has a "nationalist" orientation since it mainly targets the US population.

Other corporate and emerging country initiatives

Finally, other initiatives come from emerging countries and diverse agents such as companies, foundations, PRC, universities, or other public support, in which they have allocated an amount of $1.826 billions dollars (Figure 7). In the case of emerging countries, there are nine vaccine projects involving thirteen members of the Developing Countries Vaccine Manufactures Network (DCVMN), created in 2000. This alliance represents vaccine manufacturers involved in the research, development, manufacture, and supply of vaccines for local and international use to protect all people against known and emerging infectious diseases. Members of this network are noted for their proven manufacturing, formulation, filling, packaging, and distribution capabilities (Pagliusi *et al*., 2020). They are familiar with international regulations and supply mechanisms, including international standards, packaging requirements, labeling, and regulatory pathways to distribute vaccines across borders safely.

Collaboration and competition in COVID-19 vaccine development and access

Patterns of collaboration and competition range from public-private partnerships to those that rely predominantly on market mechanisms.

The growing public-private partnership

The production of the COVID-19 vaccine has marked the beginning of greater coordination and collaboration between governments, scientists, technologists, companies, and multilateral funding and research partners that goes beyond the logic of the market and reflects a global effort to control the SARS-CoV-2 pandemic. The goal of international collaboration is to exploit complementary capabilities, increase their international visibility, share costs of large-scale and far-reaching projects, exchange ideas and data, and obtain a commitment to joint activities and funding from governments (via agencies, institutes, universities and special programs), quasi-governmental bodies such as the World Bank, and non-governmental organizations such as the Bill and Melinda Gates Foundation (Wagner, 2006), which is only 5-10% of total funding (Loftus, 2020).

Vaccine funding resources are concentrated in a small group of DC (US, UK and France) and are being directed to vaccines with more technologically dynamic platforms. The companies closest to getting their vaccine approved have had public funding from COVAX or the OWS program, and many of them are global leaders. So far, COVAX has secured several tens of millions of doses from development companies at low prices. These agreements are evidence of greater interagency and international collaboration, and greater global inclusiveness in accessing the vaccine. In contrast, LDC are on the margins of supranational financing, which shows the institutional differences and the limited participation of other companies and PRC, especially from LDC or RICs, which reduces the possibilities of developing a greater number of vaccines and also of reducing the structural gaps in knowledge and technology (Table 1 and Figure 7). Initiatives such as COVAX, the OWS program, and others are applying different approaches to accelerate the development of the COVID-19 vaccine not only through collaborative research and development, but for the rapid approval of vaccines proven to be safe and efficient, as well as for the global population to have access to it, regardless of their different income levels (WHO, 2020c).

Patterns of collaboration and competition: Development and access

In the vaccine market, pharmaceutical development and production companies in principle follow their own logic in which they try to maximize their profitability by reducing investment risk. It is not surprising that the leading vaccine production Big Pharma companies are among the frontrunners to develop the vaccine for COVID-19, as they are for any other disease. When a disease becomes a pandemic and turns into a global emergency, multilateral institutional mechanisms are activated to accelerate vaccine production and decrease its impact, as has happened in the last previous experiences of other diseases such as Zika, Lassa, Chikungunya, Marburg, SFTS, Nipah, Ebola, MERS, or SARS (Gouglas *et al.*, 2018) and

even with global initiatives that have emerged since 2013 (Kieny *et al.*, 2020). This collaboration pattern involves other regulatory agents such as States and multilateral institutions that create incentives and coordinating mechanisms between public and private agents to collectively explore and exploit scientific and technological capabilities to create the vaccine. In this logic, the State tries to solve a market failure in the initial stages of vaccine development in which high R&D investments are required that do not necessarily reach the user or market, and also cover market failures in the later stages of scaling up and manufacturing, and even access to the end user. This pattern identified with the COVAX initiative focuses on all stages to solve the pandemic, from development (R&D), manufacturing, and mass access to the vaccine, including the population of high and low-income countries. This initiative involves the coordination of efforts between countries, multilateral institutions, and companies, making possible the financing of private and public companies and institutions to develop a vaccine with the characteristics of a semi-public good by disseminating it at lower prices so that lower income countries without the resources to pay for it can use it, assuming the criteria of equity and justice (Table 2).

On the other hand, the "nationalistic" OWS collaboration pattern is a US Government initiative in which all stages of vaccine development, from R&D to manufacturing, will be supported. In this scheme, it can be deduced that access will be mainly for US citizens. This initiative is dominated by public funds and would be less global in scope than COVAX. It focuses more on accelerating production and does not identify any equitable global access strategy. This scheme, unlike COVAX, does not propose mechanisms beyond those of the market. In the other patterns, such as those of "companies with PRCs and universities" and "companies," a market logic or agreements between countries and companies prevail, where consumers ensure their access through the price mechanism (Table 2).

Table 2
Patterns of development and access to the COVID-19 vaccine

Type of pattern	R&D and vaccine development	Scale-up and Manufacturing	Distribution and access	Scope
Supranational public-private partnership (COVAX initiative)	Multilateral agreements between governments, CPIs and companies	Initiatives between countries and multilateral agencies	Pre-purchase distribution agreements	Global
Nationalist public-private partnership (OWS program)	Government (U.S.) agreements with agents	Funding country initiative (USA)	National, (countries with agreement)	National (countries with agreement), limited Limited

Collaboration between companies with CPIs and universities	Agreements between agents	Initiatives between public and private agents	Agreements with public and private agents	
Competition between companies. Market	Own efforts	Own efforts	Market (prices)	Limited

It is not excluded that lower income countries will have difficulty accessing vaccines despite the push for mechanisms such as COVAX. Higher-income countries have already reached agreements to purchase more than 2.8 billion doses of vaccines, which could leave a limited supply in the market by 2021. By the end of August, the U.S. had secured 800 million doses of at least six of the vaccines in development, with an option to buy a billion more. Japan has made bilateral arrangements and European nations are buying partner vaccines in groups. The European Commission has signed contracts with Oxford-Astra Zeneca, Moderna, Pfizer-BioNTech-Fosum Pharma, Novavax, Sanofi-GSK, CureVac, and Jansen to purchase about 2 billion doses. The United Kingdom has purchased the equivalent of five doses for each of its inhabitants. The question remains about the capacity to manufacture the doses the world requires. Some technologies, such as genetics, have never been produced in the volumes that manufacturing companies expect to achieve. Given the size of the world's population, the vaccine portfolio aims to reduce the risk involved in the novelty of the challenge. Global collaboration and coordination should be reinforced as a permanent initiative, strengthening mechanisms for the development, production, and access of products such as vaccines.

Conclusions

The COVID-19 vaccine development process is framed in a scheme that contains elements related to the characteristics of innovation, competition, and collaboration of the traditional pharmaceutical industry, coupled with greater coordination and collaboration between governments, researchers, companies, and multilateral partners in research and funding that go beyond the logic of the market. The 42 vaccine candidates in the final stage of clinical trials reflect the early response to the global emergency. Although only 19 countries are participating at this stage, the increased presence of companies, PRCs, and universities is evident, in which not only the typical multinational vaccine development companies are involved, but also new entrants, especially from RICs and LDCs, are participating. Overall, the DCs and RICs are participating in more initiatives, especially the USA and China, while Africa and Latin America are practically absent. With 50% of the initiatives, there is a clear need for collaboration between private (companies) and public agents (PRCs, universities, governments, and national and international regulatory

institutions), as well as the implementation of cooperation mechanisms throughout the process of vaccine development, manufacturing, and distribution. Although there was a previous background of collaboration among this diversity of actors at various levels of breadth and depth, the speed of response to the pandemic has accentuated these programs in which incentives and requirements are combined to drive collaboration and acceleration in regulation. Twenty-six percent of vaccine candidates are developed in simultaneous phases 1 and 2.

The speed of development of vaccines against COVID-19 is made possible by the accumulated knowledge and the institutional and coordinating capacities among companies, PRC-universities, and regulatory agencies from the countries that have formed new public-private collaboration schemes. Collaboration has been more intense than in previous epidemics or pandemics since, with COVID-19, there has been greater regulatory flexibility and new public-private coordination. Furthermore, financing mechanisms have been generated to promote international acceleration. This acceleration of the COVID-19 vaccine reflects four patterns of cooperation or competition among companies, PRC, and universities from which the capacity to rapidly manufacture, fill, finish, and supply the necessary COVID-19 vaccines was anticipated. The first, of a multilateral nature, is promoted by organizations such as the WHO and appears to be the one with the greatest scope and access among countries. The second is driven by the U.S. government and has the greatest public resources but is of limited scope, given that the preferential distribution will be to the U.S. population. The third pattern encompasses collaboration between PRC and universities, especially public universities with the support of national governments and companies in which development, manufacturing, and access will be defined by the collaboration agreements between the two agents. Finally, the pattern of competition among companies follows a market behavior guided mainly by price criteria.

Vaccines for epidemic infectious diseases need the world's attention and investment efforts, as they are costly and would not be profitable for a single agent or private company. Hence the importance of linking PRC and universities with companies to accelerate the initial stages of the vaccine, more associated with the knowledge base in genome sequencing and preclinical stage. In this process, the basic research capabilities generated in the PRC and universities are amalgamated with those generated in the companies. Collaboration between agents and countries is necessary to respond effectively, not only to this, but also to possible future epidemics, accelerating the development of and access to vaccines and other medical solutions, thus avoiding humanitarian crises.

The development of the COVID-19 vaccine has benefited from previous experiences of global collaboration that have fostered the relaxation of requirements to validate subsequent phases up to vaccine manufacture, decreasing the amount of data or testing, without compromising the vaccine's safety. The process appears to reflect an agreement for greater collaborative participation and inclusiveness at the

global level. However, if this scheme remains a purely immediate and short-term response, it will never contribute to reducing the existing structural gaps in the world in terms of knowledge and technology, and therefore to reducing the exclusion of the least developed countries. The outbreaks in recent years indicate that humanity will be threatened repeatedly and more frequently than before by this type of pandemic, so it is necessary to be prepared to respond rapidly to emergencies of great social impact. These collaborative experiences should be strengthened, and the capabilities of each agent should be considered, combining the incentives to achieve a result of collective benefit that could even be used again to address other dilemmas such as the environment, the development of alternative energies, and the deciphering of the human genetic code. Evidently, the benefits achieved should be governed by globally shared economic, political, and social allocation criteria. Therefore, public-private collaboration and coordination could play a greater role, together with competition mechanisms, in the development of future treatments and vaccines. This experience could be the basis for anticipating and solving global problems such as those related to climate change, migration, drug trafficking, or new pandemics.

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