



## EN ESTE NÚMERO

VacCiencia es una publicación dirigida a investigadores y especialistas dedicados a la vacunología y temas afines, con el objetivo de serle útil. Usted puede realizar sugerencias sobre los contenidos y de esta forma crear una retroalimentación que nos permita acercarnos más a sus necesidades de información.

- Resumen de la información publicada por la OMS sobre los candidatos vacunales en desarrollo contra la COVID-19 a nivel mundial.
- Noticias más recientes en la Web sobre vacunas.
- Artículos científicos más recientes de Medline sobre vacunas.
- Patentes registradas más recientes en PatentScope sobre vacunas.
- Patentes más recientes en USPTO sobre vacunas.

## Resumen de la información publicada por la OMS sobre los candidatos vacunales contra la COVID-19 en desarrollo a nivel mundial

Última actualización por la OMS: 26 de febrero de 2021.

Fuente de información utilizada:



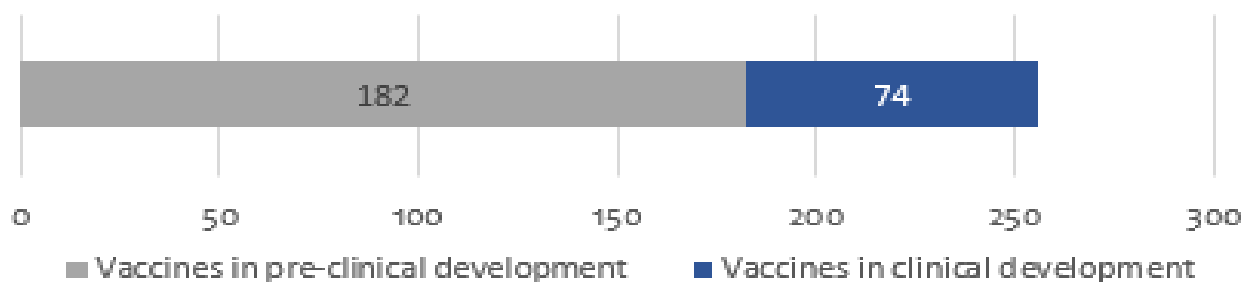
World Health Organization



R&DBlueprint

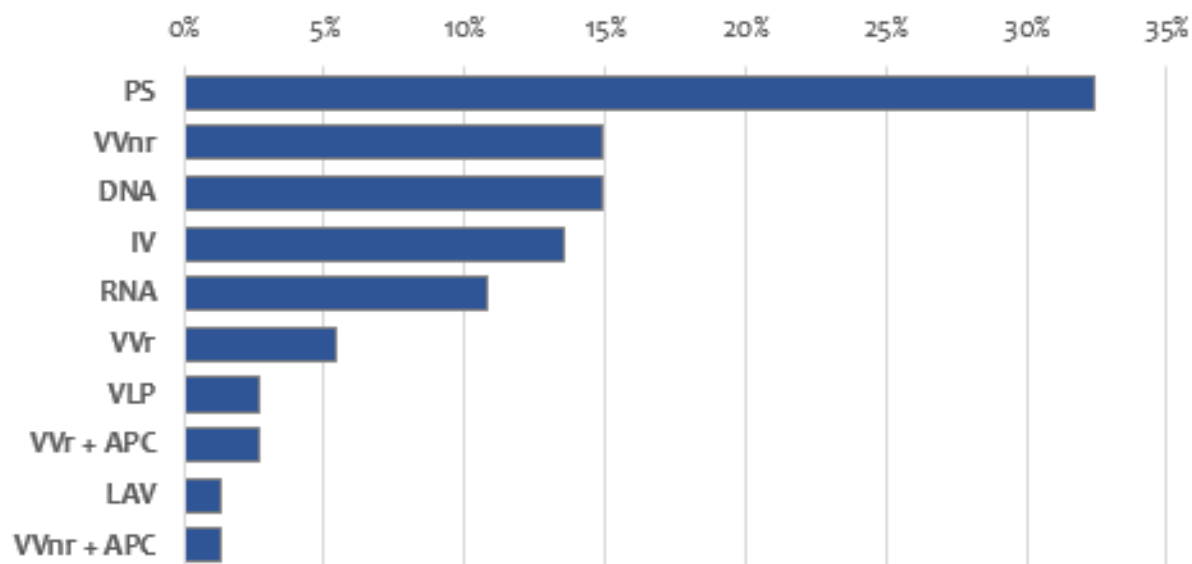
Powering research to prevent epidemics

74 candidatos vacunales en evaluación clínica y 182 en evaluación preclínica.



### Candidatos vacunales en evaluación clínica por plataforma

Platform	Candidate vaccines (no. and %)
PS	Protein subunit 24 32%
VVnr	Viral Vector (non-replicating) 11 15%
DNA	DNA 11 15%
IV	Inactivated Virus 10 14%
RNA	RNA 8 11%
VVr	Viral Vector (replicating) 4 5%
VLP	Virus Like Particle 2 3%
VVr + APC	VVr + Antigen Presenting Cell 2 3%
LAV	Live Attenuated Virus 1 1%
VVnr + APC	VVnr + Antigen Presenting Cell 1 1%
	<b>74</b>



## Candidatos vacunales más avanzados a nivel global

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Fase
Sinovac/China	Virus Inactivado	4
Wuhan Institute of Biological Products/Sinopharm/China	Virus Inactivado	3
Beijing Institute of Biological Products/Sinopharm/China	Virus Inactivado	3
University of Oxford/AstraZeneca/Reino Unido	Vector viral no replicativo	4
CanSino Biological Inc./Beijing Institute Biotechnology/China	Vector viral no replicativo	3
Gamaleya Research Institute/Rusia	Vector viral no replicativo	3
Janssen Pharmaceutical Companies/Estados Unidos	Vector viral no replicativo	3
Novavax/Estados Unidos	Subunidad proteica	3
Moderna/NIAID/Estados Unidos	ARN	4
BioNTech/Fosun Pharma/Pfizer/Estados Unidos	ARN	4
Anhui Zhifei Longcom Biopharmaceutical/Institute of Microbiology, Chinese Academy of Sciences	Subunidad proteica	3
CureVac AG	ARN	3
Institute of Medical Biology/Chinese Academy of Medical Sciences	Virus inactivado	3
Research Institute for Biological Safety Problems, Rep Kazakhstan	Virus inactivado	3
Inovio Pharmaceuticals/International Vaccine Institute/Advaccine (Suzhou) Biopharmaceutical Co., Ltd	ADN	2/3
AnGes/Takara Bio/Osaka University	ADN	2/3
Zydus Cadila Healthcare Ltd.	ADN	3
Bharat Biotech/India	Virus Inactivado	3
Clover Biopharmaceuticals Inc./GSK/Dynavax	Subunidad proteica	2/3
COVAXX/United Biomedical Inc.	Subunidad proteica	2/3
Medicago Inc./Canadá	Partículas similares a virus	2/3

## Candidatos vacunales mucosales en evaluación clínica

Desarrollador de la vacuna/fabricante/país	Plataforma de la vacuna	Vía de administración	Fase
Symvivo/Canadá	ADN	Oral	1
Codagenix/Serum Institute of India	Virus vivo atenuado	Intranasal	1
Vaxart/Estados Unidos	Vector viral no replicativo	Oral	1
Jiangsu Provincial Center for Disease Prevention and Control	Vector viral replicativo	Intranasal	2
ImmunityBio, Inc.	Vector viral no replicativo	Oral	1
Center for Genetic Engineering and Biotechnology (CIGB)	Subunidad proteica	Intranasal	1/2
Altimmune, Inc.	Vector viral no replicativo	Intranasal	1
University of Hong Kong, Xiamen University and Beijing Wantai Biological Pharmacy	Vector viral replicativo	Oral	1

## Cantidad de dosis propuestas para los candidatos vacunales en evaluación clínica

Number of doses & schedule	Candidate vaccines (no. and %)	
<b>1 dose</b>	<b>12</b>	<b>16%</b>
Day 0	12	
<b>2 doses</b>	<b>46</b>	<b>62%</b>
Day 0 + 14	6	
Day 0 + 21	17	
Day 0 + 28	23	
<b>3 doses</b>	<b>1</b>	<b>1%</b>
Day 0 + 28 + 56	1	
<b>TBD / No Data (ND)</b>	<b>15</b>	<b>20%</b>

## Noticias en la Web

### Pfizer eyes higher prices for COVID-19 vaccine after the pandemic wanes: exec, analyst

**23 feb.** Amid the high-stakes fight against COVID-19, a company at the forefront of the vaccine effort is laying plans to hike prices after the crisis. A top Pfizer exec said the drugmaker aims to charge more after the "pandemic pricing environment," and an influential analyst says the company could be eying prices 3 to 4 times higher.

On an earnings call earlier this month, Chief Financial Officer Frank D'Amelio said that "obviously," the company is "going to get more on price" after the "pandemic pricing environment." He was speaking in response to Bank of America Merrill Lynch analyst Jason Zemansky, who asked the management team about how profit margins for the program could change over time.

In short, D'Amelio explained that Pfizer expects its COVID vaccine margins to improve. Under one pandemic supply deal, Pfizer is charging the U.S. \$19.50 per dose, D'Amelio said, which is "not a normal price like we typically get for a vaccine—\$150, \$175 per dose. So, pandemic pricing."

As a specific for-instance, a dose of Pfizer's pneumococcal vaccine Prevnar 13 costs more than \$200 on the private market in the U.S., according to Centers for Disease Control and Prevention data.



Pfizer has said it expects \$15 billion from its COVID-19 vaccine this year, but if the company charges higher prices after the pandemic, it could continue to reap significant sales from the product in the years to come, particularly if routine boosters are needed as variants arise.

Even as Pfizer uses "pandemic pricing" during the crisis, the company is also paying for materials, labor, factory overhead, shipping, distribution costs and more to deliver doses, D'Amelio said. With all of its costs, "you come out with the high 20s in terms of that as a percentage of revenue," the CFO said.

Moving into the future, after the pandemic period, Pfizer is "going to get more on price," and will increase output at its factories,

driving production costs per unit lower, the CFO said. In all, D'Amelio said there's a "significant opportunity for those margins to improve once we get beyond the pandemic environment that we're in."

Bernstein analyst Ronny Gal picked up on the comments and highlighted a recent report in Germany's Sueddeutsche Zeitung in a Monday note to clients. The publication reports that Pfizer and BioNTech approached European officials seeking €54 per dose, or €27 billion for 500 million doses, last summer.

While officials negotiated the price down to €15.50 per dose, Gal suspects that all of the developments indicate a "first hint" of Pfizer's thoughts on "post-epidemic pricing." The deal, in addition to other European supply pacts, was large enough to be "at least partially ... for post-pandemic use," Gal figured.

A Pfizer representative said in a statement these are "extraordinary times, and our pricing reflects that."

"During the pandemic, we priced our vaccine consistent with the urgent global health emergency we are facing to ensure widespread vaccination for all countries," he added. During government supply negotiations, the company considers volume and equitable distribution aims, he said, and has a "tiered pricing approach that enables poorer countries to pay less."

"Moving forward, we will continue to take a thoughtful approach to pricing, balancing a number of factors—including the value of the vaccine based on the growing evidence base, and access, affordability, and sustainability considerations," he added.

In initial deals with the U.S. government, Pfizer and BioNTech's vaccine costs \$19.50 per dose, compared with \$15 for Moderna's shot, \$16 for Novavax's program, \$10 for Johnson & Johnson's vaccine and \$4 for AstraZeneca's.

Pfizer didn't take any government development funds for its shot, while other players received various amounts of assistance, and Pfizer was the first to reach the market.

The drugmaker isn't alone in viewing vaccine pricing differently during the pandemic and afterward. Johnson & Johnson and AstraZeneca have each pledged to sell their vaccines on not-for-profit basis during the pandemic.

Fuente: FIERCE Pharma. Disponible en <https://cutt.ly/Ml34B51>

## New vaccine needed for serious childhood pneumonia

**24 feb.** A rise in vaccine-resistant bacteria shows the need for a new vaccine to fight childhood empyema after a spike in hospitalisations, a new UNSW study reveals.

A UNSW Sydney-led medical research team has called for a new vaccine, improved strategies and enhanced monitoring to combat serious complications from childhood pneumonia.

The researchers examined the impact of the 13-valent pneumococcal conjugate vaccine (13vPCV) on childhood pneumonia and empyema – complicated pneumonia – after its introduction to the Australian National Immunisation Program about a decade ago.

The new study, published in *Thorax* recently, found that while 13vPCV resulted in a 21 per cent

decrease in childhood pneumonia hospitalisations, there was a contemporaneous 25 per cent increase in admissions for empyema.

This incidence data for childhood empyema hospitalisations is similar to that reported in other countries.

Approximately 7000 Australians under the age of 18 are hospitalised with pneumonia each year.

Senior author Professor Adam Jaffe, Head of the School of Women's and Children's Health at UNSW Medicine & Health, said the researchers' findings suggested an emergence of non-vaccine serotypes – those which 13vPCV does not cover.

13vPCV was introduced to cover the 13 most common serotypes responsible for invasive

pneumococcal infection, extending coverage to six additional serotypes including 1 and 3.

The previous vaccine (7vPCV) covered seven serotypes. A serotype is a distinct variation within a bacteria species.

Prof. Jaffe said: "Although we found a substantial reduction in serotype 1, serotype 3 is now the predominant organism which causes childhood empyema – in 76 per cent of cases – so, efforts must be made to create a vaccine which is more effective against serotype 3.

"In fact, Australia recently changed the vaccination dosage schedule to try and improve the effectiveness of 13vPCV against serotype 3, but we need to continue monitoring patients using molecular techniques to see if this change has had an impact.

"Childhood bacterial pneumonia and empyema are potentially

preventable diseases through vaccination. So, if Australia can develop an effective vaccine, we could prevent children from being hospitalised with pneumonia and empyema.”

Empyema is infected fluid around the lungs and about 1 per cent of children hospitalised with pneumonia develop it.

Although children are highly unlikely to die from empyema, they can expect a long stay in hospital for treatment with antibiotics and surgery, or the insertion of a drain. If adults develop empyema, about a third are likely to die.

### **Continuing enhanced surveillance needed**

The researchers conducted a similar study during the period of the superseded 7vPCV. Their new study – which took four years to complete – is part of a broader research project on 13vPCV.

“Our new study had two parts,” Prof. Jaffe said. “We analysed national hospitalisations for childhood empyema and

childhood pneumonia, then we conducted an enhanced surveillance study on children with empyema.”

The first part of the research used publicly available hospitalisations data – about 36,000 admissions – to assess whether the introduction of 13vPCV changed how many children were admitted to hospital with pneumonia and empyema.

The enhanced surveillance study involved the collection of blood and lung fluid samples from 401 children with empyema from February 2015 to September 2018.

The children were receiving treatment in 11 major children’s hospitals across Australia.

Most children were boys (208 or 52 per cent) and the median age was four years old.

The researchers then conducted molecular testing on these samples and compared the results to their previous study undertaken during the period of 7vPCV.

The multidisciplinary team included Dr Nusrat Homaira, of the Discipline of Paediatrics at UNSW Medicine & Health, and paediatric research nurse Roxanne Strachan of Sydney Children’s Hospital.

Prof. Jaffe said: “Our new research is the first of its kind in Australia – so, we now have the best data available for complicated childhood pneumonia to help guide future vaccination introductions and improve vaccine strategies.

“We are currently working on our larger study, of which this was a subset, to examine the effectiveness of 13vPCV on children with bacterial pneumonia. We will need to repeat the study in a few years’ time to help with monitoring.

“In the meantime, it would make a big difference if molecular testing of patients’ lung fluid was routine in laboratories, because that would ensure we had the best real-time data available which will help rationalise antibiotic choice; also, we would have no need to seek funding to undertake this much-needed research.”

Fuente: Mirage News. Disponible en <https://cutt.ly/fl35ka9>

## **How do we know the COVID vaccine won’t have long-term side-effects?**

**24 feb.** As Australia’s COVID-19 vaccine rollout begins this week, many people still have questions about the safety of COVID-19 vaccines, both in the short and long term.

As vaccine experts, we hear these concerns all the time, and

it’s normal to have questions about a vaccine.

The good news is that scientists have already been testing COVID-19 vaccines for months. For starters, serious side-effects are very, very rare. And, together with what we know about previous

vaccines, if side-effects are going to occur, they usually happen within a few months after getting a vaccine. This is why international medical regulators, including Australia’s Therapeutic Goods Administration (TGA), require the first few months of safety data before approving new

vaccines. This, plus information coming from vaccine recipients in the northern hemisphere, gives us confidence that COVID-19 vaccines are safe.

In fact, most side-effects occur within the first one or two days. And most of these are minor, such as pain at the injection site, fatigue or fever — which are signs your immune system is building a response against the thing you've been vaccinated against.

### What do we know about long-term side effects?

Since December, more than 200 million people have received at least one dose of a COVID-19 vaccine worldwide — more than the total number of people who have been infected with the virus (112 million).

Given the sheer number of vaccines administered to date, common, uncommon and rare side-effects would have been detected by now. What's more, we've been testing these vaccines in clinical trials since mid-2020, and both the Pfizer and AstraZeneca vaccines have shown excellent safety results.

This gives us confidence the vaccines that'll be used around Australia are safe.

We've also seen some people raise concerns online about mRNA vaccines, such as the Pfizer-BioNTech vaccine, being

a “new” technology. mRNA (or “messenger” RNA) is found in all living cells. mRNA is a message that tells cells how to make proteins that trigger the immune response inside the body. That immune response is what protects against infection if an individual is exposed to the virus. mRNA is not the same as DNA (your genes), and it cannot combine with our DNA to change our genetic code. mRNA vaccines do not affect or interact with DNA in any way. So we can be assured there'll be no long-term DNA-altering effects from these vaccines.

What's more, checking the safety of the vaccines doesn't just stop after they've been registered for use. Once a vaccine has been introduced, ongoing monitoring of its safety is a crucial part of the vaccine development process.

Australia has a robust system for this ongoing monitoring. The system was established to detect any unexpected side-effects from vaccines (if they occur) and ensure they're investigated promptly. This type of monitoring is standard practise in Australia for vaccines. The data about COVID-19 vaccination collected in these surveillance systems will be published weekly on the TGA website. This should reassure Australians that if there's a new serious side-effect, we will know about it, communicate it, and act

on it quickly.

Withdrawal of vaccines after introduction to the general population is a very rare event. In the United States, a rotavirus vaccine called Rotashield led to a small increase in the number of small intestinal blockages. This prompted its withdrawal in the late 1990s. In Australia, an increased risk of febrile seizures in young children following a specific influenza vaccine was identified in 2010. It was subsequently withdrawn from use in that age group, and we now vaccinate with a different, safer flu vaccine. This vaccine is no longer available in Australia, and has been subsequently reformulated.

Both of these side-effects were observed within weeks of vaccination.

We now have improved monitoring systems in Australia to detect such serious side-effects even sooner, in the general population after clinical trials, than we did a decade ago.

But what about short-term side-effects?

### Pfizer-BioNTech COVID-19 vaccine

The expected side-effects of the Pfizer vaccine have been reported from trials involving roughly 43,000 participants aged 16 years and older from the US, Argentina, Brazil and South Africa. Half of the participants received the Pfizer

vaccine and half received a placebo. And as part of COVID-19 vaccine rollouts around the world, millions of people have already been given this vaccine since December, meaning we have safety data now from both clinical trials and two months of “real world” vaccination.

For those receiving this vaccine in the large clinical trials which started in July 2020, about 80% have reported pain at the injection site. Other common side-effects included fatigue, headache, muscle pain, chills, joint pain and fever.

These were most often reported one or two days after the day of vaccination, and typically only lasted about one day. While some vaccine recipients may need a day off work due to some of these side-effects, this does not indicate the vaccine is unsafe.

In trials, no difference was seen in the rate of severe side-effects between the Pfizer vaccine and placebo. Early in the US program, 21 cases of anaphylaxis were reported. It's estimated anaphylaxis occurs at a rate of 11 in every one million recipients (0.0011%) of the Pfizer COVID-19 vaccine. Most occurred within 15 minutes, and all patients recovered. This is

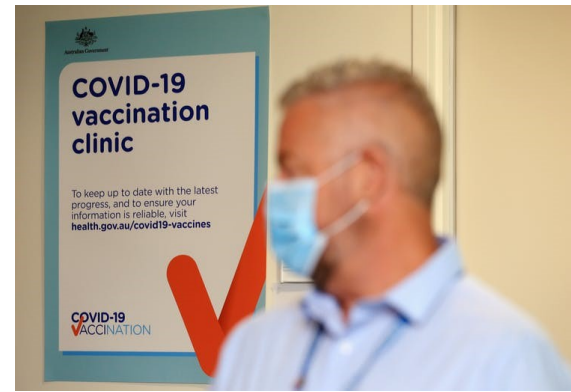
why it's a good idea though to remain at the vaccine clinic for up to 15 minutes after vaccination so that treatment and care can be provided if necessary.

A further concern was raised in January, after the death of 30 very frail elderly patients in Norway after receiving the Pfizer-BioNTech COVID-19 vaccine. But investigation by the European regulator concluded these weren't related to the vaccine, but rather to underlying conditions present before vaccination.

### **Oxford-AstraZeneca COVID-19 vaccine**

This vaccine has been tested in ongoing trials with around 55,000 participants from the United Kingdom, Brazil, South Africa and the US. About half received the Oxford-AstraZeneca vaccine and half a placebo. Millions of doses have been already been administered among the general population, particularly in the UK.

Data from four clinical trials which commenced in April 2020 in the UK, Brazil and South Africa, show the most common side-effects were pain at the injection site, fatigue, headache and muscle pain. Similar to the Pfizer vaccine, there was no difference in the rate of reported severe side-effects for the vaccine compared with the placebo.



Just 0.7% of participants (79 people) from the four clinical trials who received the Oxford-AstraZeneca vaccine reported a serious side-effect after receiving at least one dose, compared with 0.8% (89 people) of those in the placebo group. No additional safety concerns have been identified since the vaccination program began in the UK.

### **If recommended a COVID-19 vaccine, take it**

With countries continuing to monitor those who have received vaccines, we should be reassured there are no major safety concerns detected for serious side-effects so far. With millions of people vaccinated already, our confidence about the safety of COVID-19 vaccines is very high.

In Australia, and internationally, we have robust systems in place to continually monitor vaccine safety, ensuring Australians can be safely afforded the protection that COVID-19 vaccines are designed to provide.

Fuente: THE CONVERSATION. Disponible en <https://cutt.ly/Gl8irRc>



## Una sola dosis de la vacuna J&J previene COVID-19 grave

**24 feb.** La vacuna de una sola dosis de Johnson & Johnson brinda fuerte protección contra el COVID-19 grave, de acuerdo con un análisis dado a conocer el miércoles por los reguladores estadounidenses que allana el camino para una decisión final sobre una vacuna nueva y sencilla de usar para ayudar a domar la pandemia.

Esta vacuna largamente esperada sería una tercera opción y ayudaría a acelerar la inmunización al requerir una sola dosis en lugar de dos. Científicos de la Administración de Alimentos y Medicamentos (FDA por sus siglas en inglés) confirmaron que la vacuna muestra un 66% de eficacia para prevenir el COVID-19 de moderado a grave y el 85% de eficacia en los casos más graves.

La vacuna de J&J es segura, añadió la FDA. El análisis es apenas un paso de la evaluación de la FDA.

Fuente: Chicago Tribune. Disponible en <https://cutt.ly/6l62wrZ>

El viernes, los asesores independientes de la agencia debatirán si las pruebas justifican recomendar la vacuna. Tras esa recomendación, se prevé que la FDA tomará su decisión final en pocos días.

La cifra de muertes de COVID-19 en Estados Unidos superó el medio millón esta semana y la campaña de vacunación ha sido más lenta que lo previsto debido a demoras logísticas y climáticas. Hasta el momento 44,5 millones de personas en Estados Unidos han recibido al menos una dosis de la vacuna de Pfizer o Moderna y casi 20 millones la segunda dosis para la protección total.

Los tests revelaron que las vacunas de Pfizer y Moderna resultan eficaces en un 95% para proteger del COVID-19 sintomático.

El doctor Paul Offit, experto en vacunas del Hospital de Niños de Filadelfia y miembro del panel asesor de la FDA advirtió que no se ha realizado una comparación



directa entre las vacunas. Sin embargo, le complace que una dosis de la vacuna J&J parece tan eficaz para prevenir la enfermedad grave como sus competidoras de dos dosis.

“Esta es una vacuna para prevenir la hospitalización y la muerte a un nivel ciertamente comparable” con el de las de Pfizer y Moderna, aseveró.

J&J ensayó su vacuna de una dosis con 44.000 adultos en Estados Unidos, Latinoamérica y Sudáfrica. Distintas mutaciones del virus circulan en distintos países y el análisis de la FDA advierte que no está clara la efectividad de las vacunas para cada variante. J&J anunció previamente que su vacuna es más eficaz en Estados Unidos: 72% contra COVID-19 moderado o grave comparado con 66% en Latinoamérica y 57% en Sudáfrica.

## Detectan una nueva variante del SARS-CoV-2 en un bebé de EEUU que tenía una carga viral 51.418 veces más alta

**24 feb.** El coronavirus y los niños son un caso excepcional. Quienes han padecido la enfermedad presentaron síntomas leves e incluso quienes necesitaron ser hospitalizados no

escalaron hacia un estadio grave o severo. Pero la verdadera sorpresa llegó cuando los médicos estadounidenses registraron en el Hospital Nacional de Niños de Washington DC en el día de

ayer, una importante carga viral en un bebé. Esta fue 51,418 veces más alta que la media de otros pacientes pediátricos. Y cuando secuenciaron el virus en el bebé, encontraron una variante que no

habían visto antes.

Pero la alarma no terminaría ahí: tras la secuenciación del genoma del virus, encontraron una variante nunca antes vista en el hospital lo que llevó a plantear la hipótesis de que en una parte de Estados Unidos podría estar circulando una nueva mutación del virus.

**“«El hallazgo científico ocurrió en el Hospital Nacional de Niños de Washington DC y los epidemiólogos estadounidenses afirman que pertenece a la mutación N679S.»**

Jeremy Luban, virólogo de la Escuela de Medicina de la Universidad de Massachusetts, señaló que la carga viral en la nariz del bebé “es de por sí un dato alarmante y digno de atención”. Pero Luban prefirió la cautela ante el caso documentado y afirmó que “puede deberse a la mutación N679S, o simplemente a que el sistema inmunológico del bebé todavía no estaba completamente desarrollado, lo que permitió la replicación descontrolada del virus”.

Roberta DeBiasi, jefa de enfermedades infecciosas del hospital, sabía que no podía concluir nada de un solo caso. Y a medida que los investigadores profundizaron en el misterio, encontraron evidencia de que una variante con una mutación llamada

N679S puede estar circulando en la región del Atlántico Medio.

“Podría ser una completa coincidencia”, dijo DeBiasi. “Pero la asociación es bastante fuerte. Si ve a un paciente que tiene exponencialmente más virus y es una variante completamente diferente, probablemente esté relacionado”.

Los niños en general no se enferman por el coronavirus como lo hacen los adultos. La tasa de enfermedad grave es baja y unos 270 niños han muerto a causa del COVID-19, la enfermedad causada por el virus o una enfermedad asociada en un mar de 500.000 muertes en Estados Unidos. Podría ser algo sobre la biología de la juventud, han dicho algunos científicos, o quizás una mayor probabilidad de estar expuesto a un patógeno similar más recientemente.

No hay evidencia de que la variante con N679S, u otras identificadas por primera vez en el Reino Unido, Sudáfrica y Brasil, sean más peligrosas para los niños. Pero los funcionarios de salud en el Reino Unido han dicho que están monitoreando un aumento inusual de infecciones, especialmente entre los niños de 6 a 9 años, que es desproporcionado para su porcentaje de la población.

Y según un informe del 9 de febrero en la revista médica BMJ, Israel también ha experimentado

“un fuerte aumento de las infecciones por COVID-19 entre los jóvenes, con más de 50.000 niños y adolescentes que dieron positivo en enero, más de lo que Israel vio en cualquier país, durante la primera y segunda oleada”.



### La vacuna también para los niños

Cuando se habla de la necesidad de inocular al 70/80% de la población para alcanzar la tan ansiada inmunidad de rebaño, siempre se dejó afuera de las prioridades a los niños debido a que no había estudios en el mundo sobre la seguridad y la eficacia de las vacunas desarrolladas en menores de 18 años.

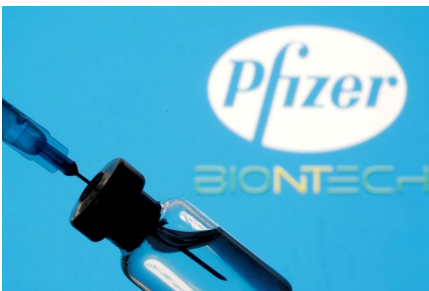
Ahora, los más importantes productores de vacunas para prevenir el COVID-19 planean comenzar a investigar sus formulaciones en esa franja etaria.

Pfizer y Moderna inscribieron a niños de 12 años o más en ensayos clínicos de sus vacunas y esperan tener resultados para el verano boreal. Dependiendo del rendimiento de las vacunas en ese grupo de edad, las empresas podrán probarlas luego en niños más pequeños. La Administración de Alimentos y Medicamentos (FDA) generalmente demora algunas semanas en revisar los datos de un ensayo clínico y

autorizar una vacuna.

Otras tres compañías, Johnson & Johnson, Novavax y AstraZeneca, también planean probar sus vacunas en niños, pero están más rezagadas.

Según los especialistas, los niños también deberán ser vacunados para que los Estados Unidos se acerque a la inmunidad colectiva, ese objetivo prometido durante mucho tiempo en el que la pandemia se detiene porque el virus se queda sin personas para infectar.



La vacuna Pfizer-BioNTech fue autorizada en diciembre para cualquier persona de 16 años o más. La compañía continuó su prueba con voluntarios más jóvenes, reclutando a 2.259 adolescentes de 12 a 15 años. Los adolescentes tienen aproximadamente el doble de probabilidades de infectarse con el coronavirus

Fuente: infobae. Disponible en <https://cutt.ly/izqylZL>

## Cuba se alista para iniciar la fase 3 de dos vacunas contra COVID-19 en marzo

**25 feb.** Autoridades científicas de la isla han dicho que Cuba tiene capacidad para fabricar en 2021 unas 100 millones de dosis de Soberana 2 y que la

que los niños más pequeños, según los Centros para el Control y la Prevención de Enfermedades.

La vacuna de Moderna, que también fue autorizada en diciembre, está en un camino similar para las pruebas pediátricas. En diciembre, la compañía comenzó a evaluar a adolescentes de 12 a 17 años y planea inscribir a 3 mil voluntarios en este grupo de edad. La compañía espera resultados "alrededor de mediados de 2021", dijo Colleen Hussey, portavoz de Moderna.

Con base en los resultados, Moderna planea evaluar la vacuna a finales de este año en niños de entre seis meses y 11 años.

Los bebés pueden tener algunos anticuerpos al nacer de madres vacunadas o infectadas, pero es poco probable que la protección materna dure hasta el primer año de edad. Y con su sistema inmunológico relativamente débil, los bebés pueden ser particularmente susceptibles a la infección si la transmisión comunitaria es alta.

La vacuna de Moderna, que



también fue autorizada en diciembre, está en un camino similar para las pruebas pediátricas. En diciembre, la compañía comenzó a evaluar a adolescentes de 12 a 17 años y planea inscribir a 3 mil voluntarios en este grupo de edad. La compañía espera resultados "alrededor de mediados de 2021", dijo Colleen Hussey, portavoz de Moderna.

Con base en los resultados, Moderna planea evaluar la vacuna a finales de este año en niños de entre seis meses y 11 años.

Los bebés pueden tener algunos anticuerpos al nacer de madres vacunadas o infectadas, pero es poco probable que la protección materna dure hasta el primer año de edad. Y con su sistema inmunológico relativamente débil, los bebés pueden ser particularmente susceptibles a la infección si la transmisión comunitaria es alta.

campana de vacunación iniciará el primer semestre.

Soberana 2 y Abdala, los dos proyectos de vacunas contra el Covid-19 más avanzados de

Cuba, pasarán en marzo a la fase 3 de ensayos clínicos, tras demostrar "seguridad y una potente respuesta inmunológica", anunció este jueves uno de los científicos responsables.

Estas dos inmunizantes en desarrollo, de los cuatro que tiene Cuba, "han demostrado ser vacunas seguras" y garantizan "la inducción de una potente respuesta inmunológica contra la enfermedad", dijo el presidente del grupo estatal BioCubaFarma (rector), Eduardo Martínez.

En un breve recorrido por dos centros científicos del oeste de La Habana, donde se producen los antígenos para ambas vacunas, Martínez precisó que este mes de marzo inicia la fase 3 de estudios clínicos.

Con trajes especiales y condiciones altamente asépticas, los científicos trabajan en las dos plantas de producción en turnos de 12 y 24 horas para cumplir los planes de producción trazados por BioCubaFarma.

Autoridades científicas de la isla han dicho que Cuba tiene capacidad para fabricar en 2021 unas 100 millones de dosis de Soberana 2 y que la campaña de vacunación iniciará el primer semestre.

Según los directivos, Cuba ya inició la producción "a escala industrial" de ambas.

Soberana 2 es uno de los dos proyectos del Instituto Finlay de Vacunas (IFV).

El otro proyecto, Soberana 1, acaba de concluir su primera fase de estudios con "buenos resultados" y un segundo "ensayo clínico en convalecientes con resultados muy buenos, lo cual es muy atractivo para el primer mundo", dijo su director Vicente Vérez.

Por su parte, el Centro de Ingeniería Genética y Biotecnología (CIGB), trabaja en otros dos candidatos, Abdala y Mambisa, este último es el único de los cuatro que se administra con un spray nasal.

Vérez precisó que en el ensayo fase 3 de Soberana 2 participarán 44,000 voluntarios, y que en paralelo se realizará otro "ensayo de eficacia" que "posiblemente llegue a más de un millón de personas".

Desde Washington, el subdirector de la Organización Panamericana de la Salud (OPS), Jarbas Barbosa, celebró el miércoles los esfuerzos de Cuba y Brasil por producir su propia vacuna anticovid pero estimó que completar la fase 3 de la Soberana 2 tomará "algunos meses".

Todas las vacunas cubanas son de proteína recombinante, indicó Vérez. La misma técnica utilizada



por la empresa de biotecnología estadounidense Novavax.

El coronavirus SARS-CoV-2 posee en su superficie unas puntas (proteínas virales) para entrar en contacto con las células e infectarlas. Estas proteínas pueden ser reproducidas y presentadas después al sistema inmunitario para hacerle reaccionar, explicó el científico.

"La apuesta cubana es tener vacunas muy eficaces en primer lugar, la segunda apuesta es que son vacunas muy seguras, y la tercera es que son vacunas que no tienen la limitación del número de dosis que se pueden aplicar", a diferencia de otras ya lanzadas al mercado, explicó.

Con 11.2 millones de habitantes, Cuba, que enfrenta actualmente un rebrote del coronavirus, mantiene un bajo índice de muertes desde que comenzó la pandemia en marzo, con 312 fallecimientos. Acumula 47,566 contagios y 42,809 recuperados.

Fuente: EL ECONOMISTA. Disponible en <https://cutt.ly/6zqiMTR>

## Children Given Flu Shot Less Likely to Have Symptomatic COVID-19

**25 feb.** Children who have received an influenza vaccine are less likely to have symptomatic COVID-19 or severe disease, according to a study recently published in *Cureus*.

Anjali Patwardhan, M.D., and Adrienne Ohler, Ph.D., from the University of Missouri in Columbia, examined the effect of influenza and pneumococcal vaccines on the disease course among severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) patients aged 20 years and younger who visited Arkansas Children's Hospital

System between Feb. 1 and Aug. 30, 2020.

The researchers found that viral interference may have played a role in the flu and COVID-19 twindemic. Comparing SARS-CoV-2-positive patients who had been vaccinated versus those who had not been vaccinated for influenza showed that patients who were vaccinated had lower odds of having symptomatic diseases (odds ratio [OR], 0.714). Patients who received the pneumococcal vaccine also had lower odds of having symptomatic disease than those who were unvaccinated (OR,

0.482). Compared with patients who were not vaccinated, patients who were vaccinated for influenza had lower odds of having respiratory symptoms (OR, 0.678).

Patients vaccinated for influenza and pneumonia had lower odds of severe disease than those not vaccinated (ORs, 0.672 and 0.412, respectively).

"It is known that the growth of one virus can be inhibited by a previous viral infection," Patwardhan said in a statement. "This phenomenon is called virus interference, and it can occur even when the first virus invader is an inactivated virus, such as the case with the flu vaccine."

Fuente: *Physician's Weekly*. Disponible en <https://cutt.ly/5zeACh5>

## La efectividad de vacunas contra covid-19: ¿cuál es la vacuna más efectiva?

**27 feb.** El proceso para aplicar la vacuna de covid-19 será el tema prioritario en el mundo en los próximos años a medida que los países intentan luchar contra la pandemia de coronavirus. ¿Cuál es la vacuna de covid-19 más efectiva?

La vacuna Sputnik V tiene un 91,6% de efectividad para prevenir el covid-19 sintomático y es 100% efectiva para prevenir enfermedad grave por coronavirus, según un análisis provisional de los datos del

ensayo de fase 3, publicado en la revista médica *The Lancet*. Varios países de América Latina recibirán la vacuna rusa.

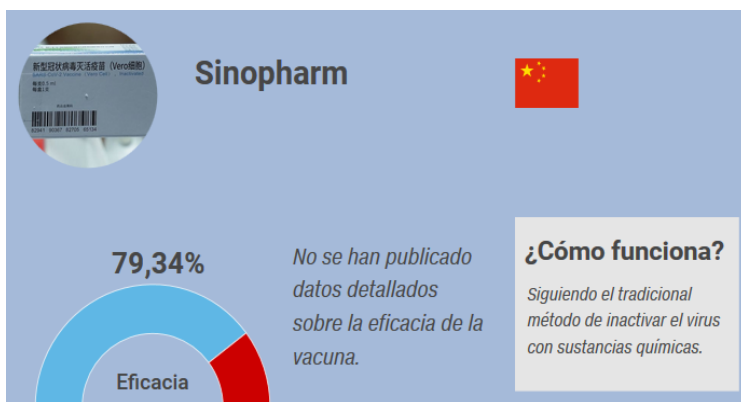
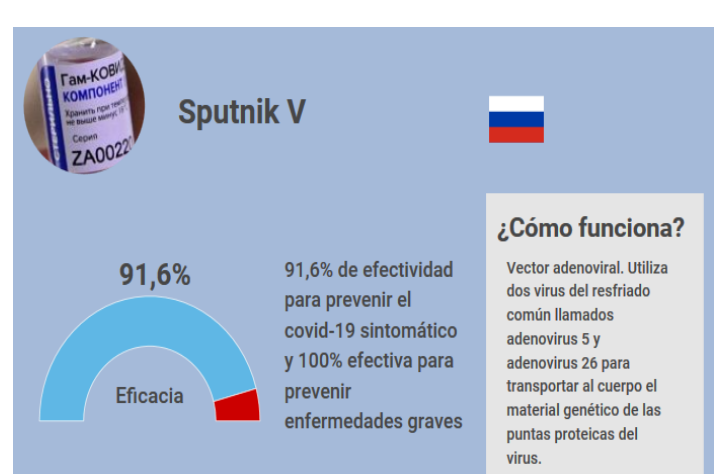
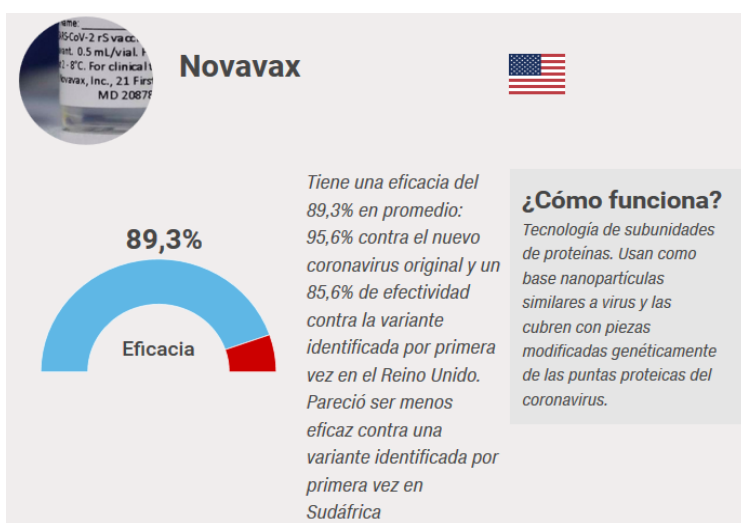
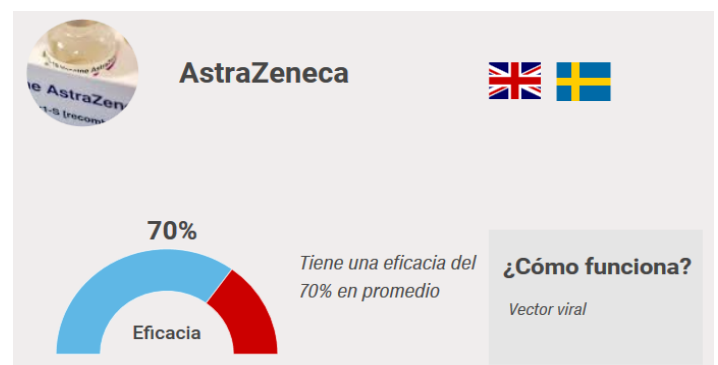
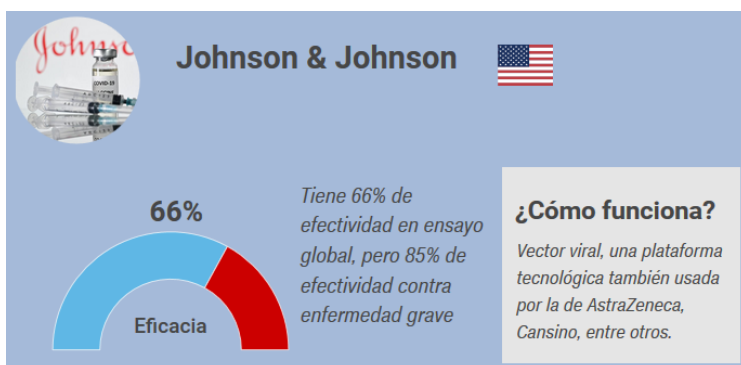
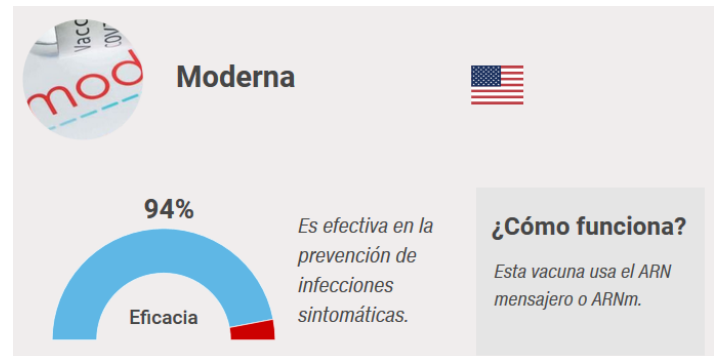
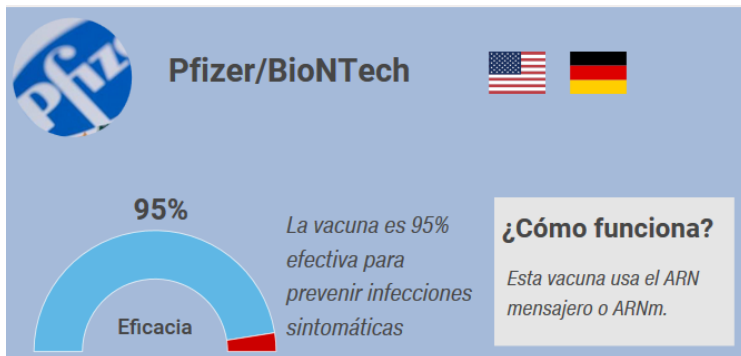
La alta efectividad de la vacuna Sputnik V, que recibió críticas en 2020 porque fue aprobada y desplegada rápidamente, se acerca a las de mayor éxito como la de Pfizer/BioNTech –que ya se aplica en Europa y Estados Unidos– que reporta una efectividad de 95% para prevenir infecciones sintomáticas, y la vacuna de Moderna, que es 94%

efectiva para prevenir infecciones sintomáticas.

En el otro lado del espectro está la vacuna Sinovac, que apenas tiene un 49,62% de eficacia en promedio, y la vacuna de Johnson & Johnson, que es 66% eficaz.

La Administración de Alimentos y Medicamentos de EE.UU. (FDA, por sus siglas en inglés) aprobó el uso de emergencia de una tercera vacuna contra el covid-19 en el país, fabricada por la división de vacunas de Johnson & Johnson, Janssen Biotech.

Mientras algunas compañías y laboratorios continúan haciendo ensayos, y otras ya están distribuyendo su vacuna contra la COVID-19, esto es lo que sabemos de la eficacia de 8 de ellas, desarrolladas por Pfizer/BioNTech, Moderna, Johnson & Johnson, AstraZeneca, Novavax, Sputnik V, Sinopharm y Sinovac.



Fuente: CNN en español. Disponible en <https://cutt.ly/vzeVwba>

## Solidaridad pide en Brasil adquirir vacuna cubana antiCovid-19

**27 feb.** El movimiento brasileño de solidaridad con Cuba comenzó una campaña para que instituciones y gobiernos regionales adquieran la vacuna cubana Soberana 02 ante la carencia que existe hoy de inmunizantes anti-Covid-19 para la inoculación masiva.

En la convocatoria, las entidades demandan que 'parte de la fase tres del estudio clínico de Soberana 02 se lleve a cabo en Brasil con la participación de alguna institución con experiencia en vacunas'.

Tal hecho, indica la nota, podría disminuir el tiempo de aprobación por la Agencia Nacional de Vigilancia Sanitaria (Anvisa) de este fármaco.

El Movimiento Capixaba de Solidaridad con Cuba, el Capítulo Brasil del Comité Internacional Paz, Justicia y Dignidad a los Pueblos, y el Comité Carioca de Solidaridad con Cuba -además de otras entidades y personalidades- invitan a todos a participar de la cruzada.

Recuerdan que el gigante suramericano 'atraviesa una situación sin precedentes en su historia. El país que alguna vez fue

referente mundial en campañas de inmunización actualmente enfrenta una pandemia, la cual crece cada día ante la imposibilidad de vacunación masiva de nuestra población'.

Hospitales abarrotados, una cifra impresionante de muertes, sin medidas de contención. Tenemos el segundo mayor número de personas fallecidas (cerca de 253 mil) en el planeta sin que ninguna agencia gubernamental se exprese o cumpla con su deber de cuidar la vida según lo determina la Constitución Federal, indica el texto.

Reconoce que no existe ningún tipo de tratamiento preventivo o específico contra la COVID-19. Solo tenemos una alternativa en este momento: la vacuna.

Insisten los demandantes en que, 'como no podemos fabricar nuestra propia droga, tenemos que adquirirla en el exterior, sin embargo, por cuestiones ideológicas innecesarias, perdimos un tiempo valioso en esta disputa'.

Para el movimiento solidario, resulta de suma importancia adquirir vacunas en cantidad suficiente para la inmunización de la población, sin importar dónde



se fabriquen, siempre y cuando cumplan con el método científico, tengan eficacia probada y estén autorizadas por la Anvisa.

'Estamos hablando de vidas. Eso no tiene precio. No podemos permitirnos el lujo de esperar. Por eso invitamos a todos a participar de la campaña que comienza con la adquisición por parte de Brasil de Soberana 02', desarrollada por el Instituto Finlay de Vacunas, con décadas de experiencia en la producción de diversos fármacos.

En total Cuba trabaja en cuatro candidatos vacunales a la vez, Soberana 01 y Soberana 02, del Finlay, y Abdala y Mambisa, desarrolladas por el Centro de Ingeniería Genética y Biotecnología. Este último es el único para administrar de forma nasal.

De esta forma, el país caribeño podría convertirse en el primero latinoamericano en tener sus propias vacunas contra la COVID-19.

Fuente: Prensa Latina. Disponible en <https://cutt.ly/Qzrwngo>

## Johnson & Johnson: Estados Unidos aprueba la primera vacuna de una sola dosis contra el coronavirus

**28 feb.** Las autoridades estadounidenses aprobaron este sábado el uso de la vacuna de una sola dosis de la farmacéutica Johnson & Johnson, la tercera que recibe el visto bueno de la Administración de Medicamentos y Alimentos (FDA).

La vacuna es vista como una alternativa eficiente a las desarrolladas por Pfizer y Moderna, dado que solo requiere de una dosis y puede almacenarse en un frigorífico en lugar de un congelador, como requieren las otras dos.

Los ensayos mostraron que la vacuna de Johnson & Johnson tiene un 66% de eficacia, previene el desarrollo de síntomas graves de la enfermedad y no se reportaron hospitalizaciones o muertes.

Estados Unidos se convierte así en el primer país en permitir el uso de la vacuna desarrollada por el fabricante belga Janssen.

La compañía se ha comprometido a entregar a Estados Unidos 100 millones de dosis antes de que termine junio, aunque medios de EE.UU. han reportado que ha enfrentado problemas con la producción.

Reino Unido y Canadá también han hecho pedidos y otros 500



millones de dosis se canalizarán a través del programa Covax, que busca que las vacunas lleguen también a los países menos desarrollados.

La autorización de FDA llegó después de que un comité de expertos independientes votara por unanimidad a favor el viernes.

Los resultados de los ensayos llevados a cabo en Estados Unidos, Sudáfrica y Brasil revelaron una eficacia superior al 85% en la prevención del desarrollo de síntomas graves y de un 66% cuando se contaban también los casos de enfermedad moderada.

No hubo muertes ni ingresos hospitalarios entre los voluntarios que recibieron la vacuna en los 28 días posteriores a haberles sido administrada.

La protección global fue inferior

en Sudáfrica y Brasil, donde variantes del virus se han vuelto predominantes, pero la defensa que la vacuna ofreció allí frente a síntomas severos o críticos de la enfermedad fue también "alta".

Sudáfrica comenzó este mes a inyectar la vacuna de Johnson & Johnson a sus trabajadores de la salud después de que los ensayos mostraran que la de la Universidad de Oxford y AstraZeneca ofrecía "mínima protección frente a la enfermedad moderada que provoca la variante del virus más extendida en el país.

Johnson & Johnson afirma que tiene previsto entregar 20 millones de dosis en total hasta final de marzo.

Al requerir una dosis menos que las de Pfizer y Moderna, también requerirá un menor número de citas y personal sanitario en su distribución.



## Quién más ha pedido la vacuna de Johnson & Johnson

- Reino Unido - 30 millones de dosis
- Unión Europea - 200 millones de dosis.
- Canadá - 38 millones de dosis.
- Países del programa Covax - 500 millones de dosis.

El producto de Johnson & Johnson usa un virus del resfriado común que ha sido modificado para hacerlo inofensivo. Introduce parte del código genético del coronavirus, lo que resulta suficiente para que el cuerpo identifique la amenaza y aprenda a combatirla.

Esto entrena al sistema inmune en la lucha contra el coronavirus para cuando llegue el momento en que se enfrente a él realmente.

Se trata de un enfoque similar al utilizado en el desarrollo de la vacuna de la Universidad de Oxford y AstraZeneca.

## Cuál es la situación en Estados Unidos

Alrededor de 72,8 millones de habitantes de Estados Unidos ya han sido vacunados y cerca de 1,3 millones de dosis se inyectan cada día en el país. El presidente Joe Biden se ha comprometido a administrar 100 millones de dosis

en sus primeros 100 días en el cargo.

Más de 508.000 personas han muerto en Estados Unidos con covid, pero las muertes, las hospitalizaciones y los contagios se han mantenido a la baja en las últimas semanas.

Los expertos en salud pública advierten, no obstante, que las nuevas variantes del virus podrían poner en peligro los progresos realizados.



Fuente: BBC News. Disponible en <https://cutt.ly/bzruNVd>





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PAT. NO.	Title
1	<a href="#">10,927,151</a> <u>Methods of optimizing nucleotide sequences encoding engineered influenza proteins</u>
2	<a href="#">10,927,147</a> <u>Muramyl peptide derivative compound, synthesis and uses thereof</u>
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6	<a href="#">10,925,954</a> <u>Vaccines against Chlamydia sp</u>
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