FINLAY
EDICIONES

BOLETÍN VACCIENCIA

No. 19 (17-23 septiembre/2020)

VaCyT

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...vacunar es prevenir.

Análisis bibliométrico sobre vacunas de adenovirus

Fuente de información utilizada:

WEB OF SCIENCE™

Estrategia de búsqueda:

TITLE: ("Adenovirus vaccine ") 4938 records

Periodo de estudio 1999-2020

Las variables utilizadas en el análisis fueron:

⇒ Productividad científica por año.

⇒ Autores con mayor productividad científica.

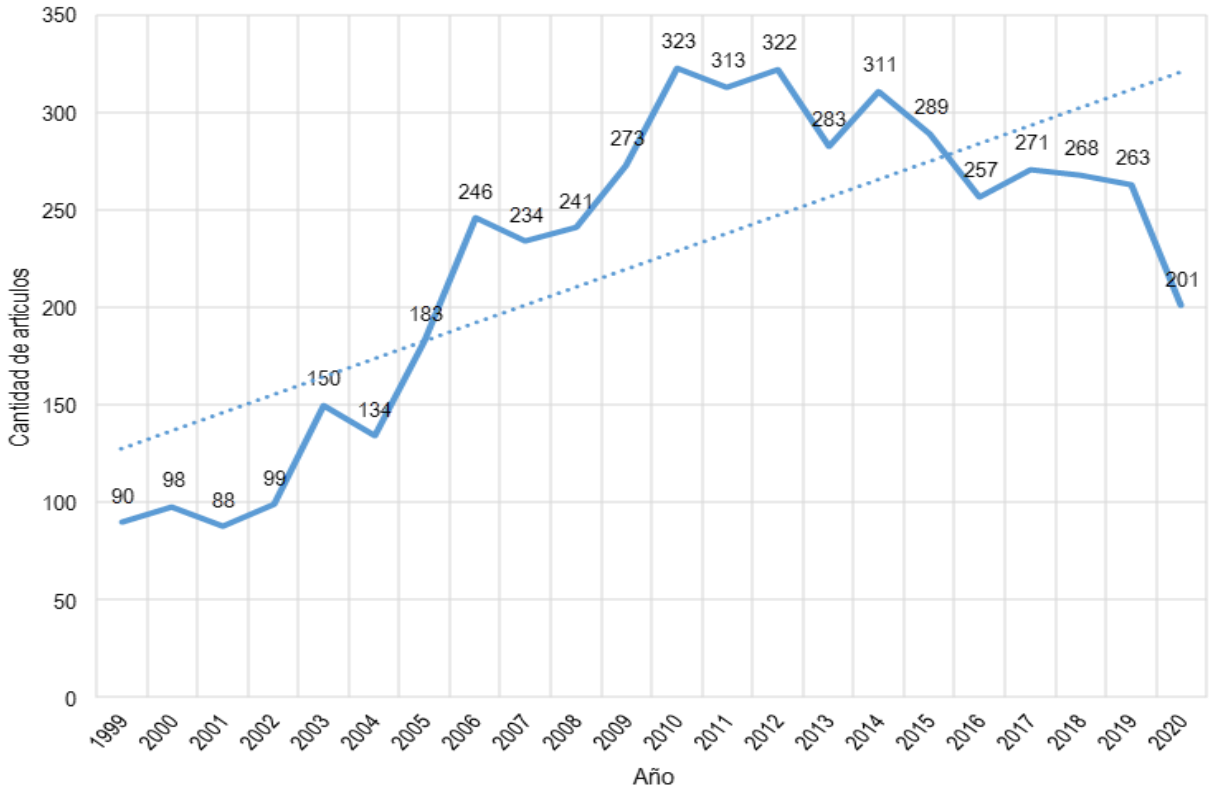
⇒ Revistas con mayor número de publicaciones sobre el tema.

⇒ Instituciones que han trabajado el tema de estudio.

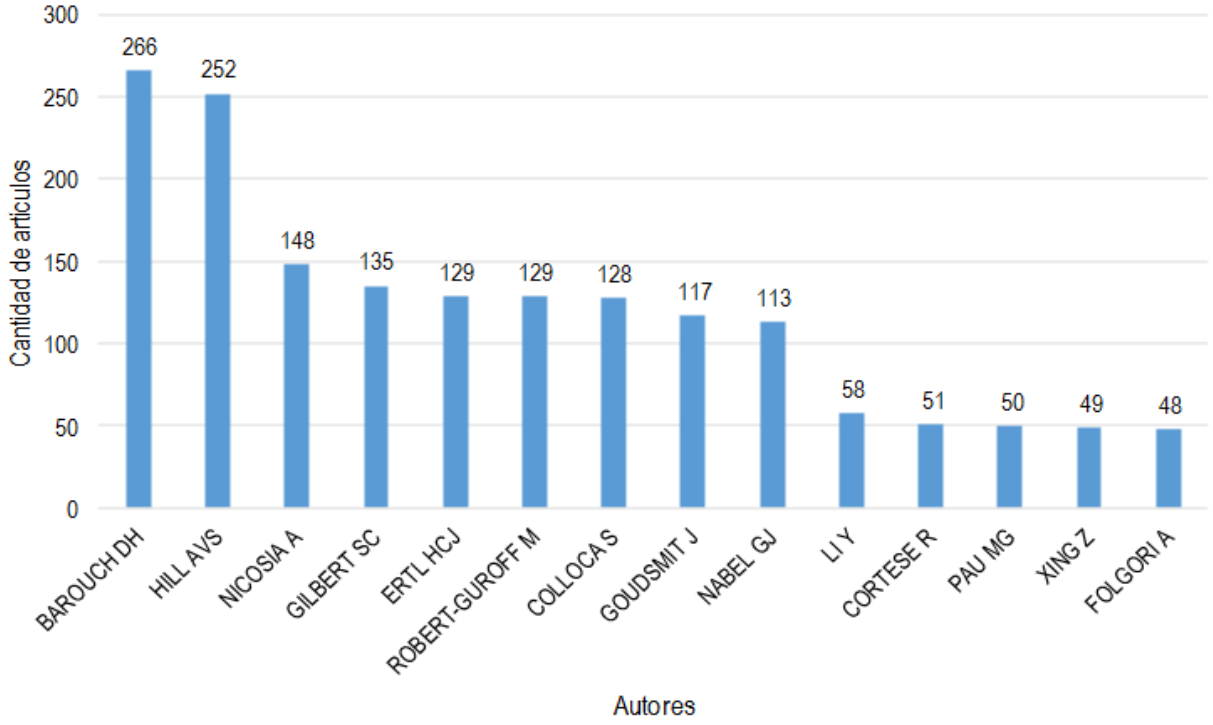
⇒ Países a la vanguardia sobre el tema.

EN ESTE NÚMERO

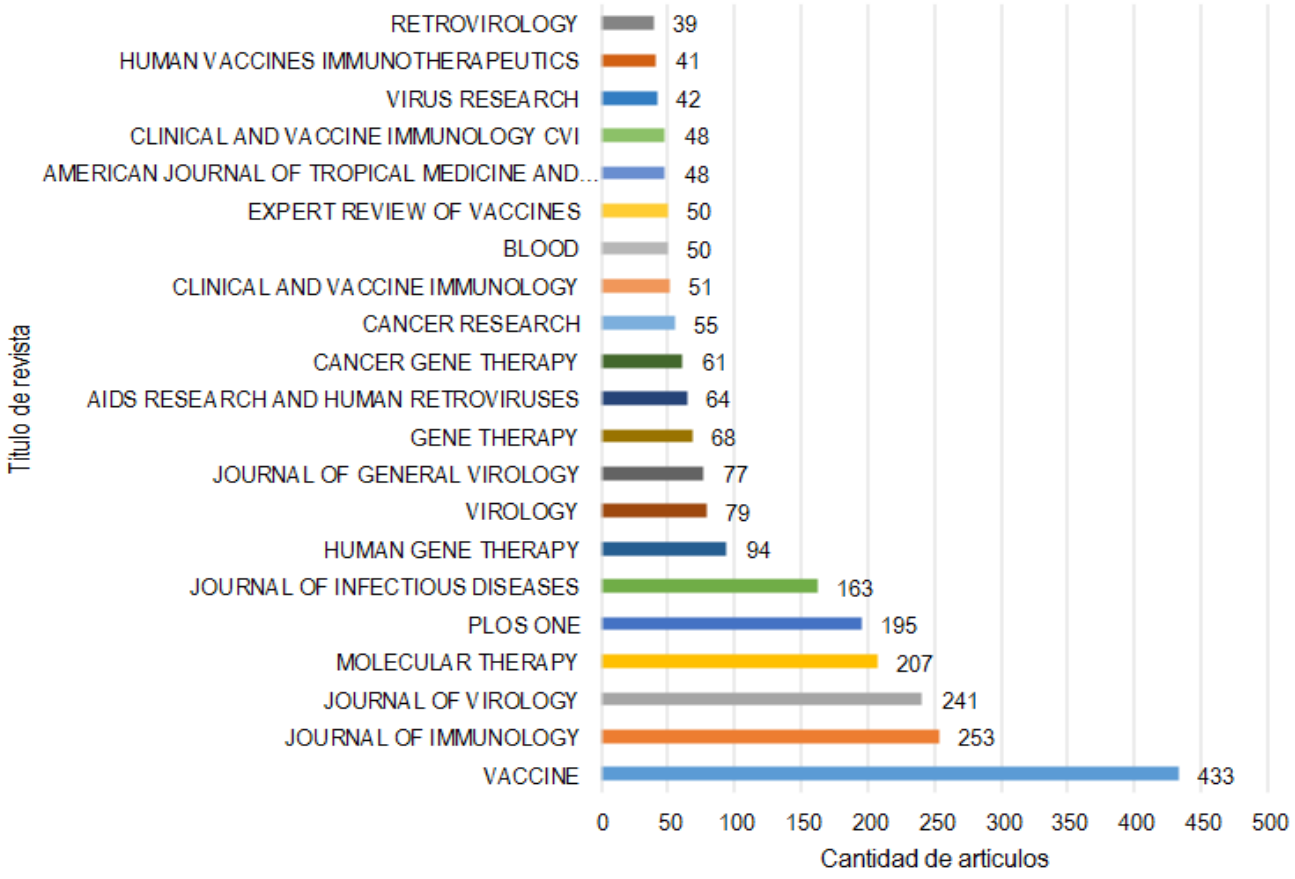
Productividad científica por año



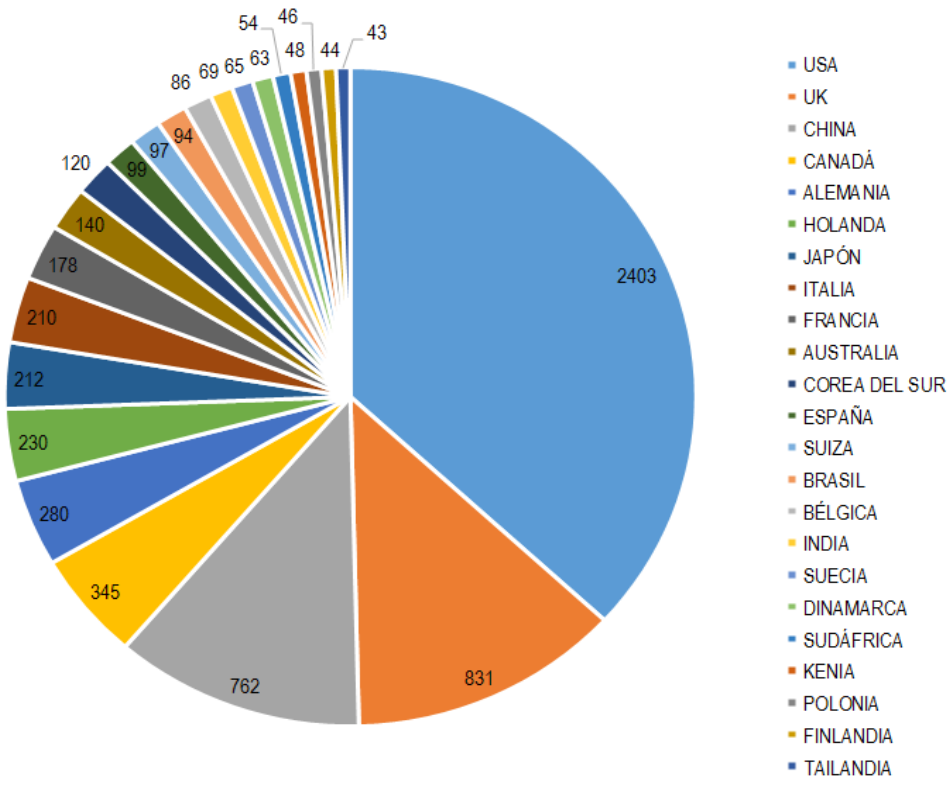
Autores con mayor productividad científica



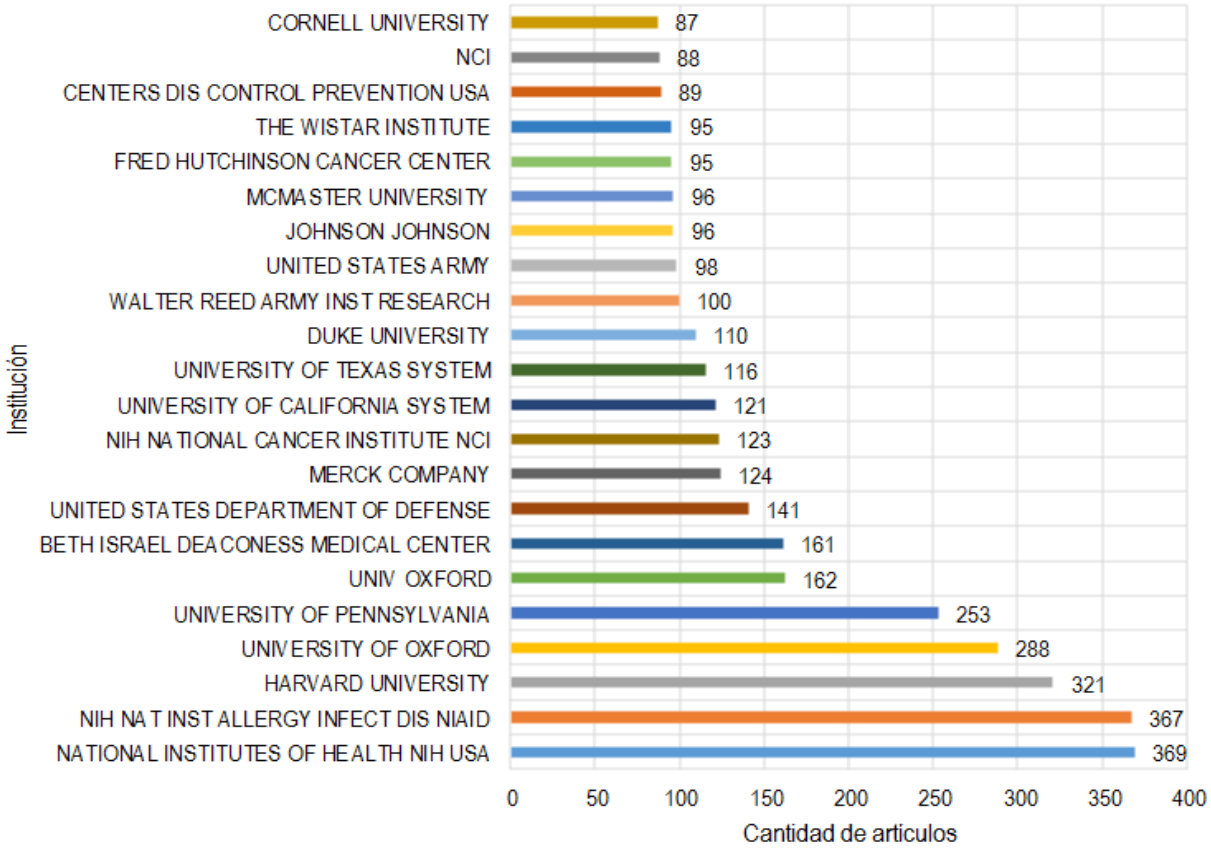
Revistas científicas que han publicado sobre el tema (2019-2020)



Producción científica por países



Instituciones que han trabajado el tema de estudio



Noticias en la Web

Moderna and Pfizer Reveal Secret Blueprints for Coronavirus Vaccine Trials

17 sep. Two drug companies that are leading the race to develop coronavirus vaccines bowed to public pressure on Thursday, abandoning their traditional secrecy and releasing comprehensive road maps of how they are evaluating their vaccines.

The companies, Moderna and Pfizer, revealed details about how participants are being selected and monitored, the conditions under which the trials could be stopped early if there were problems, and the evidence researchers will use to determine whether people who got the vaccines were protected from Covid-19.

Moderna's study will involve 30,000 participants, and Pfizer's 44,000.

Companies typically share these documents after their studies are complete. The disclosures while the trials are still underway, a rare move, are aimed at addressing growing suspicion among Americans that President Trump's drive to produce a vaccine before the election on Nov. 3 could result in a product that was unsafe.

The plan released by Moderna on Thursday morning included a likely timetable that could reach into next year for determining whether its vaccine works. It does not jibe with the president's optimistic predictions of a vaccine widely available to the public in October.

Moderna's 135-page plan, or protocol, indicated that the company's first analysis of early trial data might not be conducted until late December, though company officials now say they expect the initial analysis in November. In any case, there may not be enough information then to determine whether the vaccine works, and the final analysis might not take place until months later, heading into the spring of next year.

Moderna's timeline meshes with the cautionary estimates from many researchers, including Dr. Robert R. Redfield, the director of the Centers for Disease Control and Prevention, who told senators on Wednesday that a vaccine would not be widely available until the middle of next year. Hours later, Mr. Trump sharply contradicted him, making unsubstantiated projections that a vaccine could become widely available weeks from now.

On Wednesday, Joseph R. Biden Jr., the Democratic presidential nominee, said in Wilmington, Del., that the process used to evaluate and approve a vaccine would have to be "totally transparent" to win public confidence. He has said that Mr. Trump's calls for companies and regulators to speed the process have shaken the public's faith in vaccines and that politics has no place in vaccine development.

"I want to acknowledge a good deed done," said Peter Doshi, who is on the faculty at the University of Maryland School of Pharmacy in Baltimore and an editor with The BMJ, a medical journal. He previously requested the plans from Moderna and Pfizer. "They have opened up, for the first time, the ability for researchers not involved in the trial to form their own independent judgment about the design of this study."

Until now, none of the nine companies that are testing vaccines in large clinical trials had released this level of detail.

Moderna, AstraZeneca and Pfizer, which is collaborating with the German company BioNTech, are among the front-runners in the global race to produce a vaccine to fight the pandemic.

A spokeswoman for AstraZeneca said the company intended to publish its protocol shortly. Novavax, which is expected to start a large, advanced clinical trial later this year, also did not comment. Johnson & Johnson, which has said it plans to begin a large trial this month, said it would have "more information to share" when the trial starts.

AstraZeneca's trial was stopped temporarily because of serious illness in a participant. It has resumed in Britain and Brazil, but not in the United States.

Earlier studies of both vaccines in small numbers of people found that after the second shot, they developed so-called neutralizing

antibodies, which can inactivate the virus in lab tests. The vaccines also produced a favorable response involving T-cells, another part of the immune system.

Dr. Tal Zaks, chief medical officer for Moderna, the first coronavirus vaccine maker to release its detailed plan, said pharmaceutical companies were usually reluctant to do so, for competitive reasons.

In a statement, Pfizer said it did not usually did not release its protocols, adding, "We recognize, however, that the COVID-19 pandemic is a unique circumstance and the need for transparency is clear."

Dr. Eric Topol, a clinical trial expert at Scripps Research in San Diego, gave Moderna "big kudos" for sharing its plan but said that he was disappointed that Moderna intended to include in its data people who had developed relatively mild cases of Covid-19. He said more compelling evidence of the vaccine's effectiveness would be produced if the company counted only moderate to severe cases.

Moderna's plan also allows for the possibility of stopping the trial early after a relatively small number of cases, potentially leading to an exaggerated perception of the vaccine's efficacy and missing safety problems that could turn out to be significant later if the vaccine were given to millions of people, he said.

Dr. Topol was more critical of Pfizer's plan because it allowed even milder cases than Moderna's to be counted and provided more opportunities to stop the trial early based on few cases, which he called troubling.

In both Moderna's and Pfizer's studies, half of the participants receive the vaccine, and half receive a placebo shot consisting of salt water, with neither the volunteers nor the doctors treating them knowing who gets which. Two shots are needed, four weeks apart for Moderna and three weeks apart for Pfizer. The participants are then monitored to see if they develop symptoms of Covid-19 and test positive for the virus.

Side effects of the vaccines are also tracked. In earlier studies, both vaccines have caused transient reactions like a sore arm, fever, chills, muscle and joint pain, fatigue and headaches.

To determine the vaccine's efficacy, Moderna counts Covid-19 cases only if they occur two weeks after the second shot. Pfizer starts counting them seven days after the second shot.

A total of 151 cases of Covid-19 from among the tens of thousands of people participating in the trial — spread between the vaccine and placebo groups — would be enough to determine whether the Moderna vaccine is 60 percent effective. Pfizer's case count for 60 percent efficacy is 164. The Food and Drug Administration has said any coronavirus vaccines must be at least 50 percent effective.

Many outside researchers have been watching for details about how the trials could be stopped early, given the push to bring a vaccine to market as soon as possible.

That could happen only when outside panels of experts examine the data while the trials are underway. If the vaccine is extremely effective, they could stop the trial because it would be unethical to continue giving some participants a placebo.

Moderna has two more analysis points; Pfizer has four.

Dr. Topol said studies often allowed only one look at the data partway through, and he had sharp words for Pfizer's use of four.

"It's programming the trial to have so many looks that it might stop early," he said.

Moderna's chief executive, Stéphane Bancel, said the company would report publicly on the results of the first so-called interim analysis, and the next one, when they are conducted. Pfizer has said that it will share information about the analyses only if a decision is made that the trial should be stopped, either because it is very effective or because it does not appear to be working.

The safety board can also put the trial on hold if there is evidence that a participant may have been harmed, as occurred recently in AstraZeneca's vaccine study.

Dr. Zaks and Mr. Bancel said in interviews that the first analysis would probably not take place before November. In theory, the vaccine could be found effective at that point, though the odds of that are not high, Dr. Zaks said.

If the data are not conclusive, the panel would look again after there had been a total of 106 cases. If there were still no answer, the next and final analysis would

occur after 151 people had contracted Covid.

How long it takes to reach any of those case counts depends on the trajectory of the pandemic and how likely participants are to be exposed to the virus.

Whether or not the vaccine is effective, the participants' health will be monitored for two years after the second shot, the plan stated.

Moderna and other companies have already begun making their vaccines "at risk," meaning financial risk, because if the products are found not to work, they will have to be thrown away. Both Moderna and Pfizer have projected that millions of doses will be ready early in 2021. But the world's population is seven billion, and for a number of these vaccines, everyone would need two doses.

"In the first half of next year, at least maybe until Labor Day next year, I anticipate that the world is going to be massively supply-constrained, meaning not enough vaccine to vaccinate everybody," Mr. Bancel of Moderna said.

Fuente: The New York Times. Disponible en https://cutt.ly/afNxMwT

Uzbekistán atraído por medicamentos de Cuba contra la COVID-19

17 sep. El debate entre los especialistas, investigadores y directivos de salud de Cuba y Uzbequistán en esta jornada se desarrolló mediante una videoconferencia.

Especialistas en salud de Uzbekistán muestran gran interés por los medicamentos que utiliza Cuba en la atención a los pacientes con la COVID-19, y adelantaron su disposición a fortalecer la colaboración médica entre ambas naciones.

De acuerdo con una información divulgada por el Ministerio de Relaciones Exteriores de la mayor de las Antillas, los expertos uzbecos consideraron muy valiosa la presentación de sus colegas cubanos sobre los fármacos empleados en los protocolos de atención y tratamiento frente al virus SARS-CoV-2, causante de la COVID-19.

Entre los productos mencionados se encuentra la Biomodulina T, inmunomodulador biológico de origen natural para el tratamiento de afecciones respiratorias en adultos

mayores, el cual fue elaborado por el Centro Nacional de Biopreparados, que pertenece al Grupo de las Industrias Biotecnológica y Farmaucética de Cuba (BioCubaFarma).

Además, se destacaron los resultados satisfactorios con el uso del interferón Alfa 2B recombinante (Heberon), el péptido CIGB-258 (Jusvinza) y el Alfa 2B más gamma (Heberferon), elaborados también por BioCubaFarma.

Los profesionales de la salud de Cuba utilizan más de 20 productos de la Industria Biotecnológica y Farmacéutica nacional en todos los niveles de atención, desde las terapias en la comunidad y en los centros de vigilancia a personas sospechosas, hasta el tratamiento de los pacientes confirmados o aquellos que transitan hacia estadios graves y críticos.

En la actualidad, este país

avanza de manera acelerada en el desarrollo de candidatos vacunales para enfrentar la pandemia, pero con el máximo rigor en cada uno de los procesos regulatorios.

El debate entre los especialistas, investigadores y directivos de salud de Cuba y Uzbequistán en esta jornada se desarrolló mediante una videoconferencia, que tuvo una duración de más de tres horas.

La intervención uzbeca contó con la presencia del viceministro de salud de ese país, Abdulla Azizov, así como expertos en medicina y medicamentos.

Por la parte cubana, intervino el doctor Dalsy Torres Ávila, jefe de la brigada médica cubana en Azerbaiyán, que atiende desde el mes de julio a pacientes de ese país con COVID-19.

Hasta este 17 de septiembre, Uzbekistán reporta un total de 49 mil 162 casos confirmados con el nuevo coronavirus, de los cuales 409 fallecieron y 45 mil 474 se recuperaron.

Cuba, por su parte, registra un total de cuatro mil 933 personas diagnosticadas con la enfermedad, de ellos 109 fallecieron y cuatro mil 230 se han recuperado.

Fuente: Escambray. Disponible en https://cutt.ly/YfNvgfo

Covid-19 vaccine tracker, Sept 18: Effectiveness of Moderna shot to be known by November

18 sep. Coronavirus (COVID-19) vaccine latest update, September 18: Moderna has never made a vaccine that has been approved. For coronavirus, it is using a genetic approach that has never produced a successful vaccine for any disease.

US biotechnology company Moderna has said it would know about the effectiveness of its coronavirus vaccine by November. Moderna's vaccine candidate is one of the three undergoing large-scale phase-3 clinical trials in the United States, in which 30,000 participants are being enrolled.

Company CEO Stephane Bancel has said if the vaccine candidate was found to be at least 50 per cent effective, the minimum bar set by the US Food and Drug Administration for approving a vaccine, it would immediately move to apply for an emergency use authorisation.

The company also released a 135-page note on the ongoing phase-3 trials. According to that note, which is dated August 20 but made public only on Thursday, the company was expecting to know about the effectiveness of the vaccine candidate by December.

Moderna has never made a vaccine that has been approved. For coronavirus, it is using a genetic approach that has never produced a successful vaccine for any disease. But the company enjoys the confidence and backing of the US government which has pumped in more than a billion dollars to help the company accelerate the vaccine development, and pre-booked hundreds of millions of doses, when it becomes available.

Even if Moderna knows about the effectiveness of its vaccine by November, it might be beaten in the race by another US pharmaceutical company Pfizer,

which has said it was hoping to be ready with effectiveness data by the end of October. Like Moderna, Pfizer is also carrying out phase-3 trials of its vaccine in the United States. Pfizer has also said it would apply for emergency authorisation once the effectivenss data is available.

Along with AstraZeneca, the third vaccine under phase-3 trials in US, Moderna and Pfizer are currently being considered the likely first ones to produce a coronavirus vaccine.

More details emerge about woman whose condition had halted AstraZeneca vaccine trial: 37-year-old had confirmed case of transverse myelitis

The woman whose serious illness had stopped the global late-stage trials of a coronavirus vaccine being developed by AstraZeneca and Oxford University was a 37-year-old UK resident who developed serious complications after being administered the second dose of vaccine.

The woman was diagnosed with confirmed case of transverse myelitis, a rare neurological disorder affecting the spinal cord of the person. The woman was hospitalised on September 5.

The details are contained in an "internal safety report" prepared by AstraZeneca, which was obtained by CNN, which said that the report was probably meant for doctors who were involved in the trials. AstraZeneca has officially given no details about the participant apart from saying that she had recovered from her ailment nad been discharged from the hospital.

The AstraZeneca vaccine candidate is considered one of the frontrunners in the global rush to develop a coronavirus vaccine. It was undergoing phase-3 trials in the United States, Brazil and South Africa, and combined phase-2 and phase-3 trials in England and India, when the news of the woman participant taking ill emerged. The trials were stopped at all places.

After a safety evaluation in England, the trials have since resumed. The go-ahead to re-start the trials have been given in India as well. But the United States has ordered an investigation into this entire incident, and it is yet to decide on resuming the trials.

Hunt for coronavirus vaccine: The story so far

180 vaccine candidates in pre-clinical or clinical trials

35 of them in clinical trials

Eight in final stages, phase-III of human trials

At least eight candidate vaccines being developed in India. Two of these have entered phase -II trials after completing phase-I.

The ones most talked about:

- AstraZeneca/Oxford University
- Moderna
- Pfizer/BioNTech
- Johnson & Johnson
- Sanofi/GlaxoSmithKline
- Novavax
- Russian vaccine, developed by Gamaleya Insttiute in Moscow.

Fuente: The Indian Express. Disponible en https://cutt.ly/wfNmKjn

When it comes to international co-operation, Cuba shows the way

18 sep. Only by working together can the world emerge from this crisis, and Cuba's medical expertise and humanitarianism set a gold standard for the world, says PAULA BARKER MP.

WHILE the world is suffering through the coronavirus pandemic, it has been truly inspirational to watch how the small island of Cuba has used its experience and professionalism to assist other countries in the fight against Covid -19.

The virus affects people regardless of their nationality, and Cuba has shown just how countries that are able can help those who need assistance.

I really hope that such lessons are learnt and that Britain will share any advances in vaccine development and treatments with others across the globe.

Such international cooperation is surely the only way that the world will be able to emerge from this crisis.

Over the past few months Cuba has responded to requests for assistance from 38 countries and has sent 45 medical teams made up of more than 3,700 doctors, nurses and other medical specialists.

They have gone to nations in Central and South America and the Caribbean, but also to Africa: to Togo, South Africa, Guinea Bissau, Sierra Leone and Kenya.

The immense gratitude felt by many in these countries is clear: Charles Azilan, the head of co-operation at Togo's foreign ministry said: "As scientific and medical circles groped in the dark, Cuban medicine, strong from past experiences, brought appropriate answers."

Ralph Gonsalves, prime minister of Saint Vincent and the Grenadines, said: "They are lifesavers. In some Caribbean countries, they constitute the backbone of the response to the pandemic."

For the first time relatively wealthier European counties requested help, and Cuban brigades were sent to both Italy and Andorra where they were welcomed with open arms by the grateful local populations.

The British government has also co-operated with Cuba to facilitate medical support for four non-self governing British overseas territories: Anguilla, Turks & Caicos

Islands, Virgin Islands and Montserrat.

I really want to congratulate the British government on this initiative which builds upon the co-operation shown with Cuba in the rescuing of the passengers of the Covid-19-stricken cruise ship the MS Braemar in the early days of the pandemic.

I hope that such co-operation across frontiers will become the norm. At a time when the Trump-led US administration is pushing an "America First" policy which has prevented Cuba and other countries from obtaining life-saving PPE and ventilators, it is essential that countries like our own follow a different path of international co-operation.

The US withdrawal from the World Health Organisation at a time of world health crisis is a very dangerous portent of a catastrophic global response to this and future crises.

Of course Cuba has a long history of international medical co-operation and disaster relief efforts.

I remember the Cuban doctors bravely working in west Africa, battling against the Ebola outbreak there, and in 2005 Cuban medics travelled to Pakistan following the terrible Kashmir earthquake.

They worked in a country that at the time had no diplomatic relations with Cuba.

It also presented the most inhospitable conditions for the Cubans who had to get used to working in the freezing cold and snowy foothills of the Himalayas.

Here, as in many of the brigades, the majority of the medics were women.

There are now growing calls for the Cuban medical brigades to be recognised for their work, and I am pleased to add my name to the call for them to be awarded the 2021 Nobel Peace Prize for their efforts.

In Cuba they have a very well-regarded health system of their own, which was itself modelled on our own NHS.

The domestic response to the crisis has been well-organised and successful.

They have the highest ratio of doctors to population in the world and they have been effective in isolating cases, tracing contacts, screening and applying various treatments, including their own domestically developed antiviral agent, interferon alpha-2b.

Cuba has reported just 4,684 cases and 108 deaths so far: a tenth of the global average per capita.

There is also the hope that Cuba will be able to develop its own vaccine. It is the first country in Latin America to have one currently in the testing phase alongside vaccines around the world.

Cuba has already made clear that should they be successful they would make the vaccine available to countries across the globe, helping those who would otherwise be excluded due to cost to find a viable mass vaccine solution.

All this is a far cry from the response to the health crisis from Washington, which has continually downplayed the severity of the epidemic to the detriment of its citizens, and has at the same time attacked the Cuban medics and even tried to pressure other countries to end any co-operation.

In the build-up to the November presidential election, US anti-Cuba rhetoric will rise as candidates scurry to try to secure support from the million-strong Cuban-American community in the crucial state of Florida.

Of course this is a continuation of US efforts to force a change of direction in Havana and the biggest threat to Cuba's work is the ongoing blockade of the island.

I hope that Britain will maintain its current position of opposing the blockade each year at the United Nations during the annual vote on the policy.

I am proud to currently be one of the vice-chairs of the all-party parliamentary group on Cuba in Westminster and we will continue to help develop exchanges and co-operation between our two countries.

I hope that Labour members and parliamentarians from across the House will join me in supporting these efforts in further developing cooperation with the people of Cuba.

Paula Barker is the Member of Parliament for Liverpool Wavertree.

Fuente: Morning Star. Disponible en https://cutt.ly/8fNQD97

Perspectivas de la investigación clínica de vacunas contra SARS-CoV-2

18 sep. En el contexto actual de la pandemia mundial, todos los países requieren disponer de una vacuna que confiera inmunidad contra el virus SARS CoV-2. El desarrollo de este fármaco es la alternativa más inmediata para proteger a la población del efecto del virus, por lo que todos los gobiernos están a la expectativa de los resultados de las investigaciones que realizan las compañías farmacéuticas para asegurar la calidad, seguridad y eficacia de las vacunas.

Para utilizar una vacuna, como para cualquier otro medicamento, es necesario asegurar que son seguras y eficaces. Este proceso es complejo, largo y riguroso. Se compone de varias etapas que deben ser respetadas para proteger la salud de la población.

Antes de utilizar una sustancia en seres humanos, es necesario realizar una fase preclínica. Los estudios preclínicos tienen por

objetivo determinar el potencial de un posible fármaco, son realizados in vitro, en cultivos de células, posteriormente en varias especies de animales y pretenden demostrar la falta de efectos adversos, para luego continuar con los estudios en seres humanos.

Los estudios clínicos en humanos se dividen en estudios fase 1 a 4, cada una de estas fases responde a la necesidad de garantizar la seguridad de las personas participantes. La Fase I del desarrollo de un medicamento es el primer paso de la investigación clínica, consiste en la administración de un medicamento en seres humanos por primera vez. Participan sujetos voluntarios sanos para evaluar en qué niveles de uso del fármaco se observa toxicidad. Se prosigue con los estudios de dosis-respuesta en los pacientes para determinar la seguridad del medicamento y, en algunos casos, indicios iniciales de su efectividad. Estos estudios proponen establecer una evaluación preliminar de la seguridad y del perfil farmacocinético y, cuando sea posible, un perfil farmacodinámico. Proporcionan información preliminar de toxicidad, absorción, distribución, metabolismo, excreción, duración de la acción, interacciones con otros fármacos e incluso interacciones con alimentos. Estos ensayos sirven además para orientar la dosis, vía y pauta de administración para ensayos clínicos que se realicen posteriormente. Son imprescindibles para valorar la seguridad del medicamento en estudio. Salvo excepciones debidamente fundamentadas, se llevan a cabo en pequeños grupos de individuos voluntarios sanos.

Actualmente hay trece vacunas que están realizando estudios clínicos fase 1, se realizan en instituciones como Instituto Finlay de Vacunas, Cuba; West China Hospital, Sichuan University, Beijing Wantai Biological Pharmacy/ Xiamen University o el Imperial College London. En una Fase I más avanzada (I/II) de investigación hay once vacunas, cuatro de ellas enfocadas en ADN viral, dos enfocadas con subunidades proteicas, una de ARN y otra de virus inactivado.

Con la información obtenida en la Fase I, se procede con la fase II, la cual consiste en ensayos clínicos controlados, diseñados para demostrar la efectividad y la seguridad relativa. Constituyen la etapa inicial de la evaluación de la eficacia. Generalmente se efectúa en un número limitado de sujetos voluntarios sanos estrechamente supervisados. Siendo una población bien definida y homogénea.

En la fase II, en este momento, hay tres vacunas en desarrollo que incluyen vacunas que utilizan ARN o subunidades proteicas, desarrolladas por Curevac, Novavax y Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology y Chinese Academy of Sciences.

Después de establecer una probabilidad razonable de la efectividad del medicamento y con el objetivo de obtener información adicional sobre su efectividad para prevenir la enfermedad y una definición más precisa de los efectos adversos asociados al medicamento, se realizan los estudios Fase III, esta fase incluye estudios controlados y no controlados. Se realiza en una muestra de sujetos voluntarios mucho mayor que en las fases anteriores y, lo más importante, representativa de la población a la que irá destinado el medicamento. El elemento control con el que se compara debe ser preferiblemente el tratamiento estándar aprobado para la patología en estudio, si lo hubiera, o en su defecto placebo. Además, estos ensayos establecen la incidencia de efectos adversos comunes y son capaces de identificar el perfil de pacientes con mayor riesgo para desarrollar los menos comunes. Todas estas características hacen que los ensayos Fase III sean el soporte para la autorización de comercialización de un medicamento, ya que reproducen las condiciones de uso habituales, consideran las alternativas terapéuticas disponibles en la indicación estudiada y proporcionan datos fundamentales de seguridad y eficacia.

En la fase III hay nueve vacunas, cuatro de ellas se enfocan en vectores virales, la de University of Oxford/AstraZeneca, CanSino Biological Inc./Beijing Institute of

Biotechnology, Gamaleya Research Institute y Janssen Pharmaceutical Companies. Tres se enfocan en virus inactivados Sinovac, Wuhan Institute of Biological Products/Sinopharm y Beijing Institute of Biological Products/Sinopharm. Por último, Moderna/NIAID y BioNTech/ Fosun Pharma/Pfizer se enfocan en tecnología ARN.

De las candidatas a vacunas más conocidas está la vacuna producida por el Instituto de Investigación Gamaleya de Rusia. Si bien, esta fue la primera vacuna en ser aprobada contra la COVID-19 el 11 de agosto para un uso limitado, lo hizo sin iniciar los estudios fase 3. Fue hasta el 4 de setiembre que se publicaron sus resultados preliminares de los estudios fase I/II en la revista científica The Lancet, los cuales señalan que la vacuna tiene un buen perfil de seguridad y que genera una fuerte respuesta inmune humoral y celular en los participantes, indican en la publicación que se requieren mayores estudios para demostrar efectividad para prevenir contra el COVID-19. Es importante señalar que dicha publicación ha obtenido múltiples críticas de la comunidad científica respecto a la evidencia utilizada para concluir sobre sus resultados.

De la vacuna desarrollada en China por CanSino Biological Inc. y el Beijing Institute of Biotechnology el 15 de agosto en la revista científica *The Lancet* se publicaron resultados del estudio fase II realizado en 603 voluntarios que indican que la vacuna es segura y que induce una respuesta inmune significativa en la mayoría de las personas que recibieron una dosis de la vacuna.

La Universidad de Oxford junto a AstraZeneca han reportado un avance normal en el estudio clínico, deteniendo el estudio en varias ocasiones para analizar efectos adversos. Situación que es usual en los estudios clínicos.

Los laboratorios Moderna y Pfizer realizaron abordajes más novedosos en el desarrollo de la vacuna, enfocándose en tecnologías que usan ARN mensajero, los resultados preliminares de los estudios fase II presentaron una adecuada respuesta inmunológica y efectos adversos de leves a moderados, principalmente en el sitio de la inyección.

Estas vacunas en fase tres son las más cercanas a obtener una aprobación para ser utilizados en seres humanos para prevenir la COVID-19, sin embargo, requieren un análisis muy detallado de su seguridad y eficacia. Análisis que requiere una evaluación profunda de cada una de las personas participantes en el estudio clínico.

Es fundamental determinar la cantidad de tiempo que se genera inmunidad contra el virus, este es uno de los factores más importantes en una vacuna, ya que lo deseado es una vacuna que ofrezca una protección de al menos varios años contra el virus. Este análisis requiere un largo periodo (varios meses) de tiempo.

Unos de los riesgos más importantes son las reacciones inmunológicas que pueden generar muchos problemas en una persona vacunada. Estos riesgos deben ser minimizados lo máximo posible para no afectar la salud de las personas vacunas.

En algunos países como China y Rusia, como se mencionó anteriormente, la legislación permite una aprobación de uso en emergencia o uso limitado, estas aprobaciones se realizan sin toda la documentación completa que sí se solicita regularmente a las vacunas, como en este caso, que se aprobó sin iniciar los estudios fase 3. El riesgo principal de estas autorizaciones es el desarrollo de efectos adversos desconocidos o la falta de eficacia en la protección contra el virus.

Una vez que la vacuna ha superado la fase III de investigación clínica que tarda varios meses, es sometida al proceso de aprobación por distintos entes reguladores, hasta después de obtenida esta aprobación es que puede iniciar el proceso de distribución y comercialización. El proceso de fabricación, si bien se ha venido desarrollando en los laboratorios a pequeña escala, debe de empezar a aumentar su capacidad para producir a gran escala y cubrir la demanda mundial, y a la vez, asegurar una distribución equitativa en los diferentes países. Este proceso de aumento de la escala

de producción o transferencia de tecnología para fabricarlos en otros sitios de manufactura puede tardar varios meses.

Una vez que la autoridad sanitaria ha aprobado la comercialización del medicamento, se realizan los estudios Fase IV, estos ensayos pueden incluir investigación destinada a explorar un efecto farmacológico específico, establecer la frecuencia de las reacciones adversas o determinar los efectos de la administración a largo plazo (años) de un medicamento. Son ensayos controlados, aleatorizados y prolongados en el tiempo, y de los resultados de estos estudios es posible obtener información fundamental para la permanencia de un producto en el mercado.

Es importante que las personas sean consientes de que el adecuado diseño de estos estudios clínicos y el seguimiento detallado de las fases en la investigación clínica resultan pasos fundamentales para resguardar la seguridad de los sujetos que utilizarán el nuevo medicamento.

Fuente: DELFINO. Disponible en https://cutt.ly/qfNWOcj

El papa Francisco pidió que la vacuna contra el coronavirus sea universal

19 sep. El Sumo Pontífice sostuvo que "sería triste si en la entrega se diera prioridad a los más ricos o si pasara a ser propiedad de esta o aquella nación, y ya no fuera para todos"

El papa Francisco pidió hoy que la vacuna que se descubra contra el coronavirus sea universal y no solo esté al alcance de los países más ricos, para que todos, incluso los más pobres, puedan curarse de esta pandemia.

"La reciente experiencia de la pandemia, además de una gran emergencia sanitaria en la que ya han muerto casi un millón de personas, se está convirtiendo en una grave crisis económica, que genera pobres y familias que no saben cómo salir adelante", dijo Francisco, durante una audiencia que mantuvo este sábado con miembros de la fundación italiana "Banco Farmacéutico".

"Sería triste si en la entrega de la vacuna se diera prioridad a los más ricos o si esta vacuna pasara a ser propiedad de esta o aquella nación, y ya no fuera para todos. Debe ser universal, para todos", añadió.

Francisco lamentó que haya "poblaciones del mundo" que "no tienen acceso a determinados fármacos" y dijo que "a nivel ético, si existe la posibilidad de tratar una enfermedad con un fármaco, este debe estar al alcance de todos, de lo contrario se crea una injusticia".

Cargó contra el "peligro de la globalización de la indiferencia" y defendió "la globalización de la cura, es decir, la posibilidad de que todas las poblaciones tengan acceso a los fármacos que podrían salvar muchas vidas".

Finalmente, justificó que "las empresas farmacéuticas pueden contribuir generosamente a una distribución más equitativa de los medicamentos" y que los gobernantes, "a través de opciones legislativas y financieras, están llamados a construir un mundo más justo, en el que los pobres no sean abandonados o, peor aún, descartados".

La Organización Mundial de la Salud (OMS) instó el viernes a los países a mantener los esfuerzos en la lucha contra la pandemia, en momentos en que los casos de COVID-19 han alcanzado casi los 30 millones en el mundo.

El presidente de los Estados Unidos, Donald Trump, aseguró este viernes que la vacuna contra el Covid-19 llegará "a todos los estadounidenses" en abril, aunque las primeras dosis podrían ser administradas antes de fin de año.

El mandatario se refirió al "progreso histórico" registrado por tres vacunas, que se encuentran en las etapas finales de desarrollo, y afirmó que habrá al menos 100 millones de dosis disponibles para diciembre. "Esencialmente la tenemos", aseguró.

Se refería a aquellas desarrolladas por Moderna; Pfizer

y BioNtech; y el Instituto Jenner de la Universidad de Oxford y AstraZeneca. Todas ellas se encuentran en la tercera y última fase de testeos y, de obtener resultados positivos en ellas y su consecuente aprobación, podrían comenzar a ser distribuidas.

No obstante, son las primeras dos quienes han firmado convenios con el gobierno estadounidense para producir cientos de millones de vacunas para el país. Ambas reservaron 100 millones para el país, y el contrato incluye opciones de compra por cientos de millones más. Moderna espera publicar los resultados de sus estudios en noviembre, y Pfizer en diciembre. Cada vacuna se inyectaría en dos dosis separadas por un intervalo de tres o cuatro semanas.

Fuente: Infobae. Disponible en https://cutt.ly/KfNE82u

Soberana-01, esperanza desde Latinoamérica y el Caribe

20 sep. La humanidad interpretó como un mensaje de esperanza desde América Latina y el Caribe el inicio, el 24 de agosto del año en curso, de la primera etapa de los ensayos clínicos de Soberana-01, candidato vacunal cubano contra la Covid-19.

'Hay más de 200 candidatos en desarrollo en el mundo, y con este solamente 30 lograron ya la aprobación para iniciar ensayos clínicos', aseguró el doctor Vicente Vérez, director general del Instituto Finlay de Vacunas (IFV), en relación con la aplicación del compuesto a 676 voluntarios en dos etapas, cuyos resultados estarán disponibles a inicios de 2021.

Vérez afirmó que se trata de un hito importante porque los científicos de la mayor de las Antillas cumplieron todos los requisitos a pesar de acelerar el tiempo.

Según el experto, China aparece como la nación que tiene más candidatos, seguida por Estados Unidos, Gran Bretaña, Rusia, Alemania y algunos otros como Australia y Japón.

'Se trata de países desarrollados -subrayó el líder científico-, conectados a multinacionales, y Cuba es el primero de Latinoamérica y el Caribe en alcanzar este resultado, una nación pobre en recursos económicos, pero grande de espíritu, y esa es la razón por la cual estamos en ese grupo'.

Explicó que para avanzar resultó muy estimulante una reunión sostenida el 19 de mayo con el presidente de la República, Miguel Díaz -Canel, en la cual se resaltó la importancia de lograr un inmunizador específico cubano para tener soberanía, de ahí el nombre en el que investigadores y pueblo coincidieron.

Los especialistas señalan que una vacuna requiere de varias etapas a partir del desarrollo farmacéutico, productivo, de ensayos en animales y de toxicidad. Los sistemas regulatorios a nivel mundial ha simplificado este grupo de pasos ante el azote de la Covid-19, con el objetivo de acortar los tiempos frente a la pandemia sin restar importancia a cada uno de ellos desde el punto de vista de la seguridad.

'Tenemos que vencer una fase 1 de ensayos clínicos, que demuestra la seguridad en la vacuna, con un número pequeño de voluntarios; después pasamos a una fase dos, con una cifra más grande de sujetos en los cuales se ve si la vacuna tiene la capacidad de inducir la respuesta inmune necesaria', explicó.

Posteriormente, será necesaria una tercera etapa, en la cual aunque se sepa de la existencia de una respuesta inmune que se supone podrá evitar la enfermedad, resultará imprescindible demostrar la eficacia en la prevención. 'Ese es el camino que hay que recorrer, ya logramos vencer el primer escalón, algo muy importante en tres meses', consideró.

Ante la agresividad global de la pandemia, el sistema regulatorio mundial tuvo que adaptarse de una manera tal al problema, que permitió cambios para acortar los plazos de desarrollo de un inmunizador, con la premisa de mantener los elementos principales de seguridad.

De la capacidad de comprender esto, según Vérez, dependía estar en condiciones de producir una vacuna rápidamente, entendiendo qué se debía hacer, qué mantener y qué aprovechar de otros inmunizadores ya existentes.

'La percepción que tenemos como científicos -indicó- es que no ha habido una ocasión en la cual la humanidad haya generado tanto conocimiento científico en un período tan corto, el de las multinacionales privadas, pero también mucho conocimiento público'.

En este contexto, fueron creados sistemas especiales que posibilitaron el acceso gratuito a esos saberes oficiales, o sea, el mundo científico se enfrentó de una manera diferente a la enfermedad para acelerar el desarrollo de esta tecnología.

Todo esto permitió a los investigadores cubanos definir que el proceso de entrada del virus a la célula para colonizarla tenía como base un pequeño fragmento de la proteína conocida como RBD, 'que termina funcionando como la llave con la que el virus abre la cerradura de la célula humana a la cual él tiene que entrar para poderse reproducir', explicó Vérez en lenguaje comunicacional.

Conocido ese mecanismo, fue posible tomar esa 'llave', producirla en otra célula mediante biotecnología y utilizarla en combinación con la vacuna cubana contra la meningitis meningocócica, con más de 30 años de uso, probada en diversos grupos etarios y cuya seguridad resulta indiscutible.

'La idea fue concebir una vacuna basada en plataformas existentes para acortar tiempos', detalló, por su parte, la directora de investigaciones del IFV, doctora Dagmar García.

Al explicar el éxito del proyecto en solo tres meses, el doctor Yuri Valdés, director adjunto del IFV, en tanto, comentó que ello se concretó porque su trayectoria tuvo como fundamento cuatro pilares.

En primer lugar, entre diferentes apuestas científicas el equipo identificó la proteína RBD como antígeno principal para este proyecto, y al propio tiempo lacombinó con una plataforma nacional segura y probada durante más de tres décadas.

También constituyeron soportes trascendentales la gestión del conocimiento en tiempo real, método que significó un verdadero desafío para la comunidad científica del IFV en este trabajo, articulado con el Centro de Inmunología Molecular, la Universidad de La Habana, el apoyo del grupo empresarial BioCubaFarma y otras instituciones de biotecnología del país.

Finalmente, un aval incuestionable acerca del rigor científico de cada paso en la creación de este producto innovador resultó el permiso para los ensayos emitido por el Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos de Cuba.

Fuente: Prensa Latina. Disponible en https://cutt.ly/Gf1TpkZ

WHO unveils global plan to fairly distribute COVID-19 vaccine, but challenges await

21 sep. The World Health Organization (WHO) announced today that countries representing close to two-thirds of the world's population have joined its plan to buy and fairly distribute COVID-19 vaccines around the globe. It also unveiled the mechanism through which it plans to allocate the vaccine as it becomes available, aiming "to end the acute phase of the pandemic by the end of 2021."

"It is a huge success to have equivalent to 64% of the world's population signed up," Alexandra Phelan, a lawyer at Georgetown University who specializes in global health policy, wrote in an email. "However, this doesn't reflect the deeply unequal power dynamics in global health and vaccine manufacturing capabilities that may still challenge equitable access to vaccines." China and the United States are notably absent from WHO's list of partners in the COVID-19

Vaccines Global Access (COVAX) Facility, she and other observers noted.

With nearly 1 million deaths reported worldwide from COVID-19, and the Northern Hemisphere heading into its first winter in the pandemic, SARS-CoV-2 still has the world in its grip. WHO has pushed countries to sign up for a plan that will buy a vaccine in huge quantities and distribute it in an equitable way. But it has been grappling with two big issues: how to get high-income countries to join, instead of hoarding early vaccine supplies for their own populations; and how to share the vaccine in a fair way once it becomes available.

"As of today, 64 higher income countries, including 29 economies operating as Team Europe, have submitted legally binding commitments to join the COVAX Facility," Seth Berkley, head of GAVI, the Vaccine Alliance, said at the press conference. An additional 38 countries are expected to sign soon, he said. These countries will have access to the vaccines in the COVAX portfolio and will pay for their own doses. Lower income countries that have joined COVAX will have vaccine doses purchased for them; there are 92 such signers.

The list of high-income countries that have joined includes Canada, Japan, New Zealand, and Peru. But "The fact that the U.S. is not part of this conversation at all, as far as I can tell, is incredibly distressing," says Ashish Jha, dean of Brown University's School of Public Health. Asked about China's absence, Berkley said the goal is to work with every country in the world. "I can assure you that we have had conversations and will continue to have conversations with all countries," he said.

Many questions remain about how the COVAX Facility will work. So far, just $700 million has been raised to pay for the vaccine in lower income countries, short of the $2 billion thought to be needed by the end of the year. And it is not clear how the deals many countries already have made directly with vaccine manufacturers will impact WHO's plans. "I think the big question for COVAX, and the thing that will determine whether COVAX can really deliver on its vision, is to what extent those domestic deals that are being done by rich countries mean that they won't need COVAX so much themselves, and therefore might not provide sufficient financing for the non–self-financing countries," says Alex Harris of the Wellcome Trust.

In an ideal world, there would be no such bilateral deals, says WHO's Mariângela Simão, "but that's not how it works." And negotiations on many of those deals were already underway when COVAX was being set up, she says. As a result, such deals "are a danger in a way" to the plan.

WHO's "fair allocation mechanism" proposes distributing vaccine in two phases. In the first phase, all countries would receive vaccine proportional to their population; initially enough vaccine to immunize 3% of their population, with the first doses going to frontline workers in health care and social care. Then, additional vaccine would be delivered until 20% of a nation's population is covered. WHO envisages that these doses would be used to immunize those at the highest risk from COVID-19: elderly people and those with comorbidities.

In the second phase, vaccine to cover additional people would be delivered to countries based on how urgently immunizations are needed. The framework suggests two criteria should be used to decide priority:

how fast the virus is spreading (the effective reproduction number) and whether other pathogens such as influenza or measles are spreading at the same time; and

how vulnerable a country's health system is, based on metrics such as the occupancy of beds in hospitals and intensive care units

Ezekiel Emanuel, a bioethicist at the University of Pennsylvania, criticized WHO's approach in the first phase. Countries with the biggest need should be at the top of the list from the start, he says. He compares the situation to a doctor facing an overflowing emergency room. "The doctor doesn't go out into the waiting room and say: 'I'm giving 3 minutes to everybody sitting in the waiting room.' The doctor says: 'All right,

who's got the most serious illness? … I'm going to attend to you first.'" At the moment, he notes, sending vaccine to South Korea, New Zealand, or many African countries would not do much to reduce deaths from COVID-19 because these nations have low case rates; he says the vaccine could be put to better use elsewhere.

But WHO's Bruce Aylward notes new outbreaks can suddenly pop up in new places. "Remember, we are dealing with a ubiquitous threat (the virus) and ubiquitous vulnerability (highly susceptible high-risk populations)!" Aylward wrote. "Hence you go for rapid risk reduction as [the] first step."

Allocating some vaccine to every participating country in the beginning may have been necessary politically, Jha says. "I think [WHO is] probably balancing between trying to get enough people protected, and trying to create enough of a sense of buy-in that people are going to be willing to chip in." Emanuel says he understands WHO's position, "But we shouldn't confuse politics with ethics."

There are numerous caveats to WHO's plan, most importantly that the framework was written without knowing the characteristics of whatever vaccine first becomes available. The mechanism is based on "the current working assumption for a vaccine with a broad safety and effectiveness profile," WHO says. If the first available vaccine turns out to be much better at protecting young people than elderly people, for instance, a different strategy might be needed. "I have 40 years of public health and [helping draft the plan] is definitely the biggest challenge I ever faced," Simão says. All kinds of models and calculations were used but there is a huge amount of uncertainty, she says, noting the document is called a "final working version." Until more is known, she says, "this is as good as it gets."

The plan faces other risks. For example, countries could decide to use export controls or other means to restrict vaccine supplies and deny them to COVAX, Phelan says. "We still need global commitment to set the norms of unacceptable conduct during vaccine distribution," she says, "including discriminatory distribution within countries." But there is also the opportunity that this mechanism, patched together as the world scrambles to fight a pandemic, becomes a norm for future pandemics, she says. "As the [WHO] director-general has noted, we need to be preparing for the next pandemic now, in addition to responding to COVID."

Fuente: Science Magazine. Disponible en https://cutt.ly/Yf1TKAV

Coronavirus: en Inglaterra infectarán a voluntarios para evaluar las vacunas

23 sep. El Reino Unido será la sede de los primeros ensayos clínicos en los que los voluntarios se infectarán deliberadamente con el coronavirus para evaluar la efectividad de las vacunas contra la covid-19, según informó el diario Financial Times.

Se espera que el proyecto financiado por el gobierno británico comience en enero en una instalación en Londres, aunque aún resta la aprobación de la Agencia Reguladora de Medicamentos y Productos Sanitarios del Reino Unido.

Hasta ahora, las decenas de ensayos conocidos buscan la inmunización de la población vacunada para comprobar su eficacia ante el virus, sin que los voluntarios se contagien de forma premeditada. Sin embargo, científicos británicos proponen una metodología inversa en este ensayo de "desafío humano": los voluntarios primero serán inoculados con una vacuna y aproximadamente un mes después recibirán una dosis de Sars-Cov-2, el virus que causa el COVID-19, en condiciones controladas.

El líder académico del proyecto es el Imperial College London, y estará a cargo de hVivo, una filial de la Universidad Queen Mary de

Londres que fue comprada a principios de este año por Open Orphan, una organización de investigación farmacéutica con sede en Dublín.

Actualmente, hay 38 vacunas probándose en humanos, según recoge la Organización Mundial de la Salud (OMS). Entre ellas, la de la británica AstraZeneca en colaboración con la Universidad de Oxford y también de la británica GSK junto a Sanofi. Otras de las candidatas más avanzadas están desarrolladas por Janssen, Moderna, CureVac, Pfizer o Novavax.

Voluntarios

Según trascendió, aproximadamente 2.000 voluntarios potenciales se inscribieron para estudios de desafío en el Reino Unido a través del grupo de defensa -con sede en EE.UU.- 1Day Sooner, que hace campaña para los ensayos de infección por covid-19, y que ya reclutó a 37.000 personas en todo el mundo.

Aquellos que fueran seleccionados para participar en este ensayo podrían recibir una compensación superior a los 3.750 euros.

Desafío humano

Los ensayos de desafío tienen una larga historia que se remonta a 1796, cuando el pionero de la vacuna Edward Jenner inoculó a James Phipps, de ocho años, con el virus vivo de la viruela. Más recientemente, han sido fundamentales en el desarrollo de vacunas y tratamientos para la fiebre tifoidea, el cólera y la malaria y en la comprensión de cómo responde el sistema inmunológico a la gripe y otros virus.

Sin embargo, esta metodología clínica no deja de causar controversia entre los profesionales de la salud. Dominic Wilkinson, profesor de ética médica en la Universidad de Oxford, se manifestó a favor del polémico estudio.

"Cuando nos enfrentamos a una amenaza global sin precedentes de COVID, es un imperativo ético realizar estudios de desafío bien controlados para ayudar a desarrollar una vacuna y luego identificar las mejores vacunas", sostuvo.

En tanto, Michael Selgelid y Euzebiusz Jamrozik, integrantes del Centro de Bioética de la Universidad de Monash, sostienen que si bien "los estudios de desafío son necesarios, a veces son éticamente controvertidos".

"Los experimentos médicos que involucran la infección intencional de personas con bacterias, virus y parásitos pueden ser útiles para probar nuevas vacunas y cada vez se utilizan más a nivel internacional, particularmente en los países en desarrollo. Sin embargo, hay que considerar varias cuestiones éticas en torno a las condiciones en las que se debe realizar este tipo de investigación", exponen los científicos en un artículo publicado en *The Lancet*.

"Los estudios de desafíos humanos pueden ser éticamente aceptables siempre que cumplamos con los requisitos básicos de ética de la investigación. Entre otras cosas, esto debería implicar un consentimiento informado adecuado y minimizar los riesgos. También debe haber razones científicas legítimas para realizar el estudio", concluyeron.

Fuente: Página 12. Disponible en https://cutt.ly/0f1YhmG

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Patentes registradas en PatentScope

Estrategia de búqueda: *Vaccine in the title or abstract AND 20200725:20200731 as the publication date*

16 results

1.WO/2020/184730DENGUE VIRUS VACCINE
WO - 17.09.2020
Int.Class A61K 39/12 Appl.No PCT/JP2020/012569 Applicant TOKYO METROPOLITAN INSTITUTE OF MEDICAL SCIENCE Inventor KOHARA, Michinori
The present invention provides a recombinant Vaccinia virus as a dengue virus vaccine that can be used as a therapeutic or prophylactic agent in the clinic. This recombinant Vaccinia virus is characterized by including: all or part of a cDNA that encodes a non-structural protein from a dengue virus; and an expression promoter.

2.20200289637Compositions for Booster Vaccination Against Dengue
US - 17.09.2020
Int.Class A61K 39/12 Appl.No 16652902 Applicant Sanofi Pasteur Inventor Diana Coronel

The present invention is directed to a method of booster vaccination and to a vaccine composition for use in such a method, for inducing in a human subject a neutralizing antibody response, wherein said subject has previously received a primary vaccination against each of serotypes 1 to 4 of dengue virus and was dengue naïve before said primary vaccination, said composition comprising a dengue antigen of at least one of serotypes 1 to 4 or a nucleic acid construct capable of expressing said antigens in the subject, wherein said booster vaccination results in a 2-fold increase in the neutralizing antibody titre against each of serotypes 1 to 4. The invention is also directed to a method of inducing in a human subject a neutralizing antibody response comprising the administration of a vaccine composition, or to a vaccine composition for use in such a method, said composition comprising a dengue antigen of each of serotypes 1 to 4, or a nucleic acid construct capable of expressing in said subject a dengue antigen of each of serotypes 1 to 4; wherein said composition is administered as a primary vaccination, followed by a booster vaccination, and wherein the human subject is initially dengue naïve.

3.WO/2020/183420VACCINE COMPOSITIONS AND METHODS FOR REDUCING TRANSMISSION OF STREPTOCOCCUS PNEUMONIAE
WO - 17.09.2020
Int.Class A61P 31/04 Appl.No PCT/IB2020/052250 Applicant ST. JUDE CHILDREN'S RESEARCH HOSPITAL Inventor ROSCH, Jason W.

Compositions and methods are provided for reducing the mammalian transmission of Streptococcus pneumoniae (S. pneumoniae) through the administration to mammalian subjects of vaccine compositions comprising at least one immunogenic polypeptide comprising a S. pneumoniae protein or a fragment or variant thereof that is required for or involved in transmission of the bacteria between mammalian hosts. These vaccine compositions also serve to reduce the incidence rate of at least one invasive disease caused by S. pneumoniae. Methods are also provided for identifying additional genetic factors involved in mammalian transmission of S. pneumoniae.

4.20200289634CANINE LYME DISEASE VACCINE
US - 17.09.2020
Int.Class A61K 39/02 Appl.No 16767715 Applicant Intervet Inc. Inventor Rhonda LaFleur

The present invention provides a vaccine for canine Lyme disease and methods of making and using the vaccine alone, or in combinations with other protective agents.

5.WO/2020/182993MRNA VACCINE
WO - 17.09.2020
Int.Class A61P 35/00 Appl.No PCT/EP2020/056891 Applicant ETHERNA IMMUNOTHERAPIES NV Inventor DE KOKER, Stefaan
The present invention in general relates to a combination of mRNA molecules encoding functional immunostimulatory proteins and a CTLA4 pathway inhibitor. In particular, it relates to a combination of one or more mRNA molecules encoding at least one functional immunostimulatory protein selected from the list comprising: CD40L, CD70 and caTLR4; and a CTLA4 pathway inhibitor, optionally also in the form of an mRNA molecule. The present invention further relates to vaccines comprising such combination, as well as uses of the combinations and vaccine of the present invention in human or veterinary medicine, in particular in the prevention and/or treatment of cell proliferative disorders.

6.20200289641VACCINE COMPOSITION FOR CLASSICAL SWINE FEVER AND PREPARATION METHOD THEREOF
US - 17.09.2020
Int.Class A61K 39/225 Appl.No 16770190 Applicant BIOAPPLICATIONS INC. Inventor Yongjik LEE

Provided is a swine fever antigen fused with a porcine Fc fragment, and more particularly, to a vaccine composition having an autoimmune-enhancing effect by binding the Fc fragment to a swine fever antigen, and a preparation method thereof.

7.20200289636FILOVIRUS VACCINES AND METHODS OF USE
US - 17.09.2020
Int.Class A61K 39/12 Appl.No 16645417 Applicant Hawaii Biotech, Inc. Inventor David E. CLEMENTS

The data reported herein describe the production and evaluation of a recombinant subunit filovirus vaccine using insect cell expressed surface glycoprotein (GP) and a highly effective adjuvant. The vaccine provides protection in humans against filovirus infection, including Ebola virus and Marburg virus.

8.WO/2020/181837METHOD FOR RESCUING INFLUENZA VIRUS AND COMPOSITION THEREFOR

WO - 17.09.2020
Int.Class C12N 7/01 Appl.No PCT/CN2019/121905 Applicant ZHEJIANG SENWEI BIOPHARMACEUTICAL DEVELOPMENT CO., LTD. Inventor DAI, Dongsheng
Provided are a new method for rescuing an influenza virus and a composition therefor. The method comprises providing a host cell stably integrated with and expressing influenza virus PA, PB1, PB2 and NP genes, and introducing an influenza virus rescue system in which a stop codon is introduced into the PA, PB1, PB2 and NP genes respectively into the host cell to achieve virus rescue. The produced virus particles can be used as a live attenuated influenza vaccine, which is characterized in that, since the genes encoding the related proteins are mutated, it has no replication and proliferation ability in human and normal animal cells, and replication and proliferation can be achieved only in the host cells constructed above and it can fully stimulate the body immunity and effectively protect the body while ensuring the safety.

9.20200291088NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST ESOPHAGEAL CANCER AND OTHER CANCERS
US - 17.09.2020
Int.Class C07K 14/74 Appl.No 16887994 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

10.WO/2020/182635CARBOCYCLIC DERIVATIVES AND CONJUGATED DERIVATIVES THEREOF, AND THEIR USE IN VACCINES
WO - 17.09.2020
Int.Class A61K 47/64 Appl.No PCT/EP2020/055950 Applicant GLAXOSMITHKLINE BIOLOGICALS SA Inventor ADAMO, Roberto
The invention is in the field of vaccines and relates to oligomers having a selected degree of polymerization, obtained by connecting together a number of carbocyclic repeating units, and to conjugated derivatives thereof. The oligomers and conjugated derivatives thereof of the invention also have a selected degree of acetylation. The derivatives of the invention are useful for the preparation of immunogenic compositions, e.g. in the form of a vaccine.

11.20200289631METHOD OF TREATING WITH A PEPTIDE
US - 17.09.2020
Int.Class A61K 39/00 Appl.No 16887765 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions

that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

12.20200289632A*03 RESTRICTED PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST CANCERS AND RELATED METHODS
US - 17.09.2020
Int.Class A61K 39/00 Appl.No 16887815 Applicant Immatics Biotechnologies GmbH Inventor Colette SONG

The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

13.20200291084NOVEL PEPTIDES AND COMBINATION OF PEPTIDES FOR USE IN IMMUNOTHERAPY AGAINST OVARIAN CANCER AND OTHER CANCERS
US - 17.09.2020
Int.Class C07K 14/47 Appl.No 16889352 Applicant Immatics Biotechnologies GmbH Inventor Andrea MAHR

The present invention relates to peptides, proteins, nucleic acids and cells for use in immunotherapeutic methods. In particular, the present invention relates to the immunotherapy of cancer. The present invention furthermore relates to tumor-associated T-cell peptide epitopes, alone or in combination with other tumor-associated peptides that can for example serve as active pharmaceutical ingredients of vaccine compositions that stimulate anti-tumor immune responses, or to stimulate T cells ex vivo and transfer into patients. Peptides bound to molecules of the major histocompatibility complex (MHC), or peptides as such, can also be targets of antibodies, soluble T-cell receptors, and other binding molecules.

14.WO/2020/182901NUCLEIC ACID VACCINATION USING NEO-EPITOPE ENCODING CONSTRUCTS
WO - 17.09.2020
Int.Class A61K 39/00 Appl.No PCT/EP2020/056541 Applicant EVAXION BIOTECH APS Inventor RØNØ, Birgitte
The disclosure provides means and methods for DNA vaccination that target cancer. In particular is provided a method for anti-cancer vaccination using a plasmid based vaccine comprising regions encoding neo-epitopes and comprising amphiphilic block copolymers such as poloxamer and poloxamine agents.

15.20200289640HPV EPITOPES TARGETED BY T CELLS INFILTRATING CERVICAL MALIGNANCIES FOR USE IN VACCINES
US - 17.09.2020
Int.Class A61K 39/12 Appl.No 16884505 Applicant Academisch Ziekenhuis Leiden H.O.D.N. LUMC Inventor Sjoerd Henricus Van Der Burg

The present invention relates to novel CD4+ and CD8+ T cell epitopes that are specific for HPV-specific E6 and E7 oncoproteins, to peptides comprising these novel T cell epitopes, and to (vaccine) compositions comprising these peptides for use in methods for the prevention and/or treatment of HPV related diseases. Preferred epitopes are recognized by a T cell that infiltrates a cervical neoplastic lesion or by a T cell from a draining lymph node, and are presented by an HLA-DQ or HLA-DP molecule, or an HLA-B.

16.WO/2020/186229TLR4-TLR7 LIGAND FORMULATIONS AS VACCINE ADJUVANTS
WO - 17.09.2020
Int.Class A61K 39/145 Appl.No PCT/US2020/022786 Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA Inventor CARSON, Dennis A.
A method to enhance an immune response in a mammal, and a composition comprising liposomes, a TLR4 agonist and a TLR7 agonist, are provided.

Patentes registradas en la United States Patent and Trademark Office (USPTO)

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1	10,781,244	Peptides and combination of peptides for use in immunotherapy against ovarian cancer and other cancers
2	10,781,233	Cell epitopes and combination of cell epitopes for use in the immunotherapy of myeloma and other cancers
3	10,780,178	Scaffolded HIV-1 vaccine immunogens
4	10,780,162	Mucosal adjuvants and delivery systems
5	10,780,161	Vector co-expressing vaccine and costimulatory molecules
6	10,780,160	Process for preparing pneumococcal polysaccharide-protein conjugates
7	10,780,158	Tunable vaccine platform against pathogens of the paramyxovirus family
8	10,780,157	Multi-CBV vaccine for preventing or treating type I diabetes
9	10,780,151	Composition and therapeutic anti-tumour vaccine
10	10,780,125	Peptides and scaffolds for use in immunotherapy against head and neck squamous cell carcinoma and other cancers

11	10,780,124	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
12	10,780,123	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
13	10,780,122	Peptides and combination of peptides of non-canonical origin for use in immunotherapy against different types of cancers
14	10,780,054	Lyophilization of RNA

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