



## PATENTES / VACUNAS / SALUD PUBLICA

Como se conjuga?

Jose A. Chabalgoity

Postgrado Gestión Tecnológica - Facultad de Ingeniería

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EDITORIAL · 25 MAY 2021

#### A patent waiver on COVID vaccines is right and fair

Wealthier countries must join the United States, Russia and China in recognizing that everyone benefits if vaccine manufacturing is distributed evenly around the world.









Katherine Tai, the US representative at the World Trade Organization, announced US support for a waiver on intellectual property for COVID vaccines on 5 May. Credit: Bill O'Leary/The Washington Post/Bloomberg/Getty

Every country should have the right to make its own vaccines during a pandemic. That's the principle underpinning the campaign to temporarily waive intellectual property (IP) protection on coronavirus vaccines...

## La pandemia dejo en evidencia varias enseñanzas sobre vacunas

#### Importancia de poder acceder a vacunas en tiempo y forma: escasez de vacunas

#### Shortage of Covid-19 vaccines 'likely' to last several months - WHO

Updated / Sunday, 7 Feb 2021 15:12











David Nabarro said really strong public health-led services in the community are needed to combat Covid-19

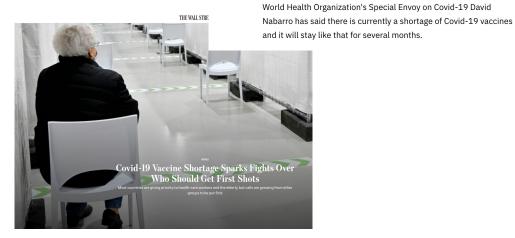
#### nany set for '10 weeks' of COVID vaccine tage

linister Jens Spahn has warned that Germany will struggle to procure enough the next months. The government is now mulling a "vaccine summit."









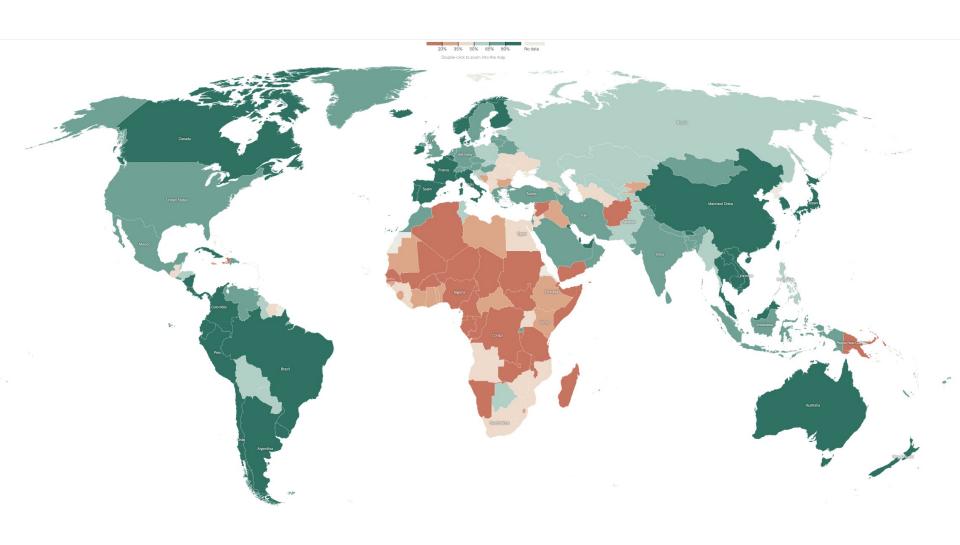


## La escasez de vacunas afectó incluso a los países de las economías centrales...

Skyrocketing demand coupled with shortages of vital components is leading to bottlenecks in the supply chain of this and other mRNA vaccines, delaying vaccine supplies.

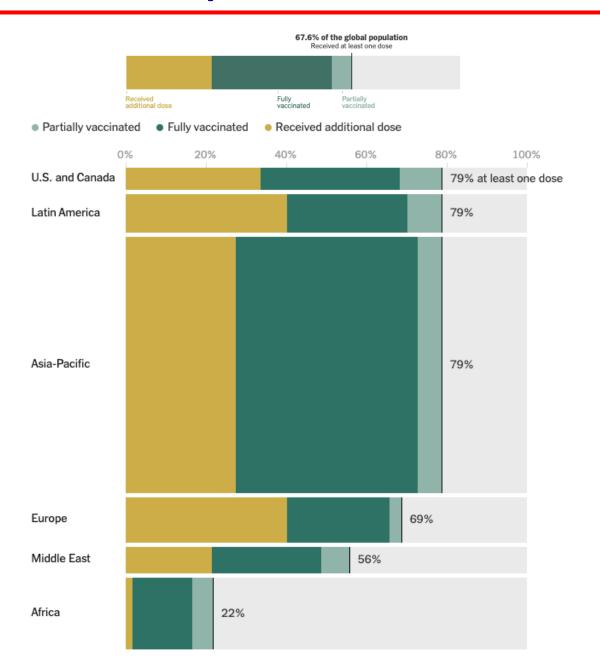
...pero mas afecto a los países mas pobres

### Acceso inequitativo a las vacunas



5.180 millones de dosis administradas

#### Acceso inequitativo a las vacunas



# La distribución equitativa de las vacunas no es solo un tema de solidaridad, es además el único reaseguro para frenar la pandemia.

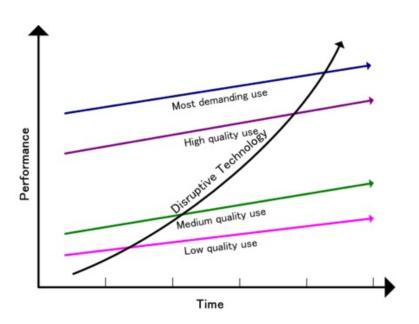
La existencia de regiones o bolsones donde el virus circule sin restricción es el escenario perfecto para que surjan nuevas variantes que por ej. sean resistente a las vacunas

Las nuevas tecnologías pueden modificar profundamente la realidad

En menos de un año, se diseñaron, desarrollaron, evaluaron clínicamente y comenzaron a producirse varias vacunas de efectividad comprobada contra el virus

## Vacunas basadas en ARNm: la emergencia de una tecnología disruptiva

Disruptive technology is an innovation that significantly alters the way that consumers, industries, or businesses operate. A disruptive technology sweeps away the systems or habits it replaces because it has attributes that are recognizably superior.



#### Vacunas a RNAm teconologia disruptiva



**REVIEW**published: 18 March 2021
doi: 10.3389/fbioe.2021.628137



## The Limitless Future of RNA Therapeutics

Tulsi Ram Damase<sup>1</sup>, Roman Sukhovershin<sup>1</sup>, Christian Boada<sup>2</sup>, Francesca Taraballi<sup>3,4</sup>, Roderic I. Pettigrew<sup>2</sup> and John P. Cooke<sup>1\*</sup>

<sup>1</sup> RNA Therapeutics Program, Department of Cardiovascular Sciences, Houston Methodist Research Institute, Houston, TX, United States, <sup>2</sup> Colleges of Medicine, Engineering, Texas A&M University and Houston Methodist Hospital, Houston, TX, United States, <sup>3</sup> Center for Musculoskeletal Regeneration, Houston Methodist Research Institute, Houston, TX, United States, <sup>4</sup> Department of Orthopedics and Sports Medicine, Houston Methodist Hospital, Houston, TX, United States

It is a disruptive therapeutic technology, as **small biotech startups**, as well as **academic groups**, can rapidly **develop new and personalized RNA constructs** 

### Las vacunas pueden ser un gran negocio económico

July 28, 2021 10:32 AM EDT Updated 11:00 AM Pharma, Coronavirus



### When a life-saving vaccine became a cash cow: Pfizer now projects \$33.5B in Covid-19 vaccine sales in 2021 alone

August 2, 2021 06:08 PM EDT Updated 11 minutes ago

Deals



### **UPDATED:** Sanofi buys mRNA player Translate Bio for \$3.2B.

#### Las vacunas pueden ser un gran negocio economico



Global Agenda COVID-19 Global Health Healthcare Delivery

## The COVID vaccine market is worth at least \$150 billion.



### Producción nacional de vacunas

Dimensión ética (Salud Pública)

Dimensión Económica

### El drama para Salud Pública

the**bmj** | BMJ 2020;368:14627 | doi: 10.1136/bmj.14627

#### ACHIEVING FAIR PRICING OF MEDICINES

## Pricing of pharmaceuticals is becoming a major challenge for health systems

Manufacturers using their market power to maximise profits results in prices that are unjustifiable

and unaffordable, argue **Steven Morgan and colleagues** 

#### **KEY MESSAGES**

- Providing universal access to necessary medicines creates tremendous social value but poses a significant policy challenge owing to the costs involved
- Many medicines are being priced at levels unaffordable for payers while more than adequately compensating sellers for costs incurred or lacking justification in their benefits to health systems
- Governments, individually and collectively, must develop laws, policies, and institutional capacity that would prevent such "unfair" pricing

## Patentes / Propiedad Intelectual

## El paradigma de desarrollo de la Biotecnología

El valor de una empresa biotecnológica es directamente proporcional al valor de su portafolio de patentes

## Las patentes son el reaseguro de las empresas para recuperar la inversión en generar la innovación

The rapid development and clinical success of COVID-19 vaccines can be credited to the relationship between inventors and innovators

**PATENTS** 

## A network analysis of COVID-19 mRNA vaccine patents

A preliminary network analysis highlights the complex intellectual property landscape behind mRNA-based COVID-19 vaccines.

he COVID-19 pandemic has had a substantial impact on global health and highlighted the importance of international cooperation to effectively combat SARS-CoV-2. Since the discovery and publication of the virus's genome in January 2020, scientists have rushed to develop vaccines, therapeutics and diagnostics on an unprecedented timescale. To date there are 80 vaccines in clinical trials and 70 more in clinical development, setting the stage for some of the fastest vaccine development and testing in modern history!. The vaccine technology platforms used

by the most promising vaccine candidates range from viral vector-based and protein-based technologies to mRNA and lipid nanoparticle technology. Despite these impressive scientific achievements, barriers such as the vaccine cold chain and multiple forms of intellectual property (IP) protection stand in the way of equitable access and fair allocation.

Webs of intellectual property claims underpin the marketing of many vaccines. For example, the underlying technology used to develop a vaccine can be protected by patents, while manufacturing methods and techniques (know-how) can be protected by trade secrets. Therapeutic development programs tend to consist of an intricate relationship between an inventor and an innovator<sup>2</sup>. The foundational technology needed to develop a vaccine could have been invented in an academic lab setting or startup research firm, protected through patents, and subsequently licensed out to a larger entity for further development and commercialization. These larger entities are designated as innovators because they transform the foundational technology into the final market product.

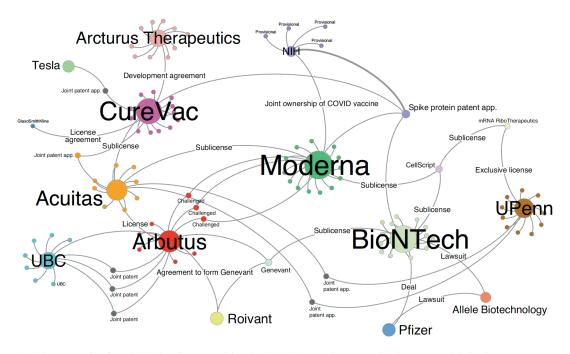


Fig. 1 | Patent network analysis of mRNA-based vaccine candidates for COVID-19. Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology (Supplementary Information). The network analysis was developed using Gephi<sup>23</sup>. UPenn, University of Pennsylvania; UBC, University of British Columbia; app., application.

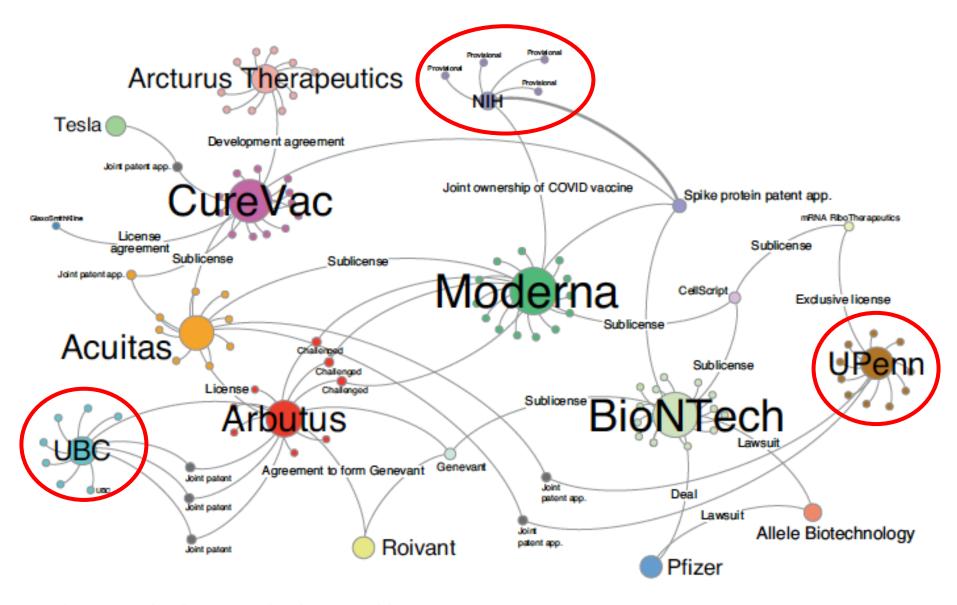


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## La investigación médica es una cuestión pública.

Dr. Christian Wagner BUKO Pharma Campaign

Sanford Burham points to the critical role independent research institutes can play. Backed with funding from federal grants, philanthropy, and the pharmaceutical industry, such institutes can perform the discovery and translational now seen as too risky for industry



Michael Jackson Vice president of drug discovery, Sanford Burnham Medical Research

pound library of a large pharmaceutical. It's Center for Chemical Genomics has about 80 people from biotech and pharma who work side-by-side with principal investigators from Sanford Burnham to identify new drug targets and new pathways for diseases, and have developed the assays and reagents needed to explore them. It has the ability to use induced pluripotent stem cells from patients with diseases and examine them with high throughput microscopy screening.

As financial pressures are forcing Big Pharma to pull back from investing in early-stage research and financial constraints on biotechs are forcing more conservative approaches, Sanford Burham points to the critical role independent research institutes can play. Backed with funding from federal grants, philanthropy, and the pharmaceutical industry, such insti-

tutes can perform the discovery and translational now seen as too risky for industry.

"Pharma used to be larger and more exploitive and possibly more innovative, and had a bit more opportunities to go wherever the molecules took them. Increasingly today, that's not the case," says Jackson. "As the money has shrunk, the people who have got the power in the majority of pharmas are in the marketing organization, which then dictates to the development organization what it wants, which then dictates to research what it wants."

Jackson argues the current model for drug development is not sustainable. The irony is



October 14, 2021 06:24 AM EDT Updated 06:52 AM

Coronavirus



Biden's fight with Moderna over providing vaccines for the poorest countries intensifies

### Dimensión Económica

## Biotecnología como motor de desarrollo económico

### El negocio económico de la biotecnología

Biotechnology Market Size Worth \$2.44 Trillion By 2028 | CAGR 15.83%

NEWS PROVIDED BY **Grand View Research, Inc.** →

Apr 13, 2021, 05:05 ET

SAN FRANCISCO, April 13, 2021 /PRNewswire/ -- The global biotechnology market size is expected to reach USD 2.44 trillion by 2028, according to a new report by Grand View Research, Inc. It is expected to expand at a CAGR of 15.83% from 2021 to 2028. The factors driving the market include favorable government policies, the launch of new and advanced products, robust investment in the biotechnology sector, and rising demand for synthetic biology.

#### Key suggestions from the report:

• The health application segment accounted for the largest share of 48.64% in 2020 owing to the COVID-19 impact, prevalence of diseases, increasing focus on the development of regenerative medicines, and improving healthcare infrastructure

## Biotecnología como motor de desarrollo económico

#### AREA PRIORIZADA (PENCTII)

#### BIOTECNOLOGÍA BIOMÉDICA EN URUGUAY

Caracterización y recomendaciones para la definición de una nueva área de oportunidad

José A. Chabalgoity

Abril 2006

## Producción Nacional de Vacunas

Oportunidades y Desafíos

## **Oportunidades**

- Industria que genera alto nivel de empleo
- Uruguay cuenta con un volumen básico de RRHH altamente calificados
- Infraestructura estratégica versátil
- Diversos modelos de negocios posibles
- Demanda insatisfecha de vacunas

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SPONSORED September 27, 2021 06:00 AM EDT







## Why it Works: Manufacturing a Vaccine in a Multi-Product Facility.



In 2020, the U.S. Department of Health and Human Services and the U.S. Department of Defense called upon CDMOs to support the expansion of the United States' capacity for manufacturing and distributing vaccines or therapeutics related to the COVID-19 pandemic. One example is through a public-private partnership where the federal government reserved fill/finish capacity on a CDMO's commercial filling line for use by federal partners that are developing COVID-19 vaccines or therapeutic treatments. That company's capacity not only supported the U.S. government's Operation Warp Speed efforts and the COVID-19 pandemic response but also supports an increase in U.S. preparedness for future public health emergencies.

Now more than ever flexibility is key to success in the pharmaceutical manufacturing industry, specifically for CDMOs that serve a variety of clients and products. Combine heightened awareness with elevated demand and reduced timelines, and the demand of CDMO capacity, quality, and modern equipment have increased exponen-



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### Adaptability is Key



### The Power of Flexible Technology

### The Value of Experience





**Looking Ahead** 

## **Oportunidades**

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- Demanda insatisfecha de vacunas



October 5-6, 2021 **New York City** 

August 10, 2021 10:15 AM EDT Updated 10:29 AM Coronavirus, Manufacturing



Moderna strikes a deal with Canada to build an mRNA manufacturing center and it's looking for more global pacts just like it





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## Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing

16 April 2021 | Expression of interest

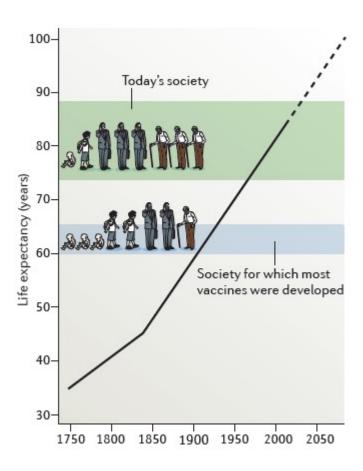
WHO and its partners are seeking to expand the capacity of low- and middle-income countries (LMICs) to produce COVID-19 vaccines and scale up manufacturing to increase global access to these critical tools to bring the pandemic under control.

WHO will facilitate the establishment of one (or more, as appropriate) technology transfer<sup>1</sup> hub(s) that will use a **hub** and **spoke model** (REF) to transfer a comprehensive technology package and provide appropriate training to interested manufacturers in LMICs. This initiative will initially prioritize the mRNA-vaccine technology<sup>2</sup> but could expand to other technologies in the future.

## **Oportunidades**

- Industria que genera alto nivel de empleo
- Uruguay cuenta con un volumen básico de RRHH altamente calificados
- Infraestructura estratégica versátil
- Diversos modelos de negocios posibles
- Demanda insatisfecha de vacunas: actual y futura

## Los nuevas realidades sociológicas: vacunas para el siglo XXI



### Las nuevas vacunas necesarias

#### a Age groups

#### Pre-birth

- Cvtomegalovirus
- Group B streptococcus
- Hepatitis B virus
- Influenza virus
- Meningococcus serogroups A. B. C. Y and W135
- Pertussis
- Respiratory syncytial virus
- Tetanus



#### Infants and children

- Diphtheria
- Group A streptococcus
- . H. influenzae type b
- Helicobacter pylori
- Hepatitis A virus
- Hepatitis B virus
- Inactivated poliovirus vaccine
- Influenza virus
- Measles
- Meningococcus serogroups A, B, C, Y and W135
- Mumps
- Pertussis
- Pneumococcus
- Respiratory syncytial virus
- Rotavirus
- Rubella
- Tetanus Varicella
- zoster virus



#### Adolescents

- Cvtomegalovirus
- Diphtheria, tetanus acellular pertussis
- Epstein-Barr virus
- Herpes simplex virus Human papilloma virus
- Influenza virus
- Meningococcus serogroups A, B, C, Y and W135
- Parvovirus B19



#### Adults

- Diphtheria
- Hepatitis B virus
- Influenza virus
- Meningococcus serogroups A, B, C, Y and W135
- Pertussis
- · Respiratory syncytial virus
- Tetanus



#### Elderly

#### Recurrent infections:

- Group B streptococcus
- Influenza virus
- Meningococcus serogroups A, B, C, Y and W135
- Pneumococcus
- Respiratory syncytial virus
- Varicella zoster virus
- Antibiotic resistance: Acinetobacter baumannii
- C. difficile
- Candida spp.
- Enterotoxigenic E. coli
- Klebsiella pneumoniae
- P. aeruginosa
- S. aureus

#### Cancer:

- Breast cancer
- Colorectal cancer
- Prostate cancer



#### b Special target groups

#### Travellers

- Cholera
- Dengue
- Enterotoxigenic E. coli
- Hepatitis A virus
- Hepatitis B virus
- Influenza virus
- Japanese encephalitis virus Malaria Meningococcus
- serogroups A, B, C, Y, W135 and X
- Paratyphoid fever
- Rabies Shiqella spp.
- Tick-borne encephalitis virus
- Tuberculosis
- Typhoid fever
- Yellow fever

#### Patients with chronic diseases

- Cytomegalovirus
- Fungal infections
- Influenza virus
- P. aeruainosa
- Parainfluenza
- Parvovirus B19
- · Respiratory syncytial virus
- S. aureus
- Tuberculosis

#### Patients with HIV

- Influenza virus
- Pneumococcus
- Pneumocystosis Tuberculosis

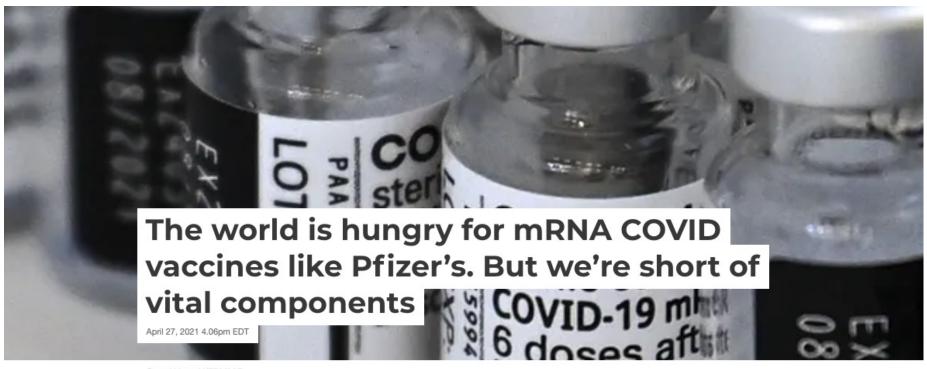
#### Emerging infection

- Anthrax Avian influenza
  - Cholera
  - Denaue
  - Diphtheria
  - Ebola virus disease
  - FV71
  - Malaria
  - Meningococcus serogroup X
  - Plaque
  - SARS
  - Smallpox
  - Swine influenza
  - Tuberculosis West Nile

#### Poverty

- Cholera
- Dengue
- Enterotoxigenic E. coli
- Hepatitis A virus
- Hepatitis B virus
- Hepatitis E virus
- Influenza virus
- Iapanese encephalitis virus
- Malaria
- Meningococcus serogroups
- A, B, C, Y, W135 and X Parasitic infections
- Paratyphoid fever
- Rabies
- Rotavirus
- Salmonella spp.
- Shigella spp.
- Tuberculosis Typhoid fever
- Yellow fever

### Desafíos que generan oportunidades...



Georgi Licovski/EPA/AAP

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Given the AstraZeneca COVID-19 vaccine is no longer recommended for under-50s following news of very rare <u>blood clots</u>, Australia is looking to other vaccines to plug the gap.

Pfizer's mRNA vaccine will become the mainstay of the rollout, with <u>40 million</u> <u>doses</u> expected to arrive before year's end.

But Australia isn't the only country eager to get its hand on this vaccine.

Skyrocketing demand coupled with shortages of vital components is leading to bottlenecks in the supply chain of this and other mRNA vaccines, delaying

### Desafíos que generan oportunidades...

## Lipids, the unsung COVID-19 vaccine component, get investment

Several specialty chemical companies are adding capacity to supply Moderna and Pfizer-BioNTech

by Michael McCoy

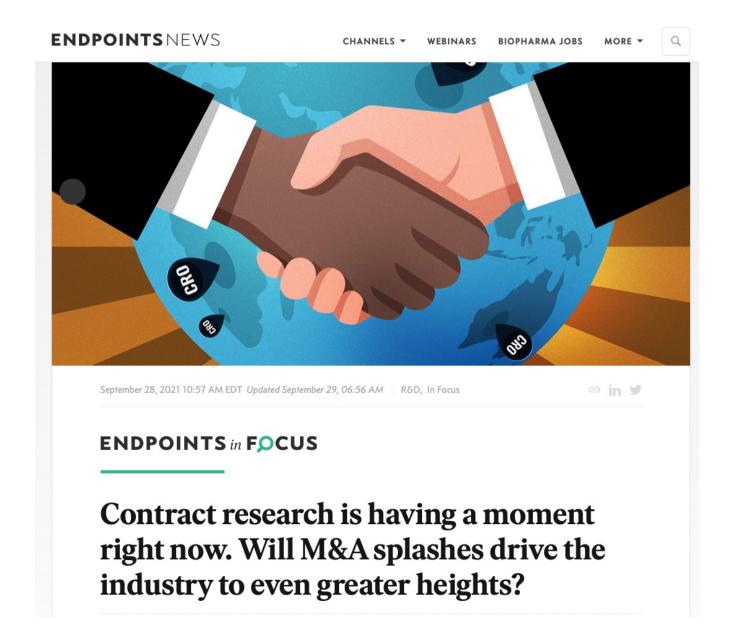
February 12, 2021



Credit: Evonik Industries

Evonik will add production of specialty lipids at this facility in Dossenheim, Germany.

### Desafíos que generan oportunidades...



## Desafíos para la producción nacional de vacunas

- Capacidad de realizar ensayos clínicos en el país (NECESIDAD de normativa)
- Capacidad de acordar licenciamiento de vacunas ya en uso para su producción en el país (NECESIDAD de infraestructura adecuada, plataformas tecnológicas, RRHH operativos y normativa)
- Capacidad de generar información científicamente robusta del impacto de vacunación (la pandemia ha generado oportunidades en esto)
- Posibilidad de atraer inversores (NECESIDAD de generar un "ambiente de negocios" adecuado)



UNIVERSIDAD DE LA REPÚBLICA - PROPUESTA DE LA UNIVERSIDAD AL PAÍS - RENDICIÓN DE CUENTAS 2020

#### **ANEXO 3**

11. Propuesta de creación del Instituto de Investigación en Vacunas

