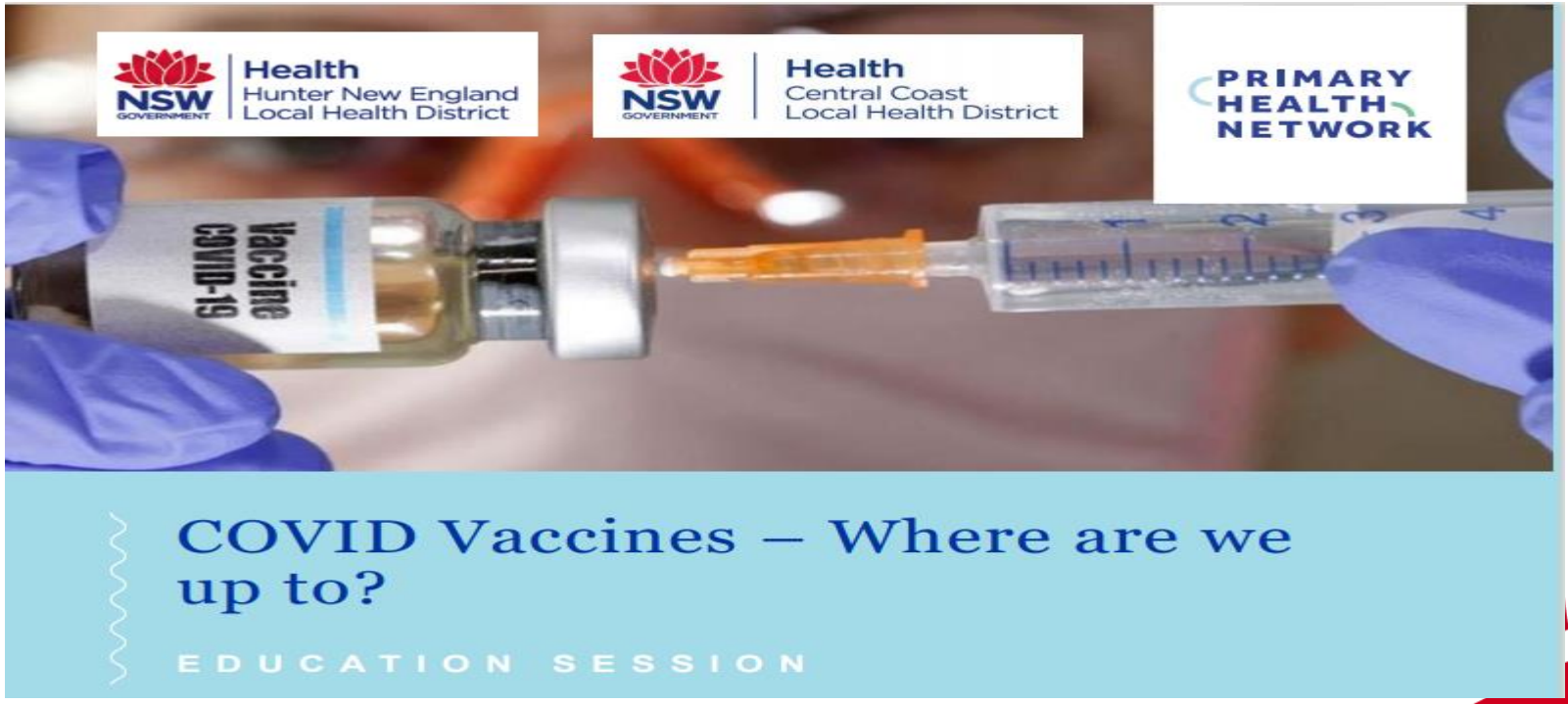
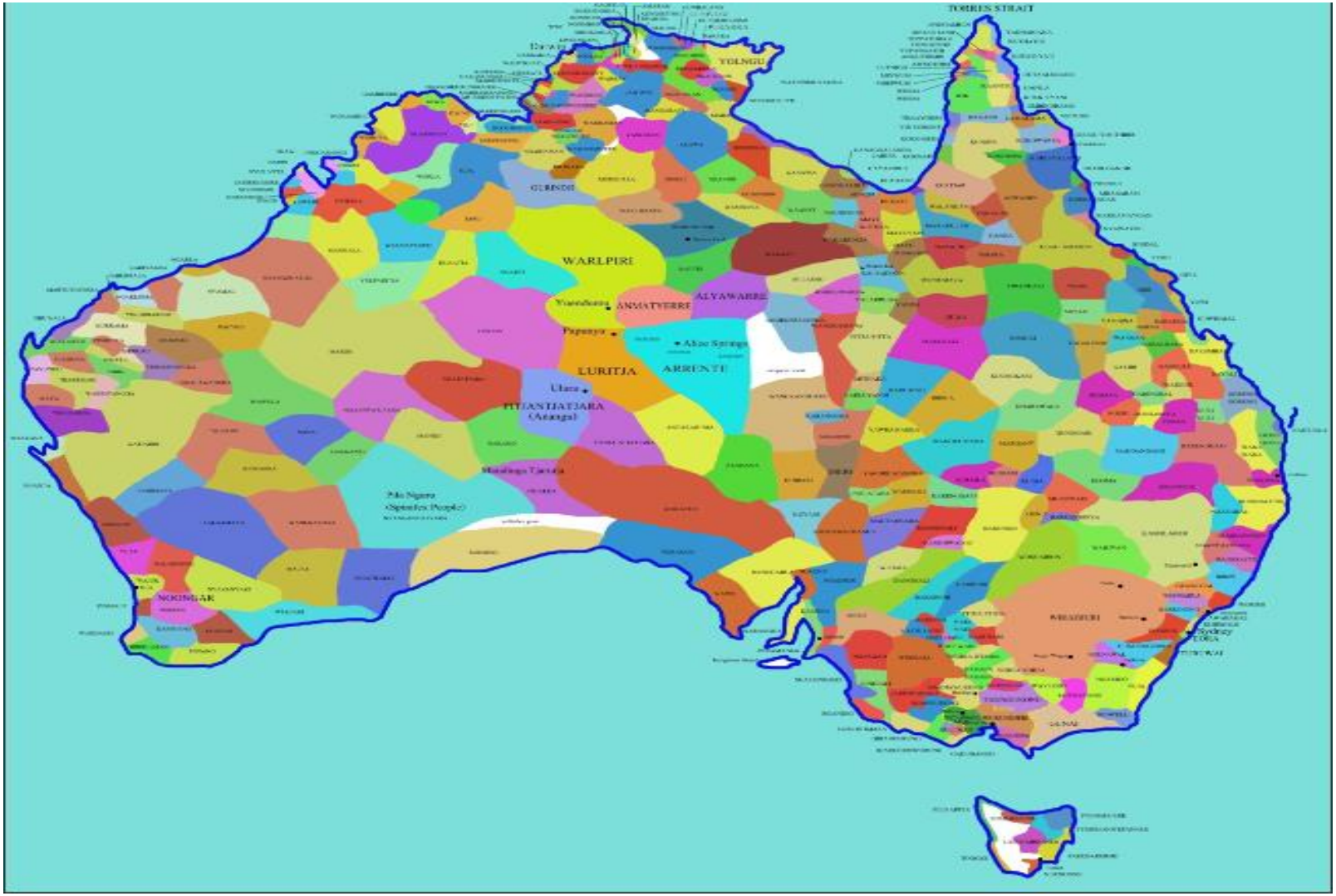
Health
Hunter New England
Local Health District



Patrick Cashman
Jody Stephenson

Always Was, Always Will Be

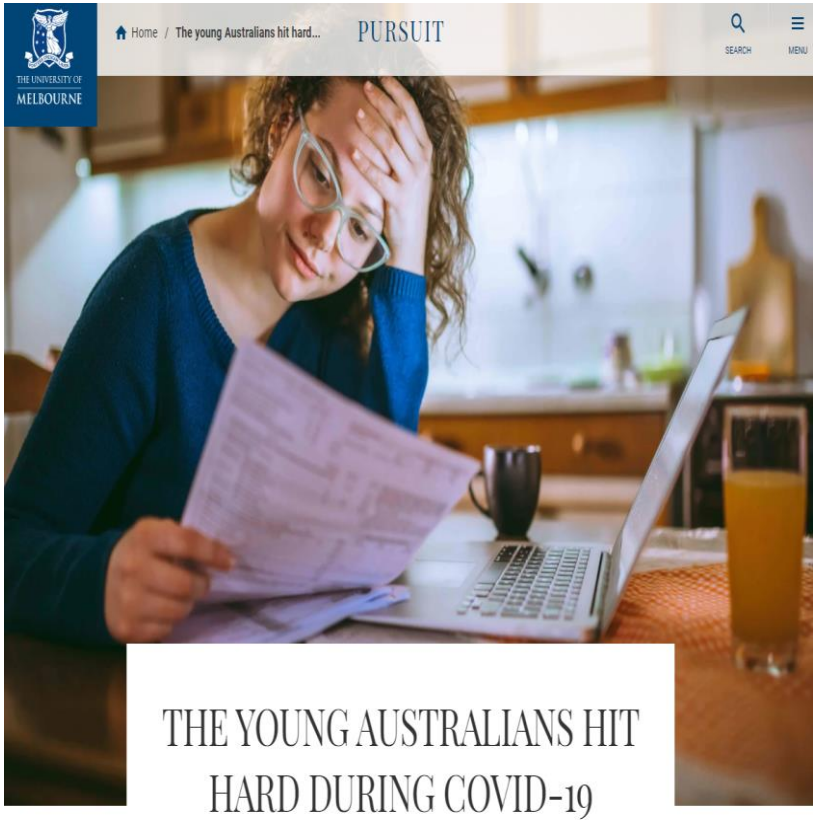


slido

- **The ultimate Q&A Team**
- Colleen Gately
- Donna Moore
- Sharon Saxby

- Slido Questions to the right of screen
- Slido event code: **#COV**
- Evaluation at the End

Why Some Young People Fear Social Isolation More Than COVID-19



There is a biological basis for young people's need for socialization. Scientists say bonding isn't a luxury; it's critical for development.

Young brains need social connection to feel secure about their identity and place in the world

https://www.npr.org/sections/health-shots/2020/07/04/885546281/why-some-young-people-fear-social-isolation-more-than-covid-19

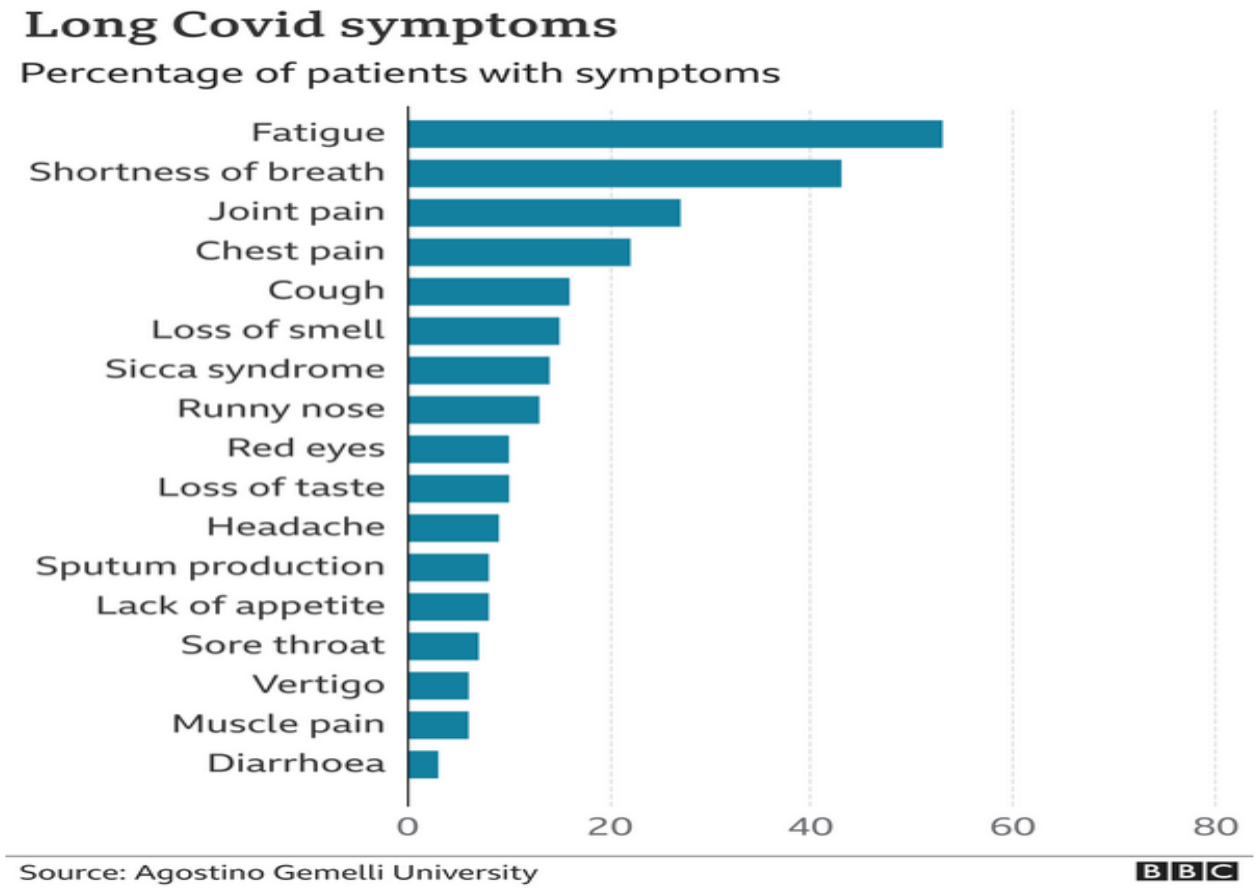
Covid-19 in Kids

Multisystem Inflammatory Syndrome in Children and Adults (MIS-C/A): Case Definition & Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data

Children and adolescents are as susceptible to infection with SARS-CoV-2 as adults, but develop symptomatic COVID-19 primary infection at significantly lesser rates and rarely develop severe disease [1, 2]. However, it has become clear that a fraction of children develop a life-threatening hyperinflammatory state 4-6 weeks after infection with primary COVID-19 termed multisystem inflammatory syndrome in children (MIS-C) [3]. A similar condition has also been reported as a rare complication of COVID-19 in adults (MIS-A) [4]. It is currently unknown if MIS-C/A might follow immunization against SARS-CoV-2, but a need exists to define this potential entity for monitoring as an adverse event following vaccination.

https://brightoncollaboration.us/

Long Covid

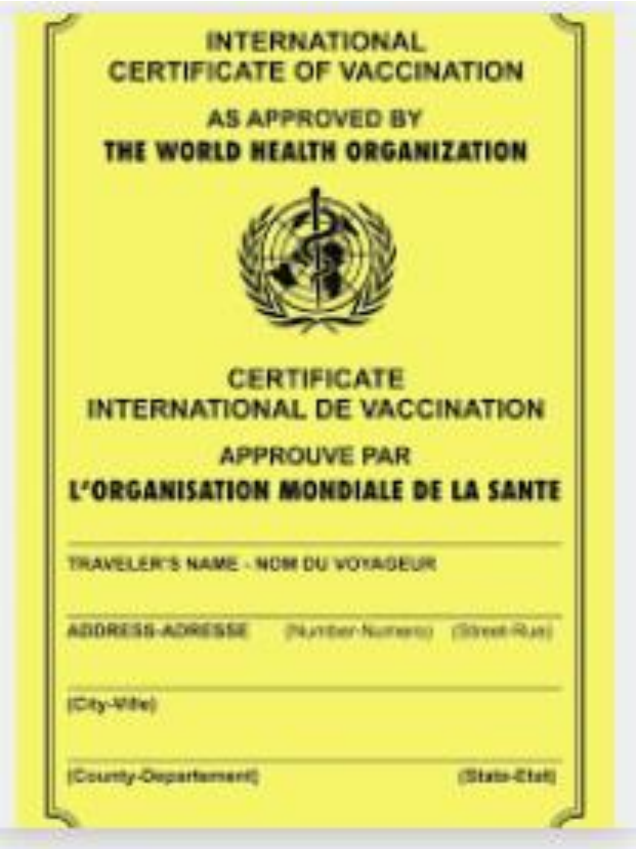


However, such studies focus only on the minority of people who end up needing hospital treatment.

The **Covid Symptom Tracker App** - used by around four million people in the UK - found 12% of people still had symptoms after 30 days. Its latest, unpublished data, suggests as many as one in 50 (2%) of all people infected have long-Covid symptoms after 90 days.

https://www.bbc.com/news/health-54296223

Vaccination for travel



INTERNATIONAL
CERTIFICATE OF VACCINATION

AS APPROVED BY
THE WORLD HEALTH ORGANIZATION

CERTIFICATE
INTERNATIONAL DE VACCINATION

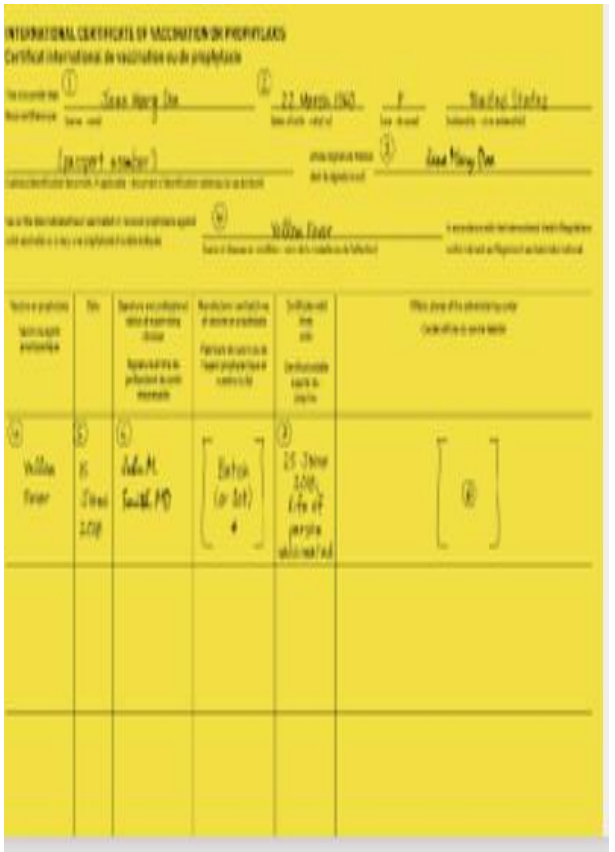
APPROUVE PAR
L'ORGANISATION MONDIALE DE LA SANTE

TRAVELER'S NAME - NOM DU VOYAGEUR

ADDRESS-ADRESSE (Number-Numero) (Street-Rue)

(City-Ville)

(County-Departement) (State-Etat)

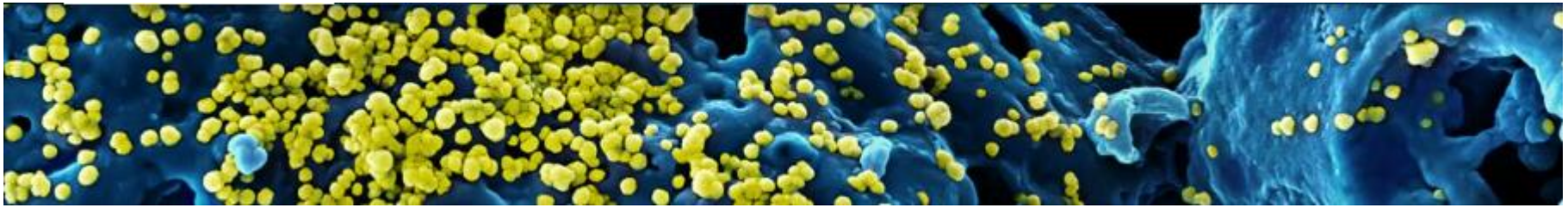


Vaccine development

- Poor business case for vaccines
- High development costs $1 billion
- No repeat business
- Role of philanthropy
- Current global effort unique – potential hope
- Operation warp speed

BILL & MELINDA GATES foundation

Coronaviruses



- Hundreds of corona viruses – animals
- Jump to humans – spillover
- 7 corona viruses cause human disease
- 4 mild disease 229E, OC43, NL63 and HKU1
- SARS (severe acute respiratory syndrome)
- MERS (Middle East respiratory syndrome
- SARS-CoV-2 causes Covid-19

Scientists were close to a coronavirus vaccine years ago. Then the money dried up.

"We just could not generate much interest," a researcher said of the difficulty in getting funding to test the vaccine in humans.

Dr. Peter Hotez, co-director of the Texas Children's Hospital's Center for Vaccine Development in Houston, at his lab in 2012.

https://www.nbcnews.com/health/health-care/scientists-were-close-coronavirus-vaccine-years-ago-then-money-dried-n1150091

Challenge of respiratory infections

There are several reasons why our upper respiratory tract is a hard area to target a vaccine.

"It's a separate immune system, if you like, which isn't easily accessible by vaccine technology," Professor Frazer told the Health Report.

Despite your upper respiratory tract feeling very much like it's inside your body, it's effectively considered an external surface for the purposes of immunisation.

"It's a bit like trying to get a vaccine to kill a virus on the surface of your skin."

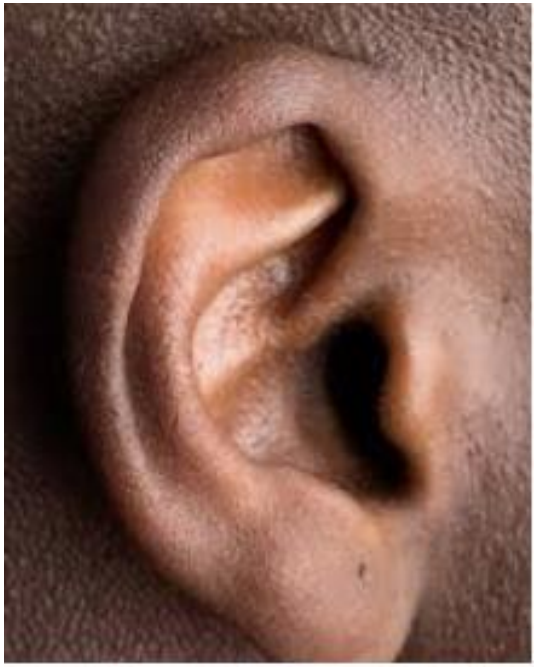
Professor Ian Frazer (right) worked on the HPV vaccine and thinks a coronavirus vaccine is unlikely anytime soon.
(Supplied: European Inventor Award)

Your skin, and the outer layer of cells in your upper respiratory tract act as a barrier to viruses, stopping them getting into the body.

And finding a way to neutralise the virus "outside" of the body is very difficult.

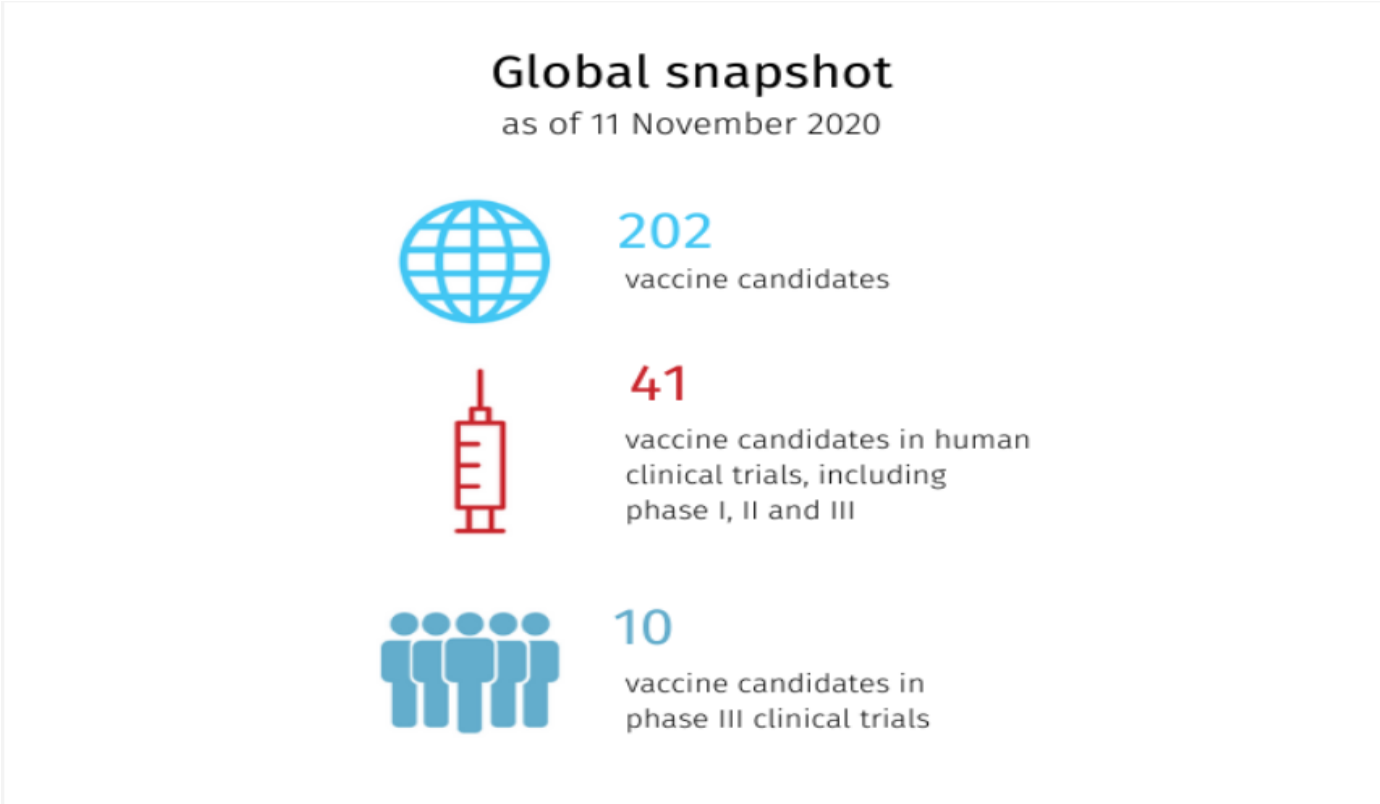
This is partly because only the outer layer of cells (the epthelial cells) get infected, which, compared to a severe infection of internal organs doesn't produce the same immune response, so is harder to target.

It's hard to produce a successful vaccine if the virus isn't activating a strong immune response.



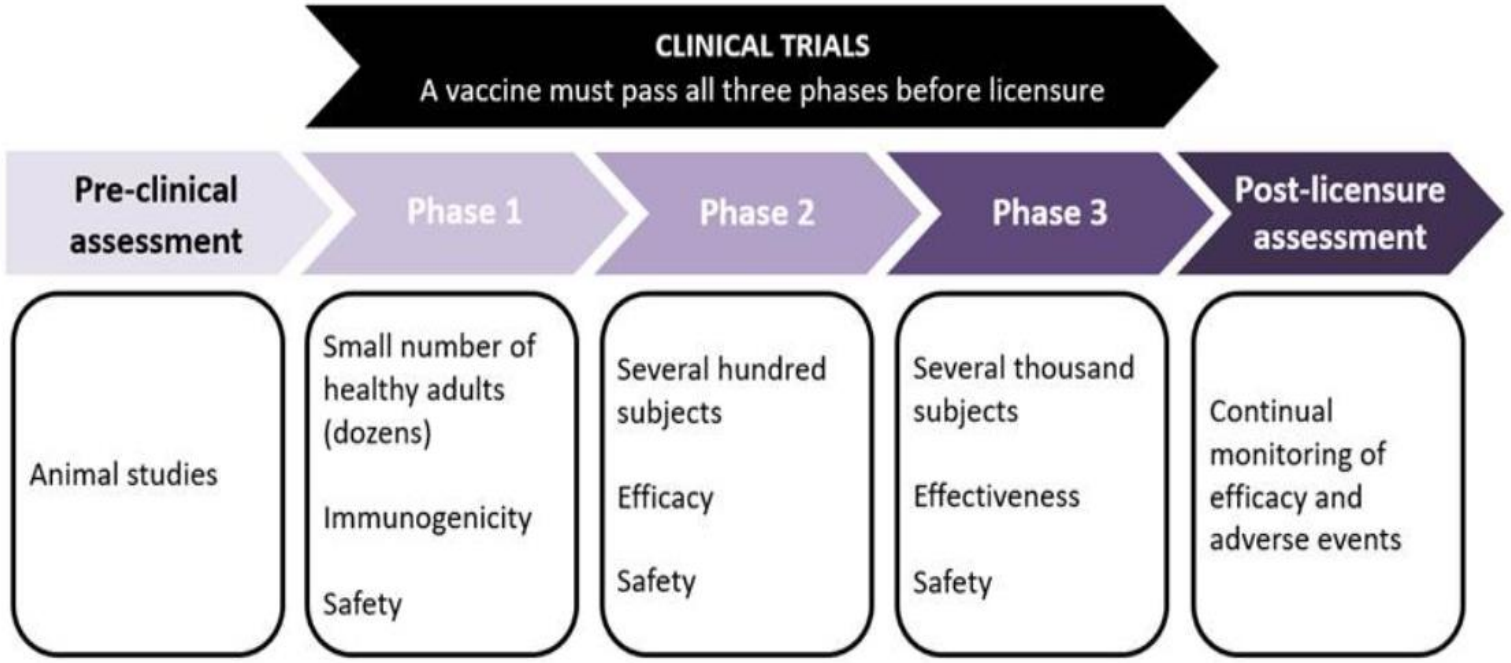
NSW GOVERNMENT

Covid has moved the case for vaccine development

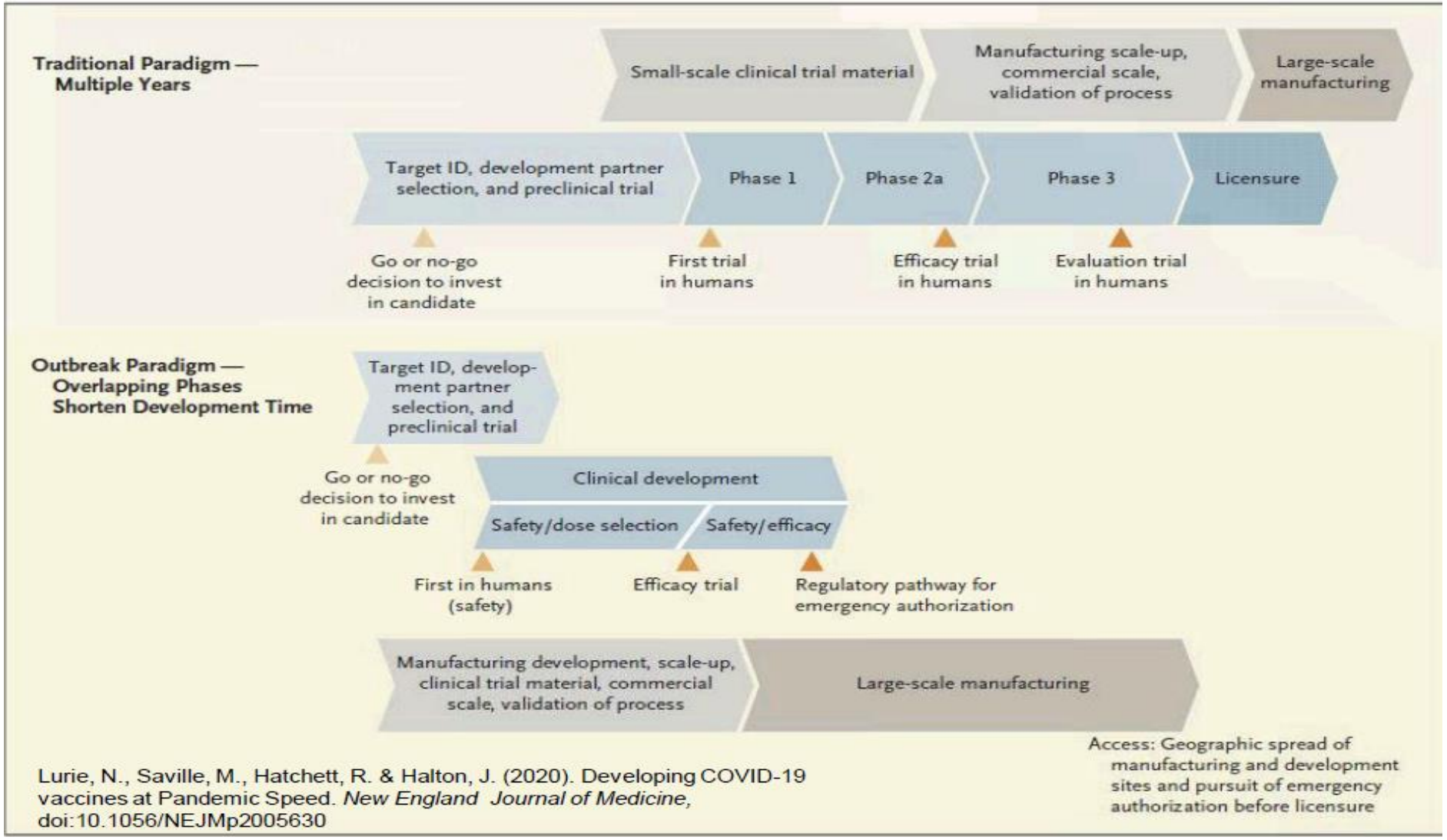


http://ncirs.org.au/covid-19/covid-19-vaccine-development-landscape

Vaccine development Phases



Vaccine development



Lurie, N., Saville, M., Hatchett, R. & Halton, J. (2020). Developing COVID-19 vaccines at Pandemic Speed. *New England Journal of Medicine*, doi:10.1056/NEJMp2005630

NEWS · 11 AUGUST 2020

Russia's fast-track coronavirus vaccine draws outrage over safety

The immunization is the first approved for widespread use but could be dangerous because it hasn't been tested in large trials, say researchers.

Ewen Callaway

Russian President Vladimir Putin receives a video report about the approval of a coronavirus vaccine. Credit: Alexei Nikolsky/Sputnik/EPA-EFE/Shutterstock

Vaccines in Phase 3

Phase III

Vaccine	Developer	Clinical trial in	Vaccine platform	Number of participants	Age range
ChAdOx1 nCoV-19	University of Oxford	Brazil	Viral vector	5,000	≥18 years
CoronaVac	Sinovac Biotech	Brazil	Inactivated	8,870	≥18 years
CoronaVac	Sinovac Biotech	Turkey	Inactivated	13,000	18-59 years
Unnamed	Wuhan Institute of Biological Products	United Arab Emirates, Bahrain, Egypt and Jordan	Inactivated	45,000	≥18 years
Unnamed	Beijing Institute of Biological Products	United Arab Emirates, Bahrain, Egypt and Jordan	Inactivated	45,000	≥18 years
Unnamed	Beijing Institute of Biological Products	Argentina	Inactivated	3,000	≥18-85 years
mRNA-1273	Moderna	USA	RNA	30,000	≥18 years
BNT162b2	BioNTech/Pfizer	USA	RNA	43,998	≥18 years
CoronaVac	Sinovac Biotech	Indonesia	Inactivated	1,620	18-59 years
AZD1222/ChAdOx1 nCoV-19	AstraZeneca/University of Oxford	USA	Viral vector	40,051	18-130 years
Gam-COVID-Vac	Gamaleya Research Institute	Russia	Viral vector	40,000	18-111 years
Ad5-nCoV	CanSino Biologics	Russia	Viral vector	500	18-85 years
Ad5-nCoV	CanSino Biologics	Pakistan	Viral vector	40,000	≥18 years
Ad26.CoV2.S	Janssen	Three continents	Viral vector	60,000	≥18 years
NVX-CoV2373	Novavax	UK	Protein	10,000	18-84 years
Gam-COVID-Vac	Gamaleya Research Institute	Belarus	Viral vector	100	18-60 years
Unnamed	Beijing and Wuhan Institute of Biological Products	Peru	Inactivated	6,000	18-60 years
CoronaVac	Sinovac Biotech	China	Inactivated	1,040	≥18 years

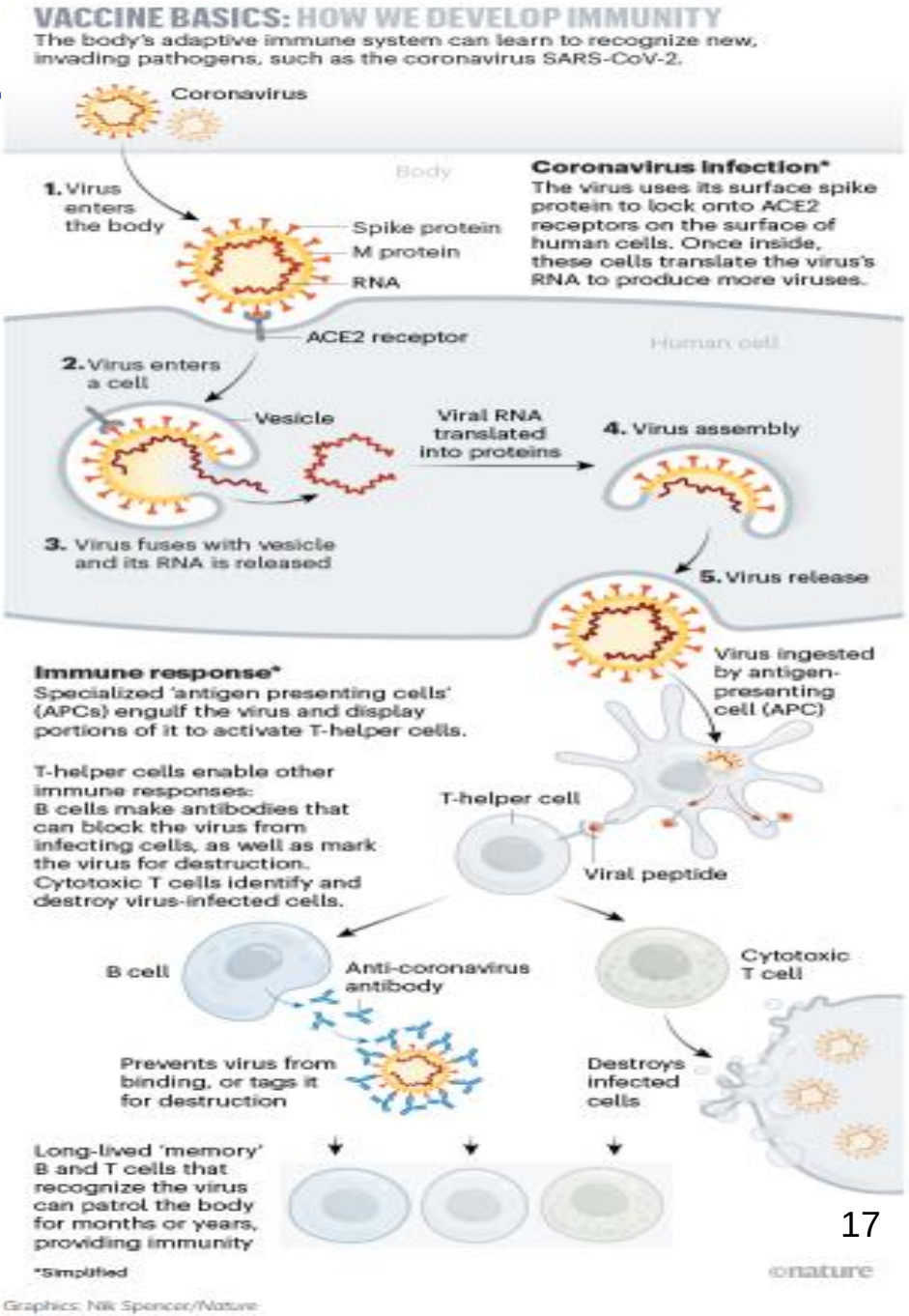
NEWS FEATURE · 28 APRIL 2020

The race for coronavirus vaccines: a graphical guide

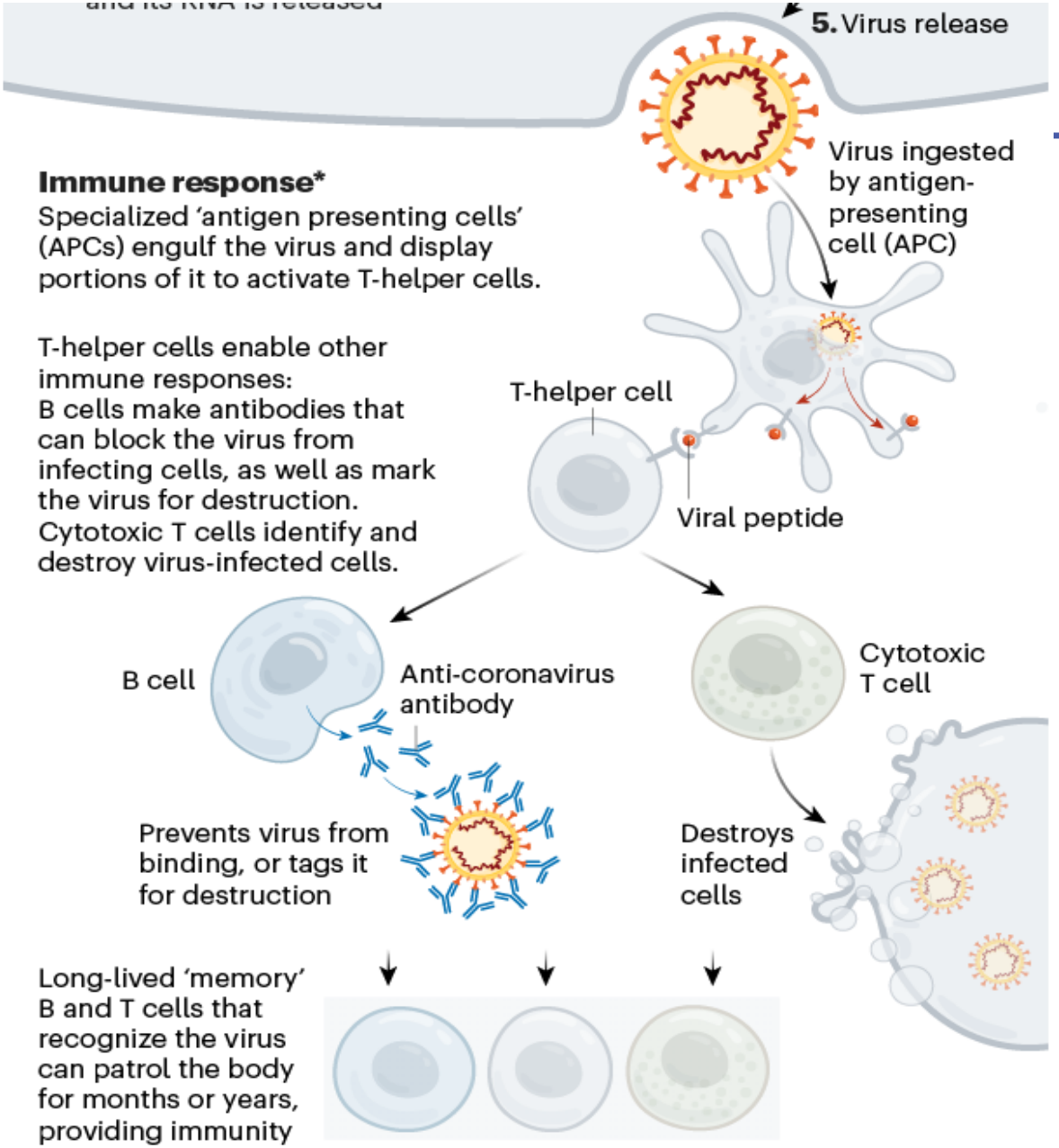
Eight ways in which scientists hope to provide immunity to SARS-CoV-2 .

Ewen Callaway

https://www.nature.com/articles/d41586-020-01221-y

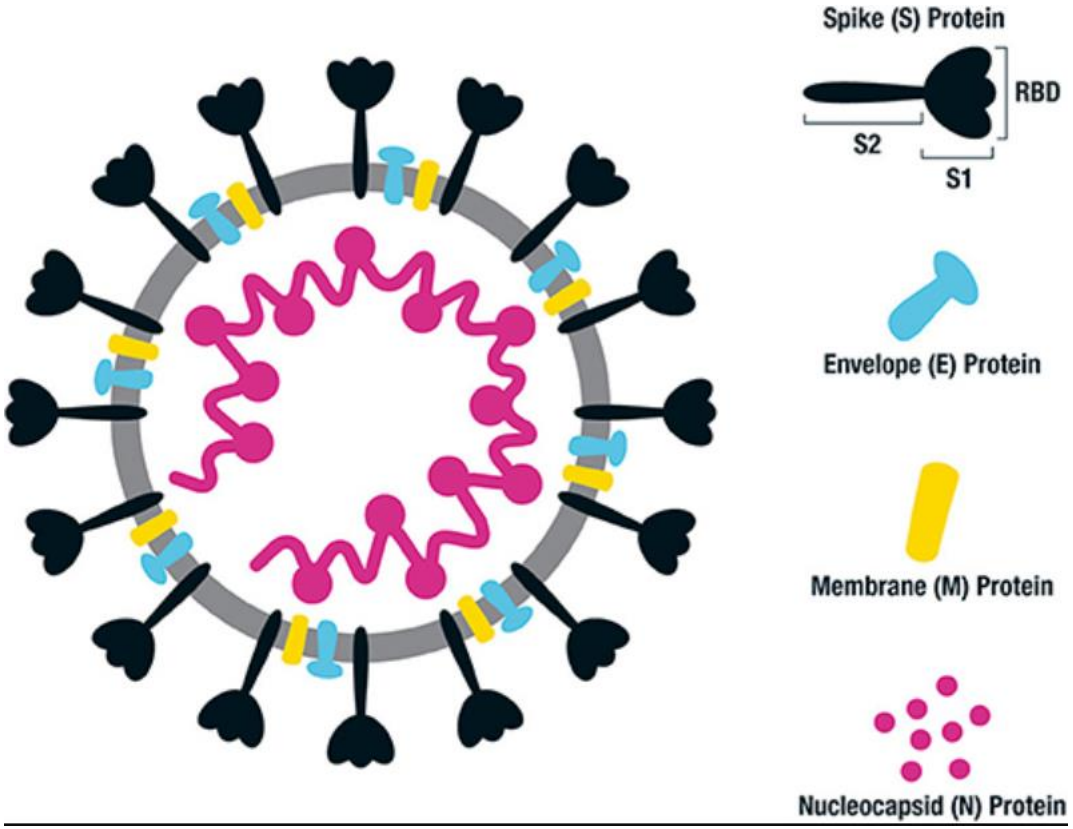


NSW GOVERNMENT Health
Hunter New England
Local Health District



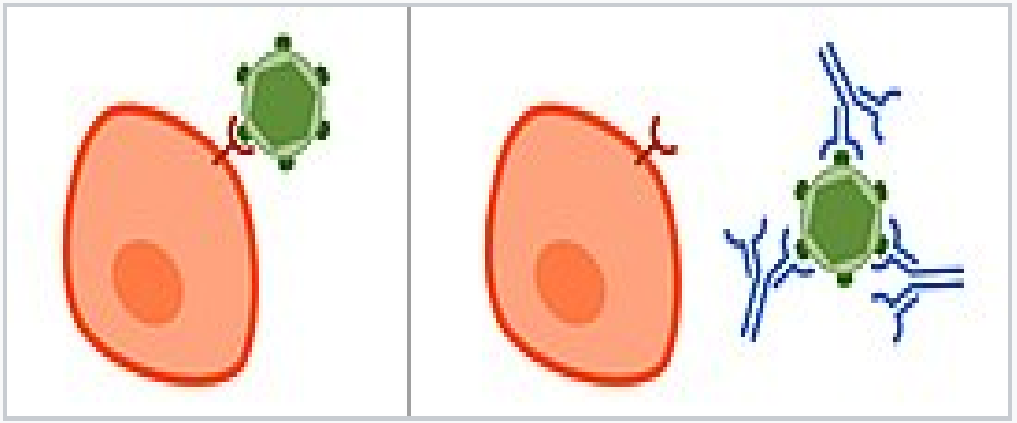
Graphics: Nik Spencer/*Nature*

Sars-C0V-2 virus



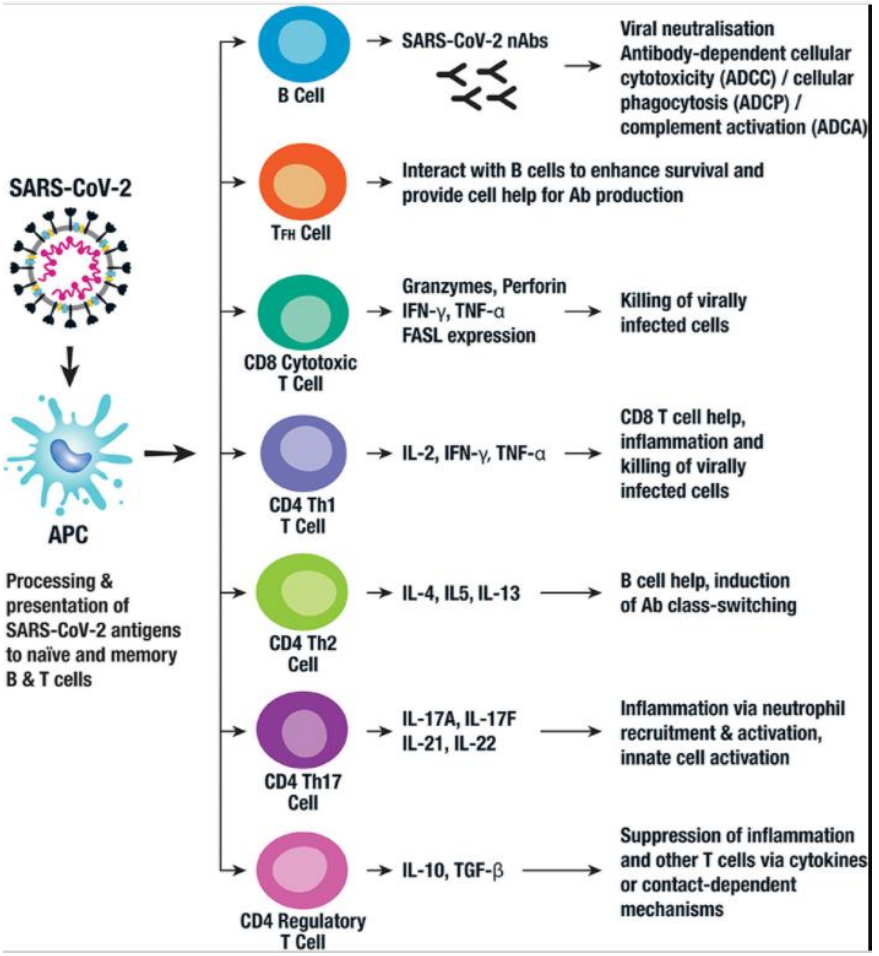
Flanagan KL, Best E, Crawford NW, Giles M, Koirala A, Macartney K, Russell F, Teh BW and Wen SCH (2020) Progress and Pitfalls in the Quest for Effective SARS-CoV-2 (COVID-19) Vaccines. Front. Immunol. 11:579250. doi: 10.3389/fimmu.2020.579250

Neutralising Antibodies



Covering an antigen in antibodies make it less infectious and less pathogenic. In the image on the right, virus entry to the cell is prevented by neutralizing antibodies binding to the virus.

Key components of the adaptive immune response to SARS-CoV-2



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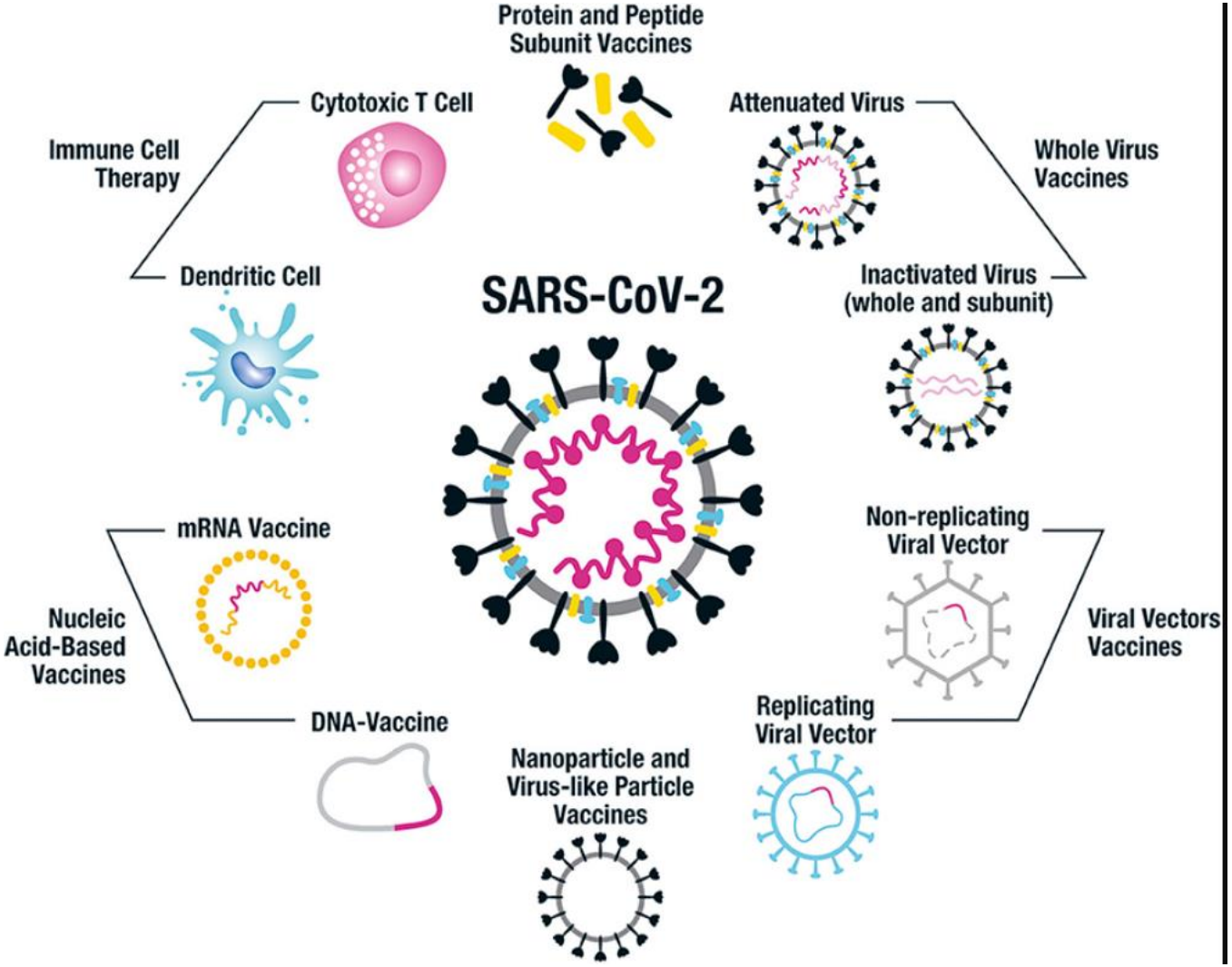
Vaccine platforms being employed for SARS-CoV-2 vaccine design



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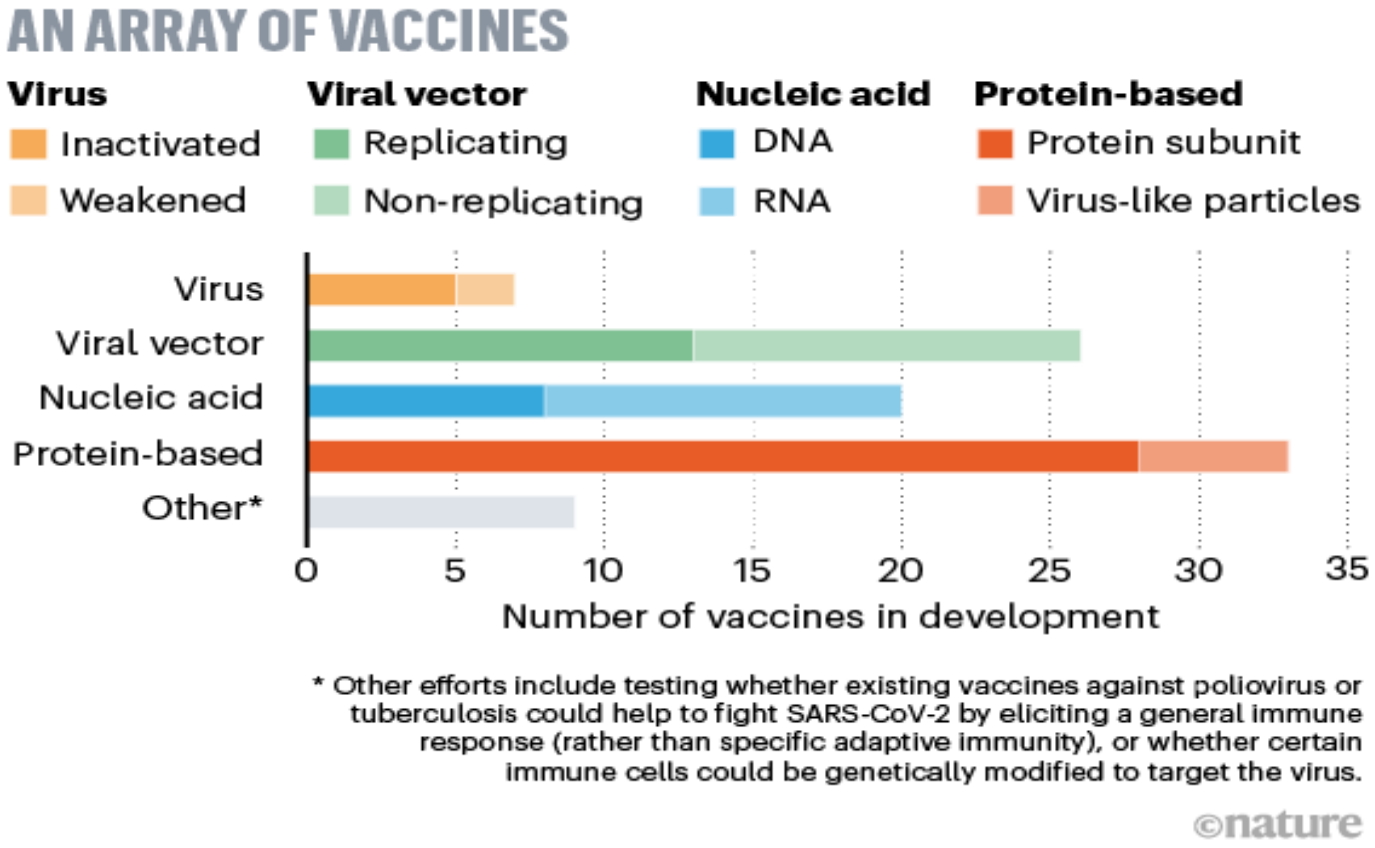
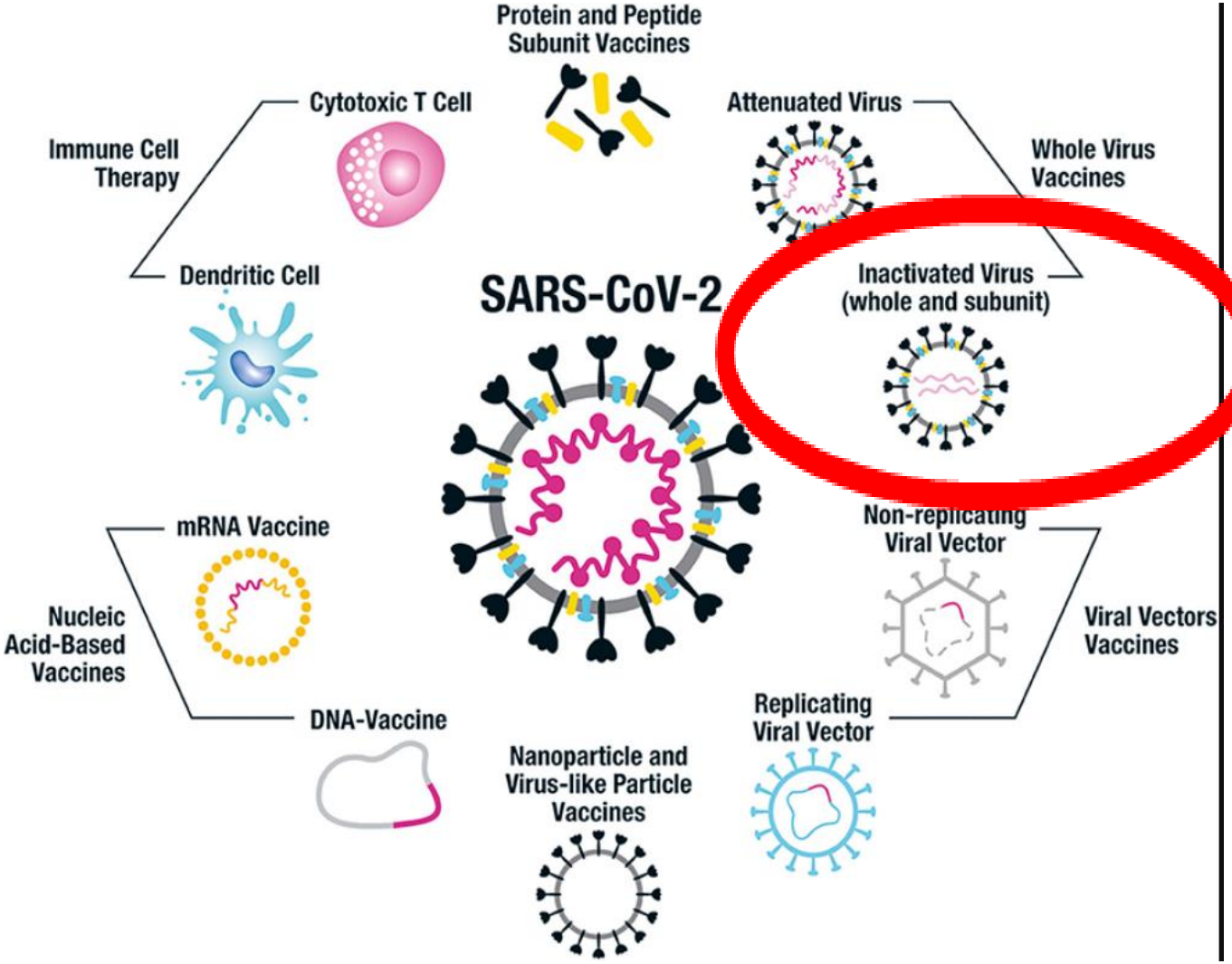
Types of Vaccines

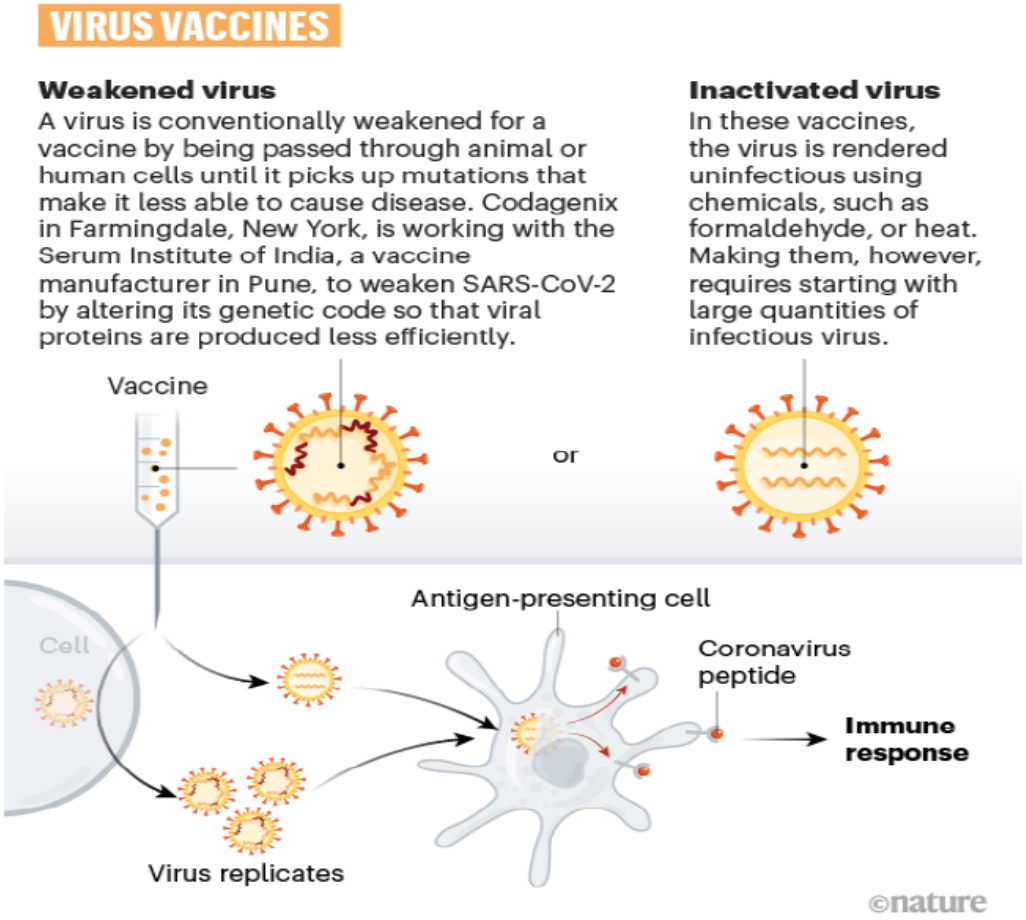


Sources: *Nature* analysis based on: WHO COVID-19 Vaccine Landscape/Milken Institute COVID-19 Treatment and Vaccine Tracker/T. Thanh Le *et al. Nature Rev. Drug. Disc.* http://doi.org/ggrnbr (2020)/F. Amanat & F. Krammer *Immunity* **52**, 583–589 (2020)/W. Shang *et al. npj Vaccines* **5**, 18 (2020).

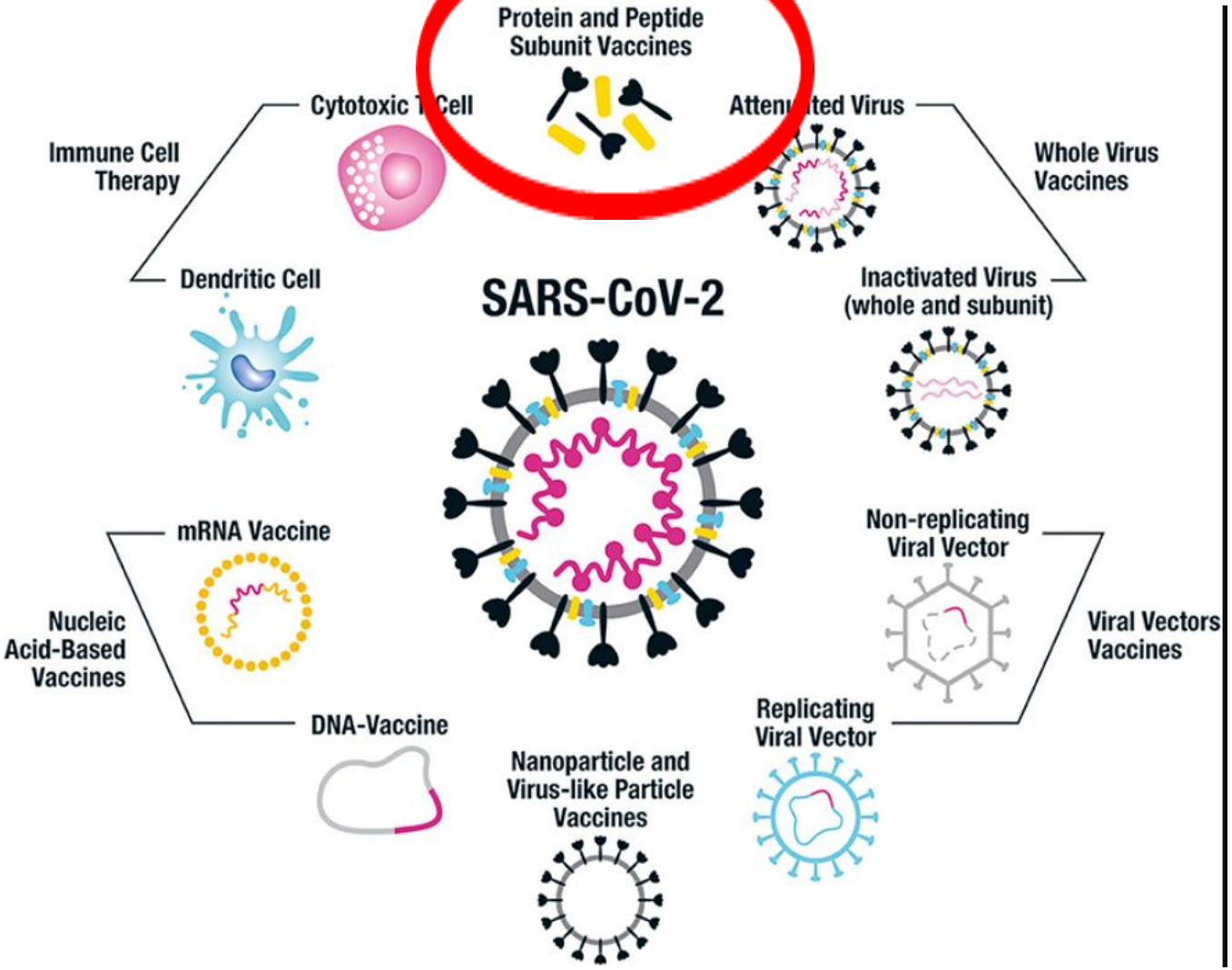
Vaccine platforms being employed for SARS-CoV-2 vaccine design



Inactivated or live attenuated virus vaccines



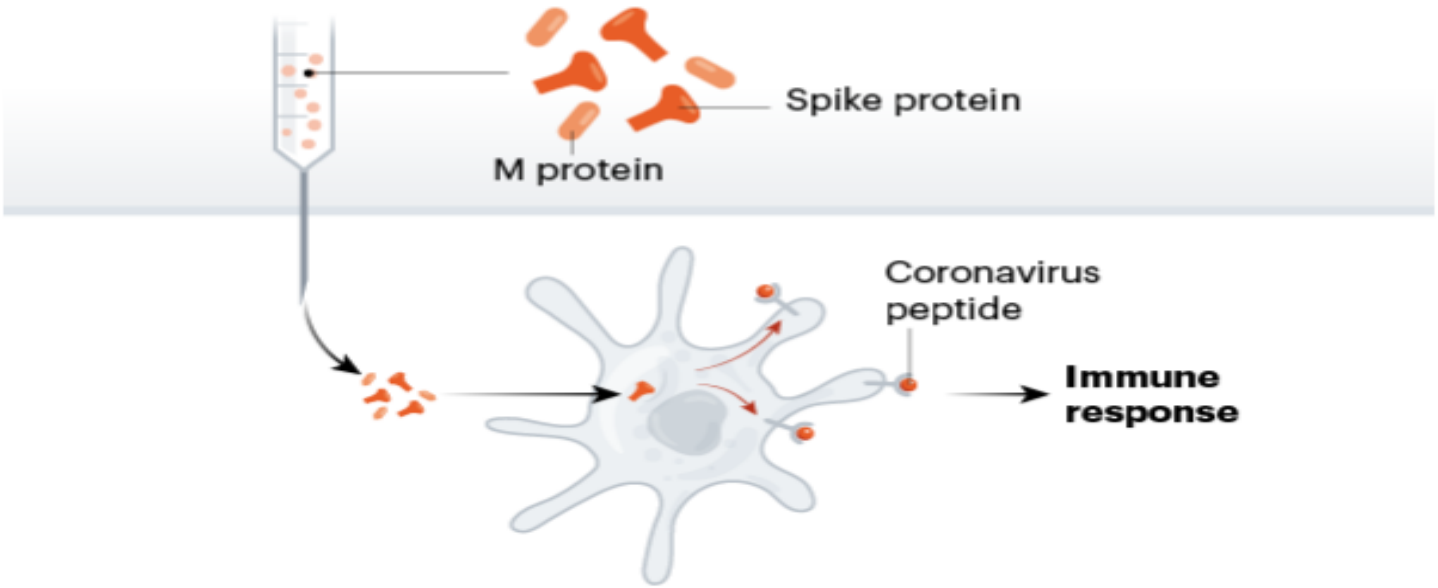
Vaccine platforms being employed for SARS-CoV-2 vaccine design



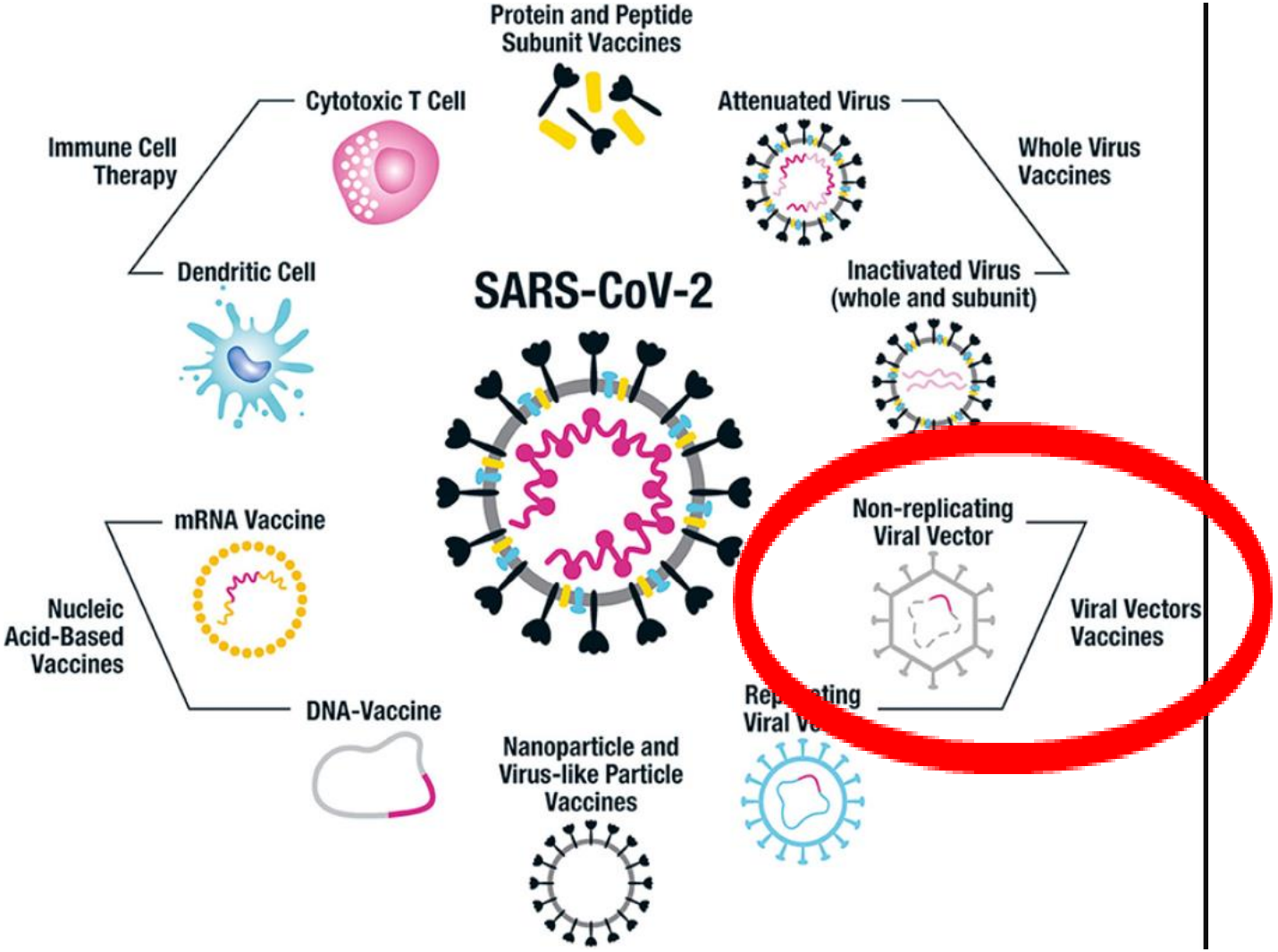
PROTEIN-BASED VACCINES

Protein subunits

Twenty-eight teams are working on vaccines with viral protein subunits — most are focusing on the virus's spike protein or a key part of it called the receptor binding domain. Similar vaccines against the SARS virus protected monkeys against infection but haven't been tested in people. To work, these vaccines might require adjuvants — immune-stimulating molecules delivered alongside the vaccine — as well as multiple doses.



Vaccine platforms being employed for SARS-CoV-2 vaccine design



Viral-vector vaccines

Replicating viral vector (such as weakened measles)
The newly approved Ebola vaccine is an example of a viral-vector vaccine that replicates within cells. Such vaccines tend to be safe and provoke a strong immune response. Existing immunity to the vector could blunt the vaccine's effectiveness, however.

Non-replicating viral vector (such as adenovirus)
No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.

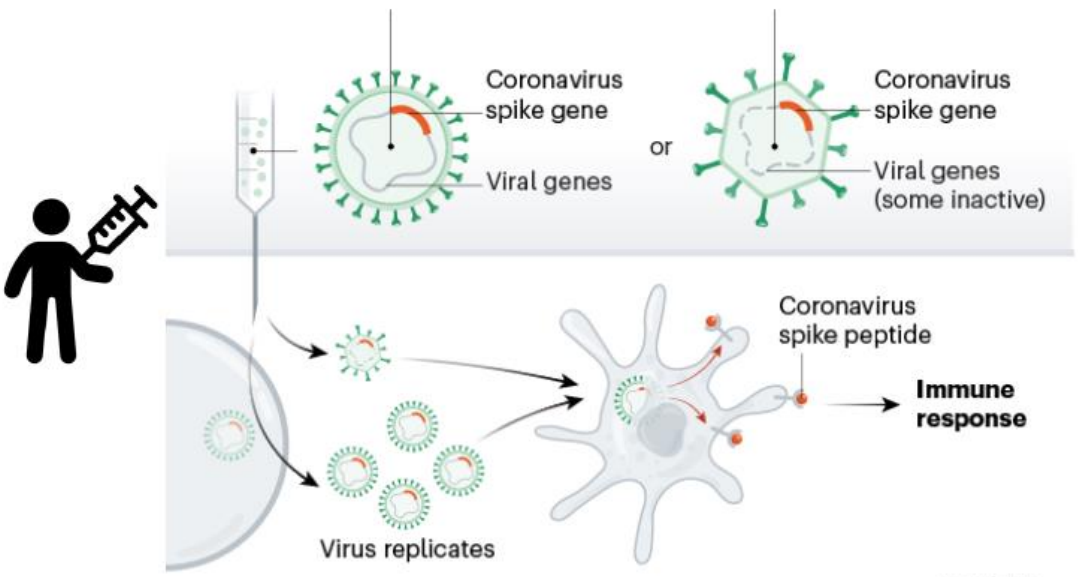


Diagram: Callaway, E. (2020). The race for coronavirus vaccines: a graphical guide. *Nature*, https://www.nature.com/articles/d41586-020-01221-y
Image from the Noun Project

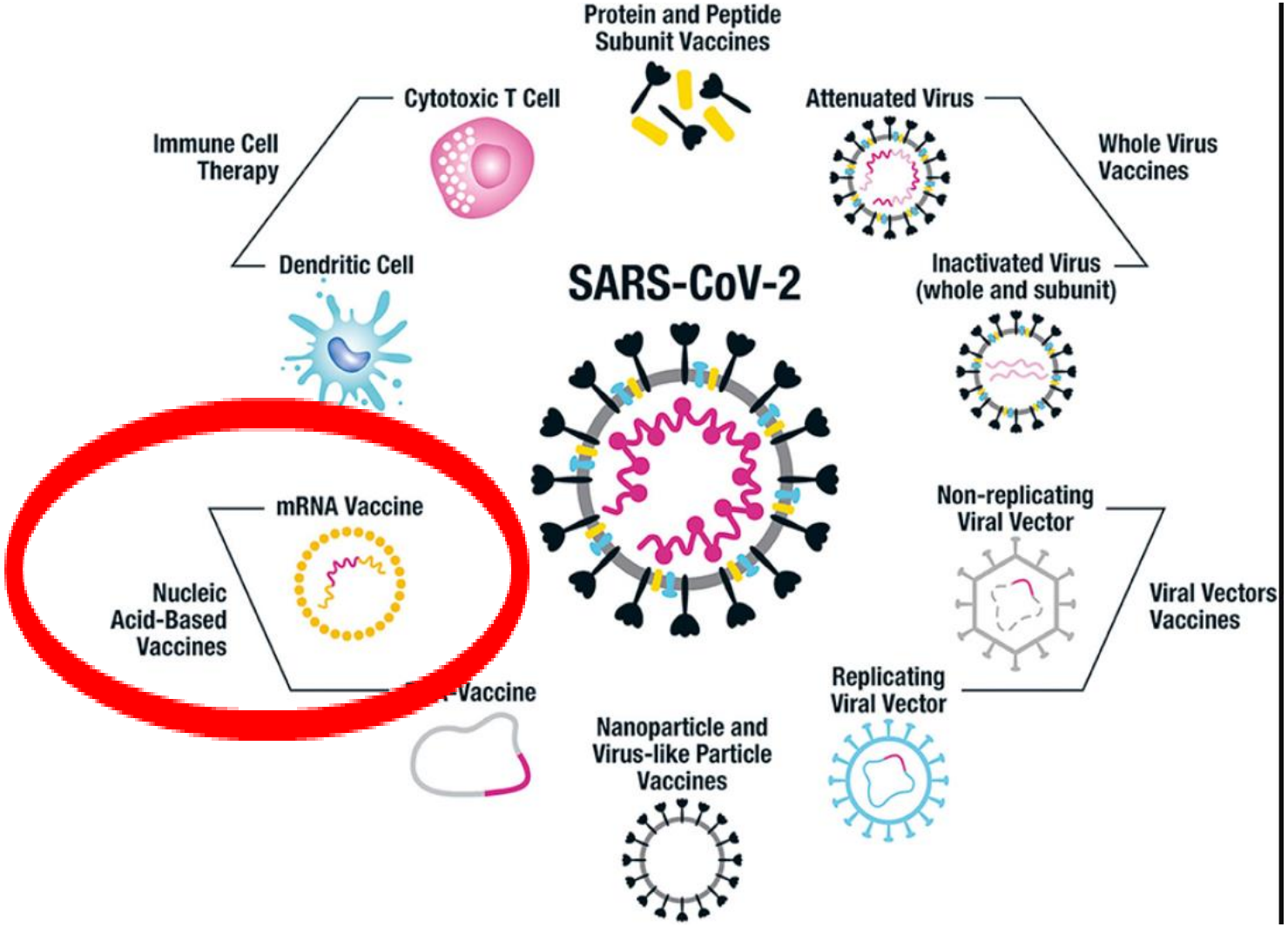
Good immune response (including SARS/MERS vaccines in human trials)

Limitation in scaling up virus vector production

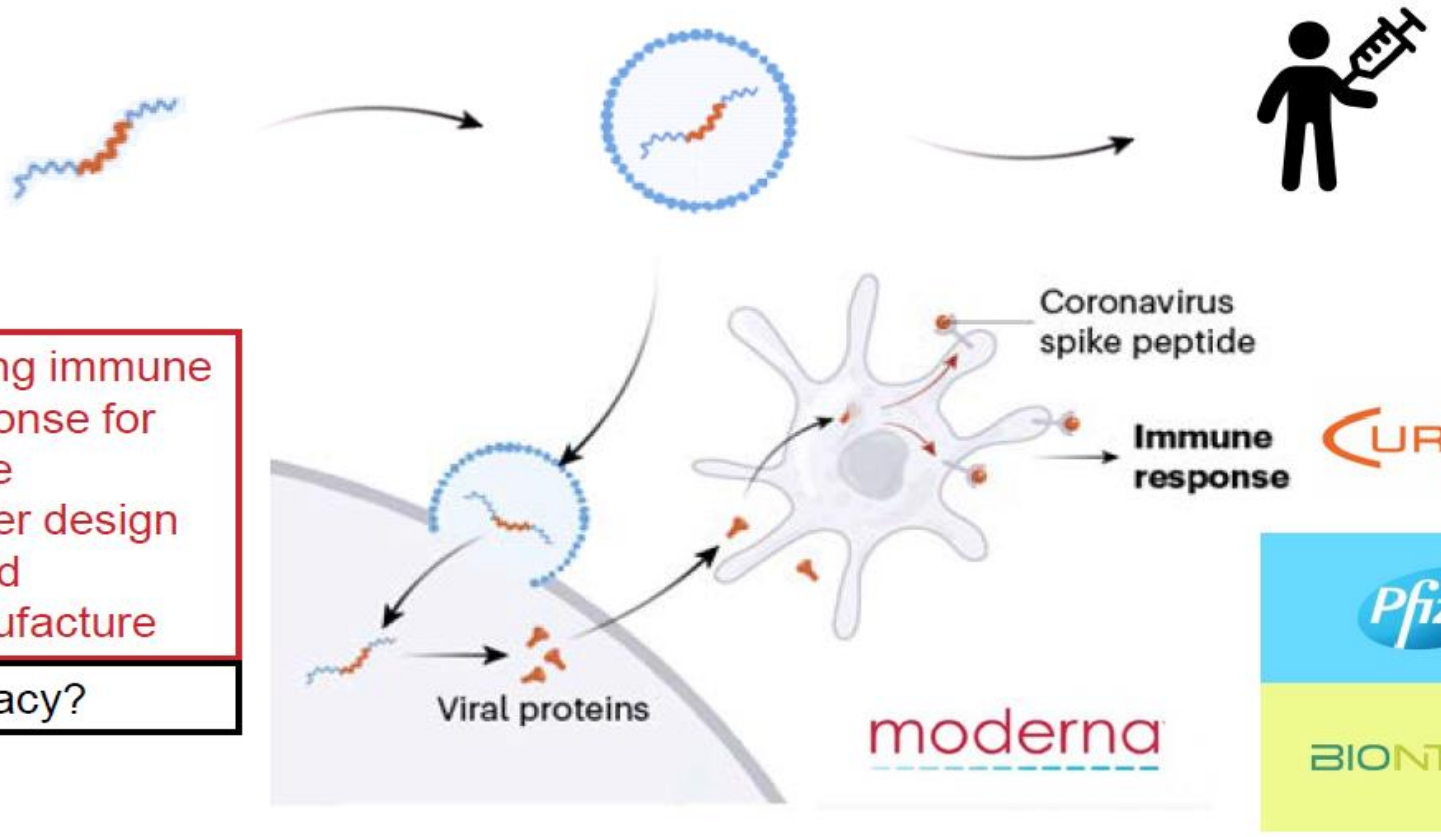
CanSinoBIO

UNIVERSITY OF OXFORD

Vaccine platforms being employed for SARS-CoV-2 vaccine design



mRNA vaccines



Strong immune response for some
Easier design
Rapid manufacture

Efficacy?

Diagram: Callaway, E. (2020). The race for coronavirus vaccines: a graphical guide. *Nature*, https://www.nature.com/articles/d41586-020-01221-y
Image from the Noun Project

WD40

Chimp adenovirus (ChAdOx1 nCoV-19) S protein (now called AZD1222)

ChAdOx1 nCoV-19

Phase II (Lancet)
China, N= 508, 18–60 years
Single dose, low or middle dose
Comparator: Placebo
Human adenovirus type 5 vector

- **Pain and fatigue were commonly reported adverse events**
- **Local and systemic reactions were reduced with paracetamol**
- **No serious adverse event reported in ChAdOx1 group**
- **High proportion of participants achieved neutralising titres with single dose, 100% with prime/boost**

Novavax (NVX-CoV2373)

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Short communication

NVX-CoV2373 vaccine protects cynomolgus macaque upper and lower airways against SARS-CoV-2 challenge

Mimi Guebre-Xabier [a,1], Nita Patel [a,1], Jing-Hui Tian [a], Bin Zhou [a], Sonia Maciejewski [a], Kristal Lam [a], Alyse D. Portnoff [a], Michael J. Massare [a], Matthew B. Frieman [b], Pedro A. Piedra [c], Larry Ellingsworth [a], Gregory Glenn [a], Gale Smith [a,*]

[a] Novavax, Inc., 21 Firstfield Road, Gaithersburg, MD 20878, USA
[b] University of Maryland, School of Medicine, 685 West Baltimore St, Baltimore, MD 21201, USA
[c] Department of Molecular Virology and Microbiology, and Pediatrics, Baylor College of Medicine, Houston, TX, USA

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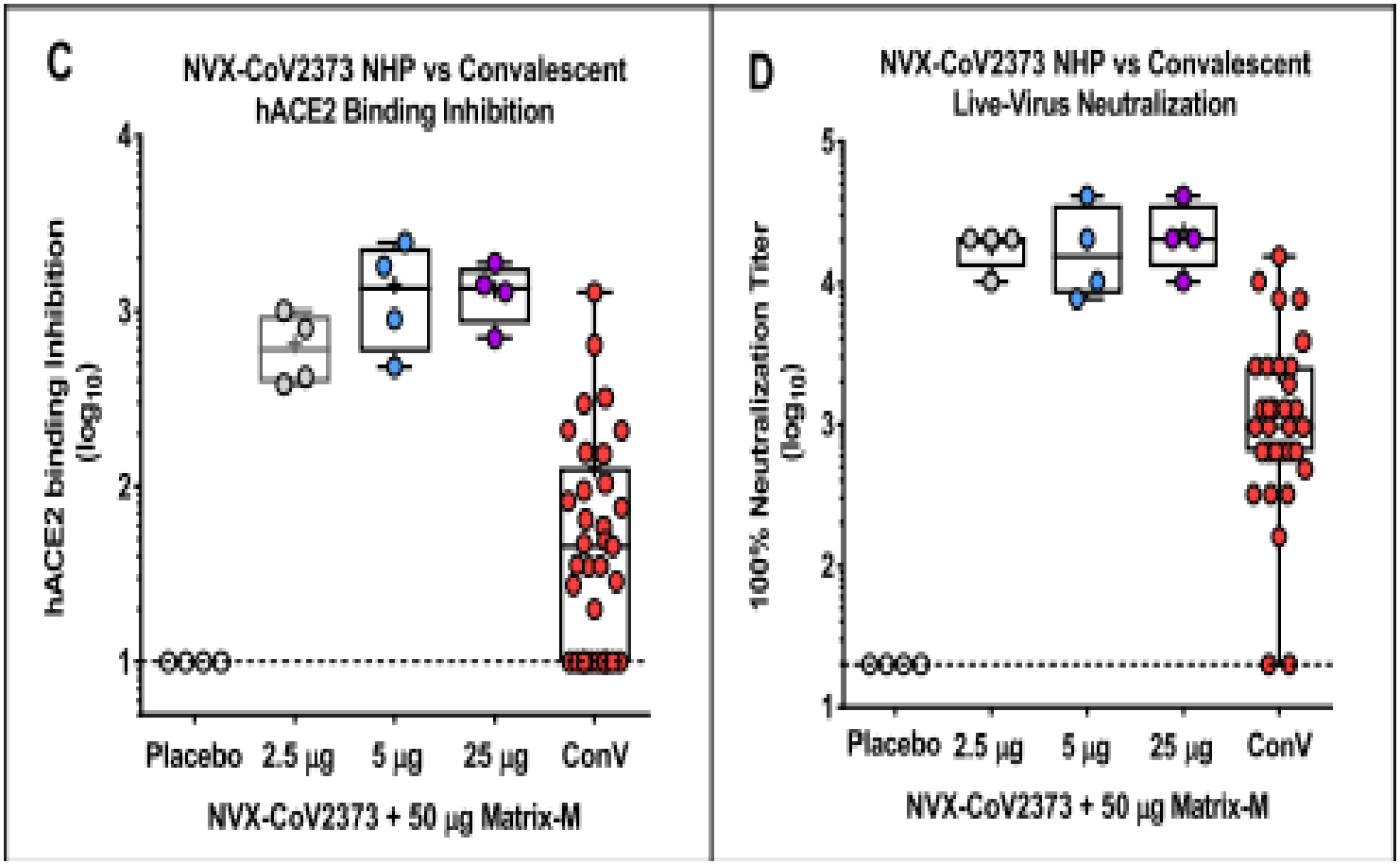
SARS-CoV-2
COVID-19
Spike glycoprotein
NVX-CoV2373 nanoparticles
Matrix-M adjuvant
Nonhuman primate

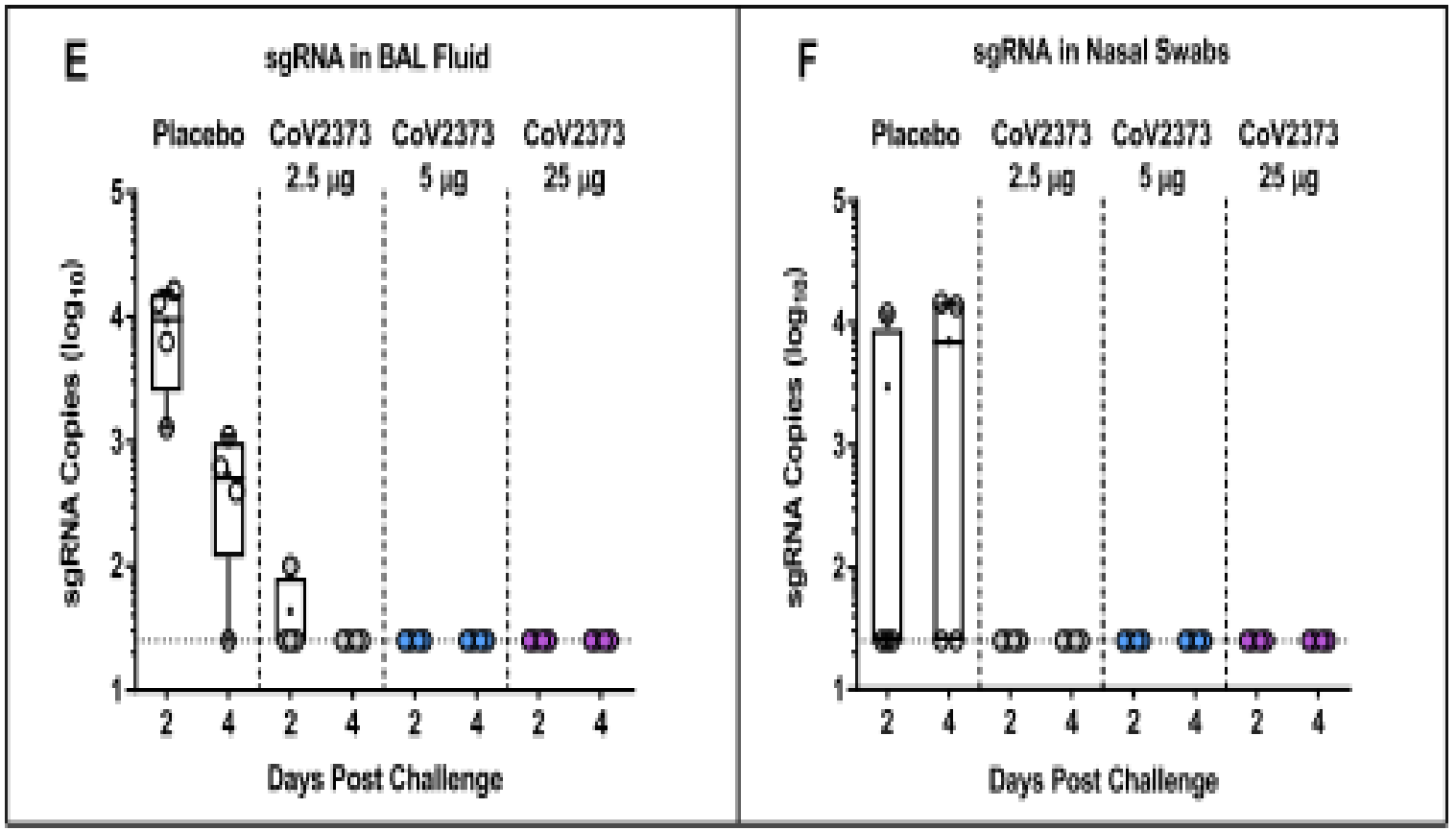
ABSTRACT

There is an urgent need for a safe and protective vaccine to control the global spread of SARS-CoV-2 and prevent COVID-19. Here, we report the immunogenicity and protective efficacy of a SARS-CoV-2 subunit vaccine (NVX-CoV2373) produced from the full-length SARS-CoV-2 spike (S) glycoprotein stabilized in the prefusion conformation. Cynomolgus macaques (*Macaca fascicularis*) immunized with NVX-CoV2373 and the saponin-based Matrix-M™ adjuvant induced anti-S antibody that was neutralizing and blocked binding to the human angiotensin-converting enzyme 2 (hACE2) receptor. Following intranasal and intratracheal challenge with SARS-CoV-2, immunized macaques were protected against upper and lower infection and pulmonary disease. These results support ongoing phase 1/2 clinical studies of the safety and immunogenicity of NVX-CoV2327 vaccine (NCT04368988).

Novavax (NVX-CoV2373)



Novavax (NVX-CoV2373)



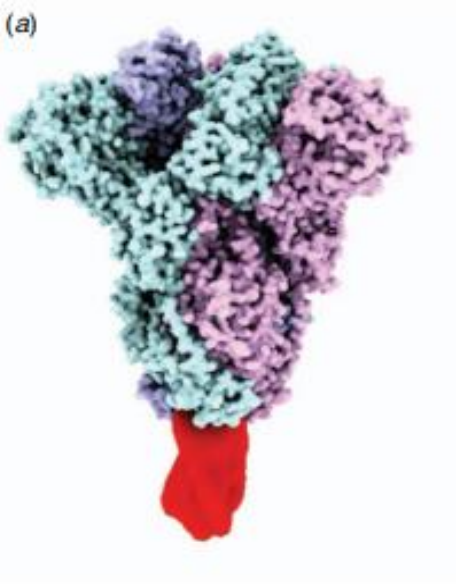
UQ COVID-19 Vaccine Candidate Clinical Trials

Clinical Trial NCT04495933: A Study on the Safety, Tolerability and Immune Response of SARS-CoV-2 Sclamp (COVID-19) Vaccine in Healthy Adults

- A Phase 1, Randomised, Double-Blind, Placebo-Controlled, Dosage-Escalation, Single Centre Study to Evaluate the Safety and Immunogenicity of an Adjuvanted SARS-CoV-2 Sclamp Protein Subunit Vaccine in Healthy Adults Aged 18 to 55 Years Old and Healthy Older Adults, Aged 56 Years and Over

- This trial will involve about 120 volunteers aged between 18 and 55 who will receive 2-doses off the UQ-CSL V451, with a proportion of participants to receive a placebo. The initial participant was dosed at the Brisbane Clinic.

University of Queensland – (V451)



The UQ-CSL V451 developed a rapid response "molecular clamp" vaccine platform, a transformative technology patented by UniQuest, UQ's technology transfer company that enables rapid vaccine design and production against outbreak viral pathogens.

Enveloped viruses have proteins on their surface that drive the fusion of the virus and host cell membranes, a key process in infection. These proteins are also the major target of a protective immune response.

Although they are able to induce an immune response, they are inherently unstable and can change shape when expressed on their own. This means that the immune response induced does not efficiently recognize the protein on the virus surface and so does not provide protection from subsequent infection.

UQ-CSL V451 has overcome this problem by using its proprietary "molecular clamp" technology that locks the unstable, prefusion version of the surface proteins in a form that allows the immune system to respond more effectively.

The New York Times

Pfizer's Early Data Shows Vaccine Is More Than 90% Effective

Pfizer announced positive early results from its coronavirus vaccine trial, cementing the lead in a frenzied global race that has unfolded at record-breaking speed.

Dr. Albert Bourla, Pfizer's C.E.O., was in occasional contact with President Trump on the vaccine's timeline. "Every time I spoke with the president I told him that he should not worry about us compromising safety or efficacy, but that we would do it as quickly as science allows us," said Dr. Bourla.Credit...Bryan Derballa for The New York Times

Deep freezers

A worker passes a line of freezers holding coronavirus disease (COVID-19) vaccine candidate BNT162b2 at a Pfizer facility in Puurs, Belgium in an undated photograph. Pfizer/Handout via REUTERS

https://www.reuters.com/article/us-health-coronavirus-freezers/u-s-states-race-to-buy-ultra-cold-vaccine-freezers-fueling-supply-worries-idINKBN27T2S6

Pfizer's thermal shipper

https://edition.cnn.com/2020/11/10/health/pfizer-vaccine-distribution-cold-chain/index.html

Cold Chain - Jody

The COVAX facility

Global procurement for COVID-19 Vaccines

Co-led by Gavi, CEPI and WHO

Goal:

- To vaccinate the most vulnerable 20% of the population of every country that participates, regardless of income level by the end of 2021
- To deliver two billion doses of safe, effective vaccines that has passed regulatory approval and/or WHO prequalification by 2021

There are:

- 92 COVAX AMC-eligible countries
- 78 potentially self-financing countries that have expressed written interest in the COVAX facility

https://www.gavi.org/covid19/covax-facility

Australia's commitments to the COVAX Facility

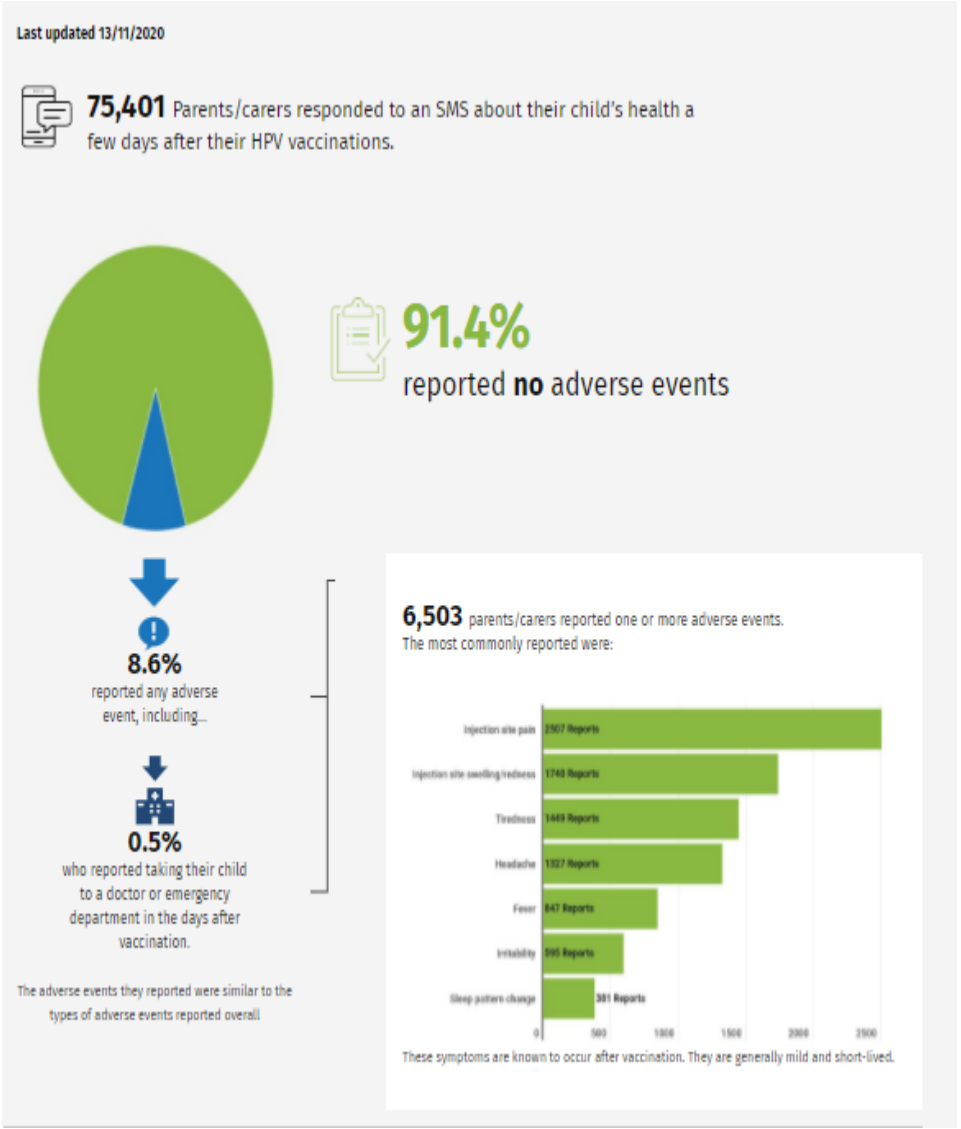
- The Australian Government has made 2 financial commitments to Gavi's COVAX Facility for the supply of safe and effective COVID-19 vaccines:
- An upfront payment of $123.2 million to allow the purchase of over 25,000,000 doses of COVID-19 vaccines for the Australian population. This would be sufficient for 50 percent of the population to receive a 2 dose regimen.
- A further $80 million to support vaccine access for up to 94 lower-income countries through the Facility's Advanced Market Commitment.

Vaccine Safety – Phase 4

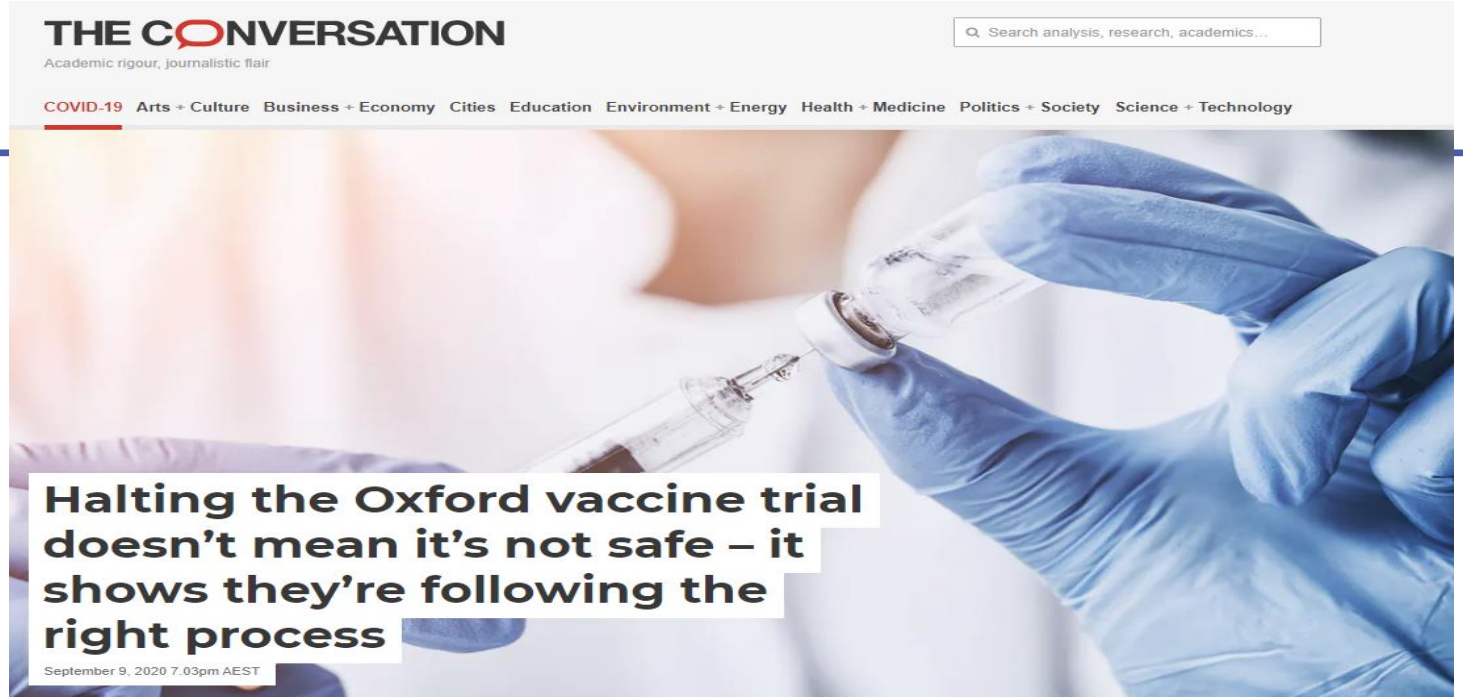
Vaxtracker
Monitoring Vaccine Safety

AusVaxSafety
An NCIRS led collaboration

SAEFVIC



NSW GOVERNMENT Health
Hunter New England
Local Health District



The TGA is also responsible for post-marketing surveillance, which we regard as phase 4. When the vaccine is being rolled out, we continue to monitor for adverse events, and follow these up using both jurisdictional vaccine safety units, such as SAEFVIC in Victoria, and active surveillance systems, such as Smartvax and Vaxtracker.

SPEAC

Safety Platform for Emergency vACcines

D2.3 Priority List of Adverse Events of Special Interest: COVID-19

TABLE 1. AESI RELEVANT TO VACCINATION IN GENERAL (EVENTS LISTED IN RED HAVE EXISTING BC CASE DEFINITIONS) IN THE TOOLBOX.)

BODY SYSTEM	AESI TYPE	RATIONALE FOR INCLUSION AS AN AESI (SEE FOOTNOTE)
Neurologic	Generalized convulsion	1, 2, 4
	Guillain-Barré Syndrome (GBS)	2
	Acute disseminated encephalomyelitis (ADEM)	3
Hematologic	Thrombocytopenia	1, 2
Immunologic	Anaphylaxis	1, 2
	Vasculitides	3, 4
Other	Serious local/systemic AEFI	1, 2

TABLE 3. AESI RELEVANT TO COVID-19

BODY SYSTEM	COVID-19 (red font identifies AESI with existing published Brighton Case Definitions)	RATIONALE FOR INCLUSION AS AN AESI (SEE FOOTNOTE)
Immunologic	Enhanced disease following immunization	1 formalin-inactivated measles/RSV vaccines; HIV vaccine 2 Chimeric Yellow Fever Dengue vaccine 5 mouse models SARS/MERS-CoVs
	Multisystem inflammatory syndrome in children	3, 4
Respiratory	Acute respiratory distress syndrome (ARDS)	3, 4
Cardiac	Acute cardiac injury including: • Microangiopathy • Heart failure and cardiogenic shock • Stress cardiomyopathy • Coronary artery disease • Arrhythmia • Myocarditis, pericarditis	3, 4
Hematologic	Coagulation disorder • Deep vein thrombosis • Pulmonary embolus • Cerebrovascular stroke • Limb ischemia • Hemorrhagic disease	3, 4
Renal	Acute kidney injury	3, 4
Gastrointestinal	Liver injury	3, 4
Neurologic	Guillain Barré Syndrome	4
	Anosmia, ageusia	3, 4
	Meningoencephalitis	1, 4
Dermatologic	Chilblain-like lesions	3, 4
	Single organ cutaneous vasculitis	3, 4
	Erythema multiforme	3, 4

1. Proven association with immunization encompassing several different vaccines
2. Proven association with vaccine that could theoretically be true for CEPI vaccines under development
3. Theoretical concern based on immunopathogenesis.
4. Theoretical concern related to viral replication during wild type disease.
5. Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

Commentary

Chilblain-like lesions on feet and hands during the COVID-19 Pandemic

Nerea Landa[1], MD, Marta Mendieta-Eckert[1], MD Pablo Fonda-Pascual[2], MD and Teresa Aguirre[3], MD

[1]Department of Dermatology, Dermitek Clinic - Grupo stop, Bilbao, Spain; [2]Department of Dermatology, Hospital Gómez Ulla, Madrid, Spain; and [3]Primary Care Physician, Centro Bombero Echaniz, Bilbao, Spain

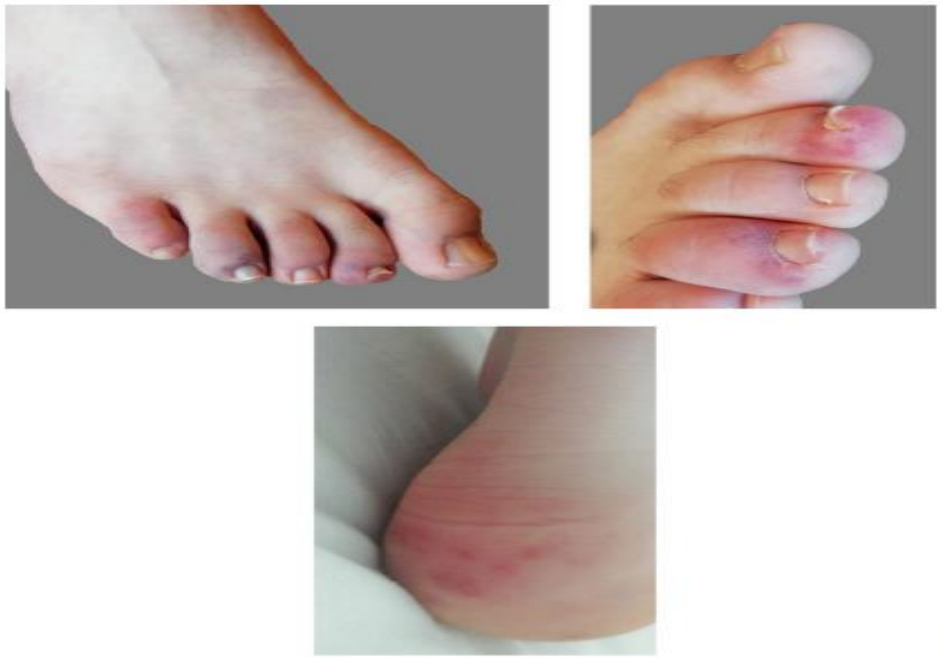


Figure 1 (a) chilblain lesions on toes (b) detail of the toe lesions (c) similar lesions on heel

Australia's vaccine agreements

Australia has entered into 5 separate agreements for the supply of COVID-19 vaccines, if they are proved to be safe and effective.

University of Oxford/AstraZeneca

Status	Type	Developer	Likely Doses*
Phase 3 clinical trials	Viral vector vaccine	AstraZeneca	2

*Based on early trial results

- 3.8 million doses will be delivered to Australia in early 2021
- 30 million doses will be manufactured in Australia between from early 2021 in monthly batches through to September 2021 in monthly batches.
- CSL will manufacture these doses on behalf of AstraZeneca.

University of Queensland/CSL

Status	Type	Developer	Likely Doses*
Phase 1 clinical trials	Protein vaccine	CSL	2

*Based on early trial results

- 51 million doses will be available from mid-2021
- These doses will be manufactured in Australia by CSL

https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/vaccines-and-treatments/australias-vaccine-agreements

Australia's vaccine agreements

Novavax

Status	Type	Developer	Likely Doses*
Phase 3 clinical trials	Protein vaccine	Novavax Inc.	2

- 40 million doses will be made available in Australia during 2021
- Australia will have the option to purchase an extra 10 million doses.

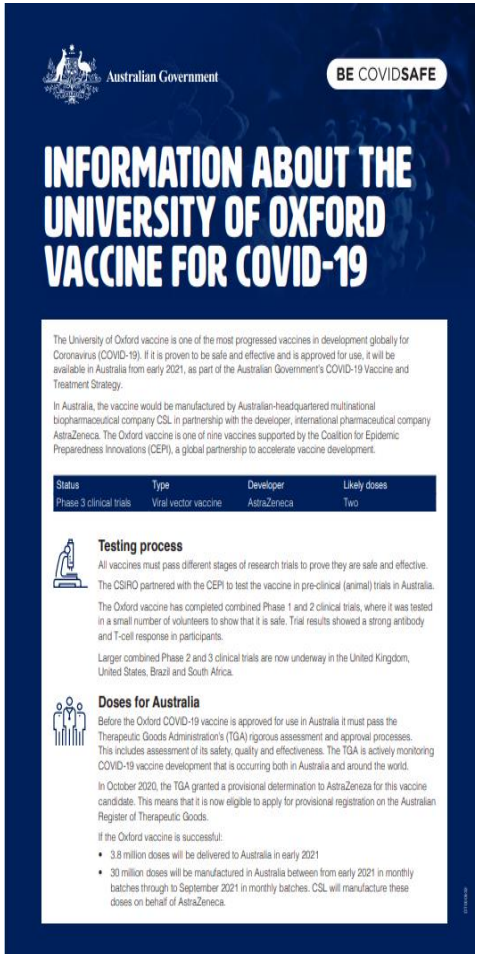
Pfizer/BioNTech

Status	Type	Developer	Likely Doses*
Phase 3 clinical trials	mRNA-based vaccine	Pfizer/BioNTech	2

- 10 million doses will be available from early 2021
- these doses will be manufactured offshore
- Australia will have the option to purchase additional doses where supply is available.

https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/vaccines-and-treatments/australias-vaccine-agreements

Australia's vaccine agreements



Australian Government

BE COVIDSAFE

INFORMATION ABOUT THE UNIVERSITY OF OXFORD VACCINE FOR COVID-19

The University of Oxford vaccine is one of the most progressed vaccines in development globally for Coronavirus (COVID-19). If it is proven to be safe and effective and is approved for use, it will be available in Australia from early 2021, as part of the Australian Government's COVID-19 Vaccine and Treatment Strategy.

In Australia, the vaccine would be manufactured by Australian-headquartered multinational biopharmaceutical company CSL in partnership with the developer, international pharmaceutical company AstraZeneca. The Oxford vaccine is one of nine vaccines supported by the Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership to accelerate vaccine development.

Status	Type	Developer	Likely doses
Phase 3 clinical trials	Viral vector vaccine	AstraZeneca	Two

Testing process

All vaccines must pass different stages of research trials to prove they are safe and effective.

The CSIRO partnered with the CEPI to test the vaccine in pre-clinical (animal) trials in Australia.

The Oxford vaccine has completed combined Phase 1 and 2 clinical trials, where it was tested in a small number of volunteers to show that it is safe. Trial results showed a strong antibody and T-cell response in participants.

Larger combined Phase 2 and 3 clinical trials are now underway in the United Kingdom, United States, Brazil and South Africa.

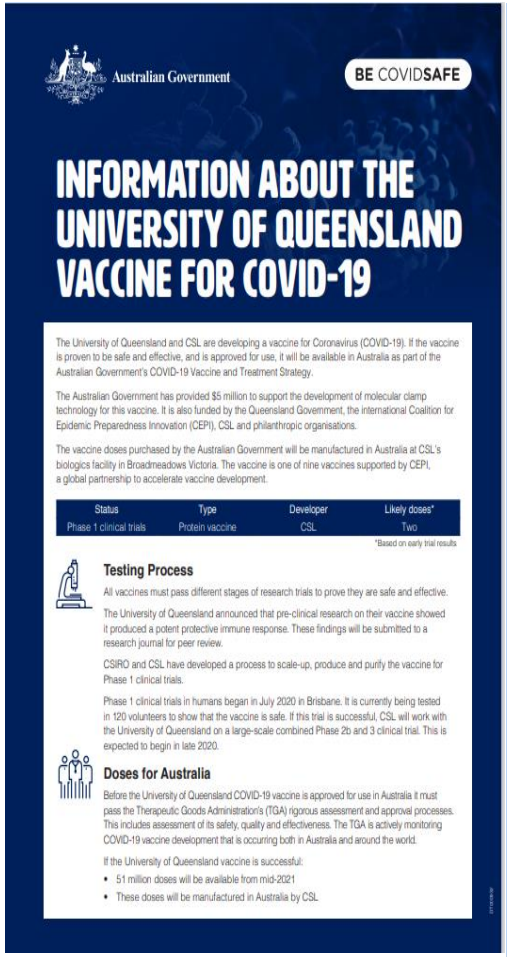
Doses for Australia

Before the Oxford COVID-19 vaccine is approved for use in Australia it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world.

In October 2020, the TGA granted a provisional determination to AstraZeneza for this vaccine candidate. This means that it is now eligible to apply for provisional registration on the Australian Register of Therapeutic Goods.

If the Oxford vaccine is successful:

- 3.8 million doses will be delivered to Australia in early 2021
- 30 million doses will be manufactured in Australia between from early 2021 in monthly batches through to September 2021 in monthly batches. CSL will manufacture these doses on behalf of AstraZeneca.



Australian Government

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INFORMATION ABOUT THE UNIVERSITY OF QUEENSLAND VACCINE FOR COVID-19

The University of Queensland and CSL are developing a vaccine for Coronavirus (COVID-19). If the vaccine is proven to be safe and effective, and is approved for use, it will be available in Australia as part of the Australian Government's COVID-19 Vaccine and Treatment Strategy.

The Australian Government has provided $5 million to support the development of molecular clamp technology for this vaccine. It is also funded by the Queensland Government, the international Coalition for Epidemic Preparedness Innovation (CEPI), CSL and philanthropic organisations.

The vaccine doses purchased by the Australian Government will be manufactured in Australia at CSL's biologics facility in Broadmeadows Victoria. The vaccine is one of nine vaccines supported by CEPI, a global partnership to accelerate vaccine development.

Status	Type	Developer	Likely doses*
Phase 1 clinical trials	Protein vaccine	CSL	Two

*Based on early trial results

Testing Process

All vaccines must pass different stages of research trials to prove they are safe and effective.

The University of Queensland announced that pre-clinical research on their vaccine showed it produced a potent protective immune response. These findings will be submitted to a research journal for peer review.

CSIRO and CSL have developed a process to scale-up, produce and purify the vaccine for Phase 1 clinical trials.

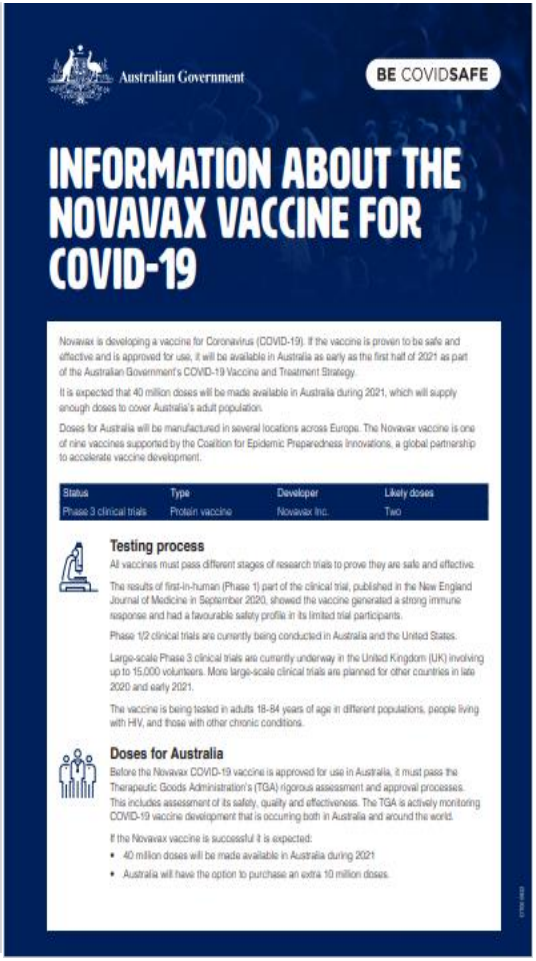
Phase 1 clinical trials in humans began in July 2020 in Brisbane. It is currently being tested in 120 volunteers to show that the vaccine is safe. If this trial is successful, CSL will work with the University of Queensland on a large-scale combined Phase 2b and 3 clinical trial. This is expected to begin in late 2020.

Doses for Australia

Before the University of Queensland COVID-19 vaccine is approved for use in Australia it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world.

If the University of Queensland vaccine is successful:

- 51 million doses will be available from mid-2021
- These doses will be manufactured in Australia by CSL



Australian Government

BE COVIDSAFE

INFORMATION ABOUT THE NOVAVAX VACCINE FOR COVID-19

Novavax is developing a vaccine for Coronavirus (COVID-19). If the vaccine is proven to be safe and effective and is approved for use, it will be available in Australia as early as the first half of 2021 as part of the Australian Government's COVID-19 Vaccine and Treatment Strategy.

It is expected that 40 million doses will be made available in Australia during 2021, which will supply enough doses to cover Australia's adult population.

Doses for Australia will be manufactured in several locations across Europe. The Novavax vaccine is one of nine vaccines supported by the Coalition for Epidemic Preparedness Innovations, a global partnership to accelerate vaccine development.

Status	Type	Developer	Likely doses
Phase 3 clinical trials	Protein vaccine	Novavax Inc.	Two

Testing process

All vaccines must pass different stages of research trials to prove they are safe and effective.

The results of first-in-human (Phase 1) part of the clinical trial, published in the New England Journal of Medicine in September 2020, showed the vaccine generated a strong immune response and had a favourable safety profile in its limited trial participants.

Phase 1/2 clinical trials are currently being conducted in Australia and the United States.

Large-scale Phase 3 clinical trials are currently underway in the United Kingdom (UK) involving up to 15,000 volunteers. More large-scale clinical trials are planned for other countries in late 2020 and early 2021.

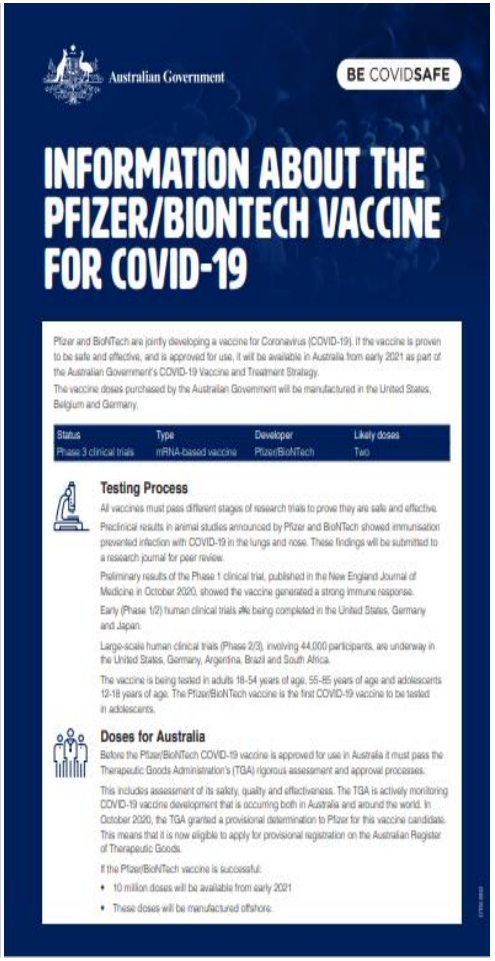
The vaccine is being tested in adults 18-84 years of age in different populations, people living with HIV, and those with other chronic conditions.

Doses for Australia

Before the Novavax COVID-19 vaccine is approved for use in Australia, it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world.

If the Novavax vaccine is successful it is expected:

- 40 million doses will be made available in Australia during 2021
- Australia will have the option to purchase an extra 10 million doses.



Australian Government

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INFORMATION ABOUT THE PFIZER/BIONTECH VACCINE FOR COVID-19

Pfizer and BioNTech are jointly developing a vaccine for Coronavirus (COVID-19). If the vaccine is proven to be safe and effective, and is approved for use, it will be available in Australia from early 2021 as part of the Australian Government's COVID-19 Vaccine and Treatment Strategy.

The vaccine doses purchased by the Australian Government will be manufactured in the United States, Belgium and Germany.

Status	Type	Developer	Likely doses
Phase 3 clinical trials	mRNA-based vaccine	Pfizer/BioNTech	Two

Testing Process

All vaccines must pass different stages of research trials to prove they are safe and effective.

Preclinical results in animal studies announced by Pfizer and BioNTech showed immunisation prevented infection with COVID-19 in the lungs and nose. These findings will be submitted to a research journal for peer review.

Preliminary results of the Phase 1 clinical trial, published in the New England Journal of Medicine in October 2020, showed the vaccine generated a strong immune response.

Early (Phase 1/2) human clinical trials are being completed in the United States, Germany and Japan.

Large-scale human clinical trials (Phase 2/3), involving 44,000 participants, are underway in the United States, Germany, Argentina, Brazil and South Africa.

The vaccine is being tested in adults 18-54 years of age, 55-85 years of age and adolescents 12-18 years of age. The Pfizer/BioNTech vaccine is the first COVID-19 vaccine to be tested in adolescents.

Doses for Australia

Before the Pfizer/BioNTech COVID-19 vaccine is approved for use in Australia it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes.

This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world. In October 2020, the TGA granted a provisional determination to Pfizer for this vaccine candidate. This means that it is now eligible to apply for provisional registration on the Australian Register of Therapeutic Goods.

If the Pfizer/BioNTech vaccine is successful:

- 10 million doses will be available from early 2021
- These doses will be manufactured offshore.

https://www.health.gov.au/resources/publications/coronavirus-covid-19-information-about-the-university-of-oxford-vaccine-for-covid-19

Thank you – Vaccine will bring us a post Covid world

Less time at home
Long queues