

Vacunas COVID-19

Impacto en los Sistema de Salud de Iberoamérica

COIFFA | 17 Septiembre, 2021

**Ana Céspedes, PhD, PDG
Chief Operating Officer, IAVI**

Today, we will review:

- 1. Latest available evidence on COVID-19 vaccines.**
- 2. What we don't (yet) know about approved vaccines.**
- 3. Global supply challenges, potential solutions and implications.**



40' presentation

10' Q&A

IAVI is a global organization focused on developing *globally accessible vaccines and antibodies for infectious diseases*.



Four areas of diseases:



HIV/AIDS



Tuberculosis



Emerging Infectious Diseases



Neglected Emerging Diseases



~280 Employees

Based in

New York

6 Global Offices:

New York, London,
Amsterdam, New
Delhi, Nairobi, and
South Africa



4 Research laboratories in association with main research institutions:

Antibody Neutralization Center
(IAVI/Scripps Research, La Jolla)

Design and Development Laboratory (IAVI, Brooklyn)

Human Immunology Laboratory
(IAVI/Imperial College, London)

Translational Health Science and Technology Institute
(IAVI/Government of India, Delhi)



\$100M income

57 ongoing research and development programs

> 150 partnerships with public and private organizations around the world, including leading pharma and biotechnology

www.iavi.org

IAVI gratefully acknowledges the generous support provided by the following major donors



BILL & MELINDA
GATES foundation



From
the People of Japan



CEPI | New vaccines
for a safer world

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
DANIDA | INTERNATIONAL
DEVELOPMENT COOPERATION



The Research Council
of Norway

Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research |
The Buimer Group | Broadway Cares/Equity Fights AIDS | Cancer Research UK | The City of New York, Economic Development Corporation |
Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation |
Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

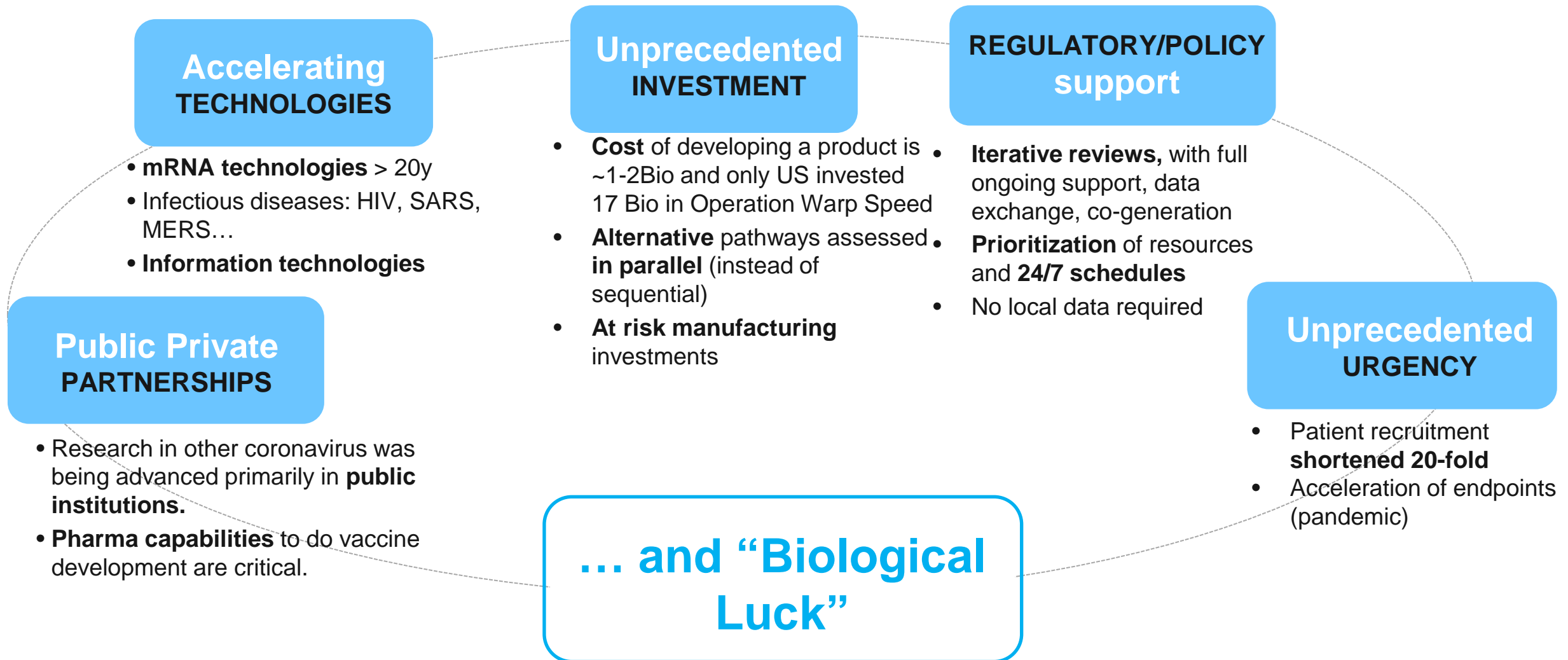
And many other generous individuals and partners around the world

As of September 2020

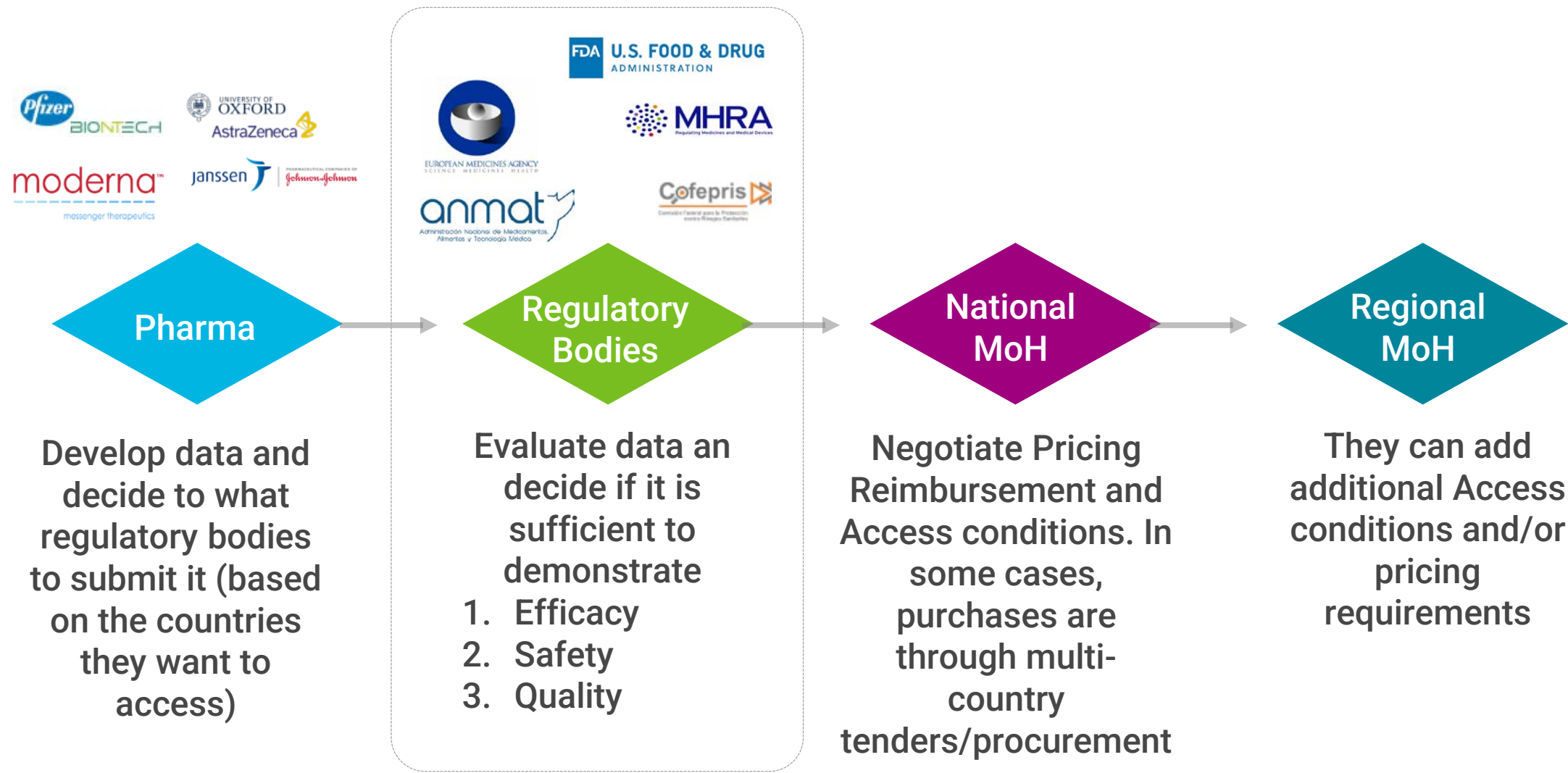
1

COVID-19 Vax: breakthrough success
with no scientific shortcuts

No “scientific shortcuts” taken in this 10-fold reduction of Vaccine Development timelines: collaboration and sense of urgency have been the keys for success









Drug/Vaccine approval is a well-established process where regulatory bodies play a critical role ensuring efficacy, safety and quality



What is a vaccine and what are the different types of vaccines?



A vaccine is a biological preparation that stimulates active acquired immunity to a particular infectious disease.

Platform		About	Licensed products
Inactivated		Inactivated vaccines consist of the whole virus, which has been killed with heat or chemicals so that it can't cause illness. In general, inactivated virus vaccines do not provide as strong of an immune response as live attenuated vaccines, so additional doses may be needed.	Polio
Live attenuated		Live attenuated vaccines are made up of whole viruses that have been weakened in a lab (usually through culturing). They tend to elicit a stronger immune response than inactivated vaccines.	MMR Varicella TB
Subunit		Subunit vaccines introduce a fragment or portion of the virus into the body. This fragment is enough to be recognized by the immune response and stimulate immunity.	Pertussis HPV Hep. B
Viral vector		Viral vector vaccines insert a gene for a viral protein into another, harmless virus (replicating or non-replicating). This harmless virus then delivers the viral protein to the vaccine recipient, which triggers an immune response.	Ebola Veterinary vaccines
mRNA		RNA vaccines work by introducing an mRNA sequence (the molecule that tells cells what to build) coded for a disease-specific antigen. Once this antigen is reproduced within the body, it is recognized and triggers an immune response.	None
DNA		DNA-based vaccines work by inserting synthetic DNA of viral gene(s) into small DNA molecules called plasmids. Cells take in the DNA plasmids and follow their instructions to build viral proteins, which are recognized by the immune system, and prepare it to respond to disease exposure.	None

Sinopharm, Sinovac

Novavax

AZ/Oxford; J&J/Janssen; Sputnik; Bharat

Pfizer/BioNTech; Moderna; Cansino

US, EU, LaTam and other approved

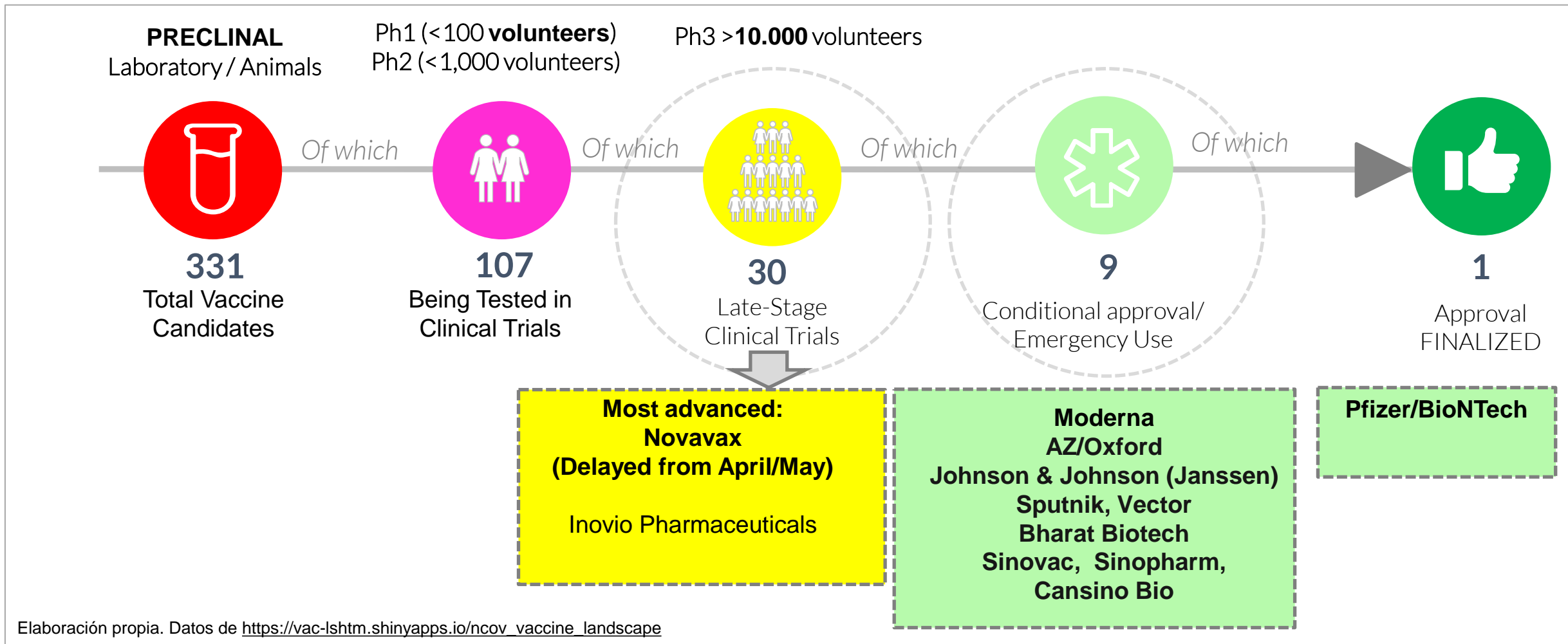
Approved in different countries outside EU and/or US

Rolling Reviews ongoing in different countries

Sources: <https://www.avac.org/resource/cheat-sheet-covid-19-vaccine-pipeline>

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines>

The **unprecedented collaboration & prioritization** has led to 331 programs, 107 in clinical trials (CT), 9 EUA/conditionally/used outside CT, 1 approved

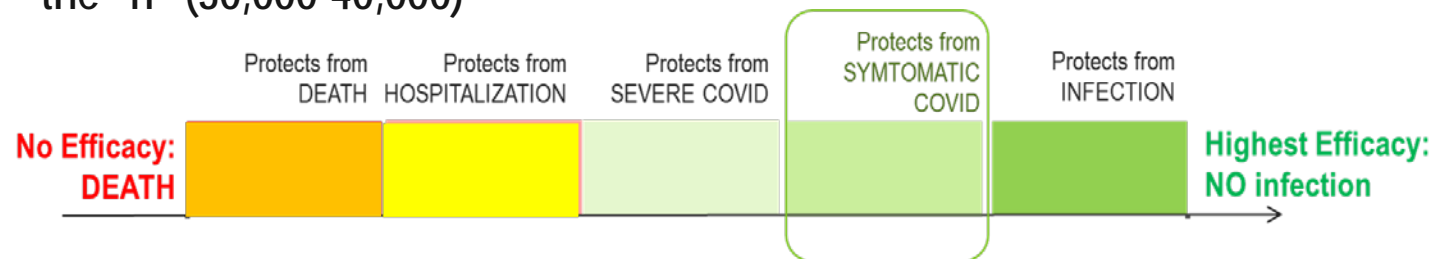


Regulatory approval is decided based on initial efficacy, safety and quality information from *Clinical Trials* and *Manufacturing Sites*

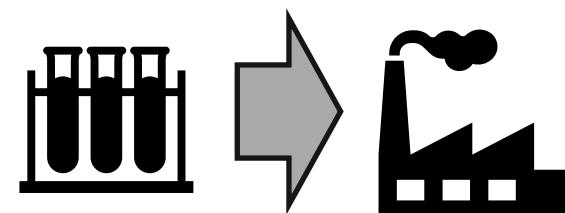


Information presented during the initial regulatory process

CT measure **Efficacy** based on a predefined “endpoint” and **safety** based on the “n” (30,000-40,000)



Vaccine production: process development and manufacturing

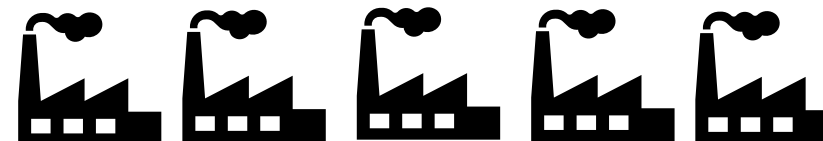


In biologics “the manufacturing process is the molecule”

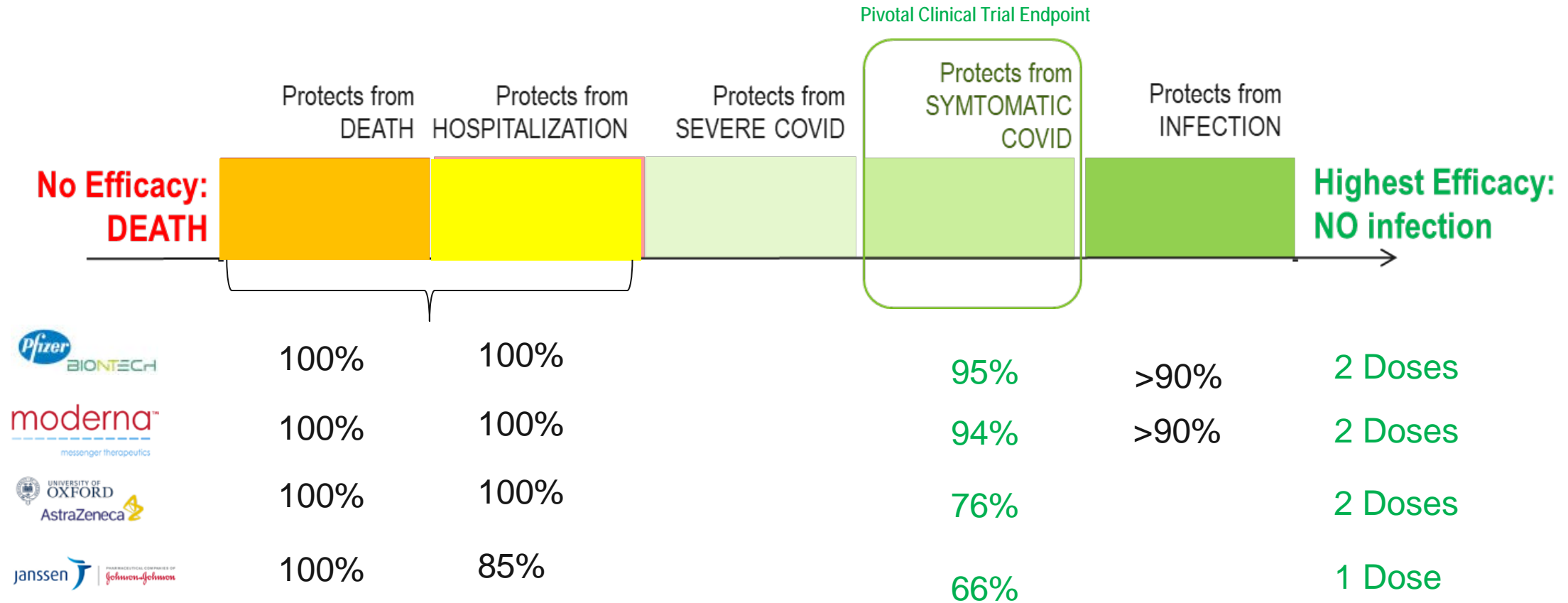
Additional information obtained during Emergency Use / Conditional Approval and Commercialization

Real World Data measures **Effectiveness** and identifies **very rare adverse events** when used in **Millions of people** (DATA is **not directly comparable** unless in Head-to-Head trials)

New Manufacturing Sites



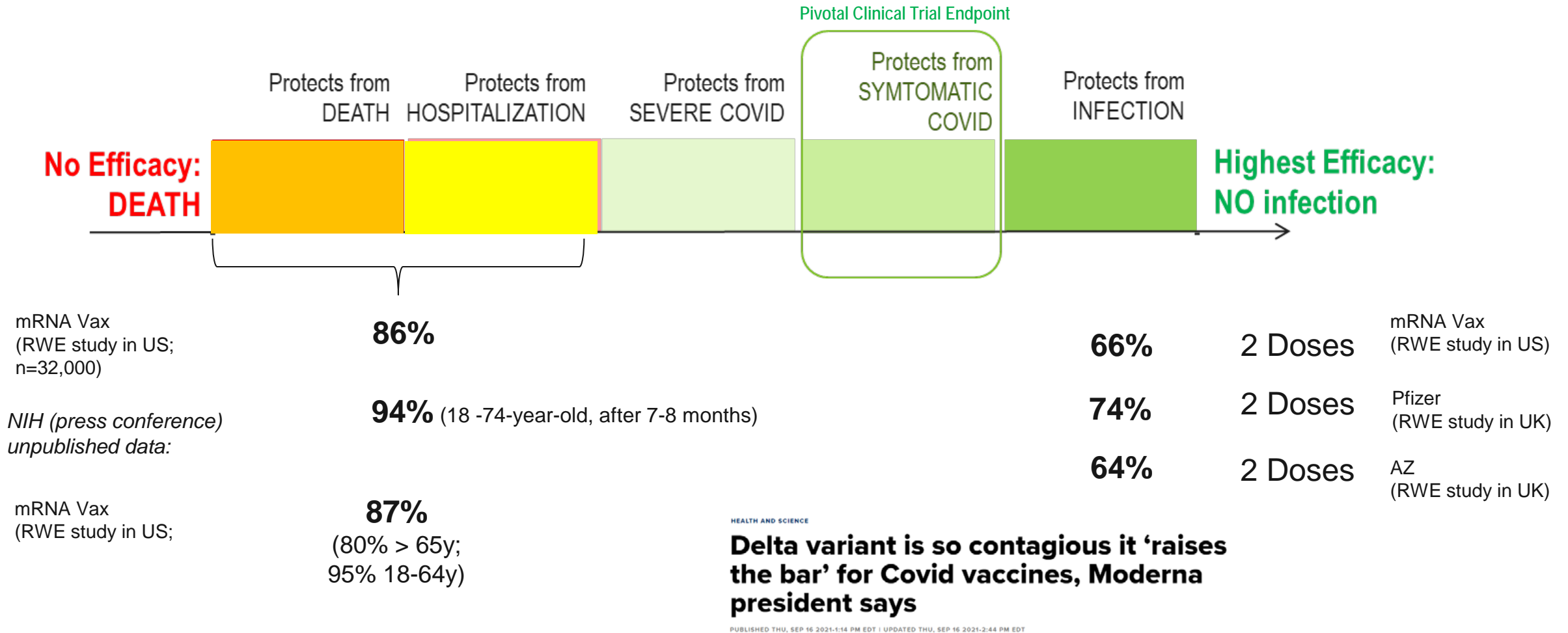
Data pre-DELTA variant, showed that approved Vax^(*) *decreased by 100% the risk of death from COVID-19*



NOTE: Data not directly comparable: not all trials done at the same time and/or the same populations/geographies

(*) Data from Sinovax, Sinopharm and Sputnik not included due to lack of widespread availability .

Data post-DELTA variant, shows that approved Vax^(*) **decrease by 86-94% the risk of hospitalization and death**



NOTE: Data not directly comparable: not all trials done at the same time and/or the same populations/geographies

Pharmacovigilance data^(*) shows that Moderna, Pfizer and Janssen vaccines have significant reactogenicity



Pfizer/BioNTech: “Comirnaty”

Reaction	# of cases	Percentage
Redness	123	5.9%
Swelling	131	6.3%
Pain at the injection site	1632	78%
Fever	331	16%
Fatigue	1247	59%
Headache	1085	52%
Chills	737	35%
Vomiting	40	2%
Diarrhea	219	10%

Moderna: “COVID-19 Vaccine Moderna”

Reaction	# of cases	Percentage
Redness	928	9%
Swelling	1309	12%
Pain at the injection site	2990	83%
Fever	1806	17%
Fatigue	7002	67%
Headache	6500	63%
Chills	5001	48%
Vomiting	2209	21%
Myalgia	6353	61%

Janssen COVID-19 Vaccine

Reaction	# of cases	Percentage
Erythema	184	9%
Swelling	142	7%
Pain at the injection site	1193	59%
Fever	261	13%
Fatigue	891	44%
Headache	905	44%
Nausea	315	16%
Myalgia	796	39%

The US has administered over 282 million vaccines, which is 55% of the US population

- 54% of adults are fully vaccinated and >60% have received one dose
- 88% of >65 have been given the vaccine
- 7,653 cases of death (0.0020%) among people who received a COVID-19 vaccine have been reported in the US

(*) US data. Sources: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>
<https://usafacts.org/visualizations/covid-vaccine-tracker-states/>

Very rare adverse events have been identified during the widespread use of available vaccines (i.e. unusual blood clots with low blood platelets)

AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

[Share](#)

News 07/04/2021

EMA confirms overall benefit-risk remains positive

April 7

25 million people have received the vaccine in EU+UK
86 cases of very rare cases of blood clots combined with low levels of blood platelets and sometimes bleeding, occurring **within 2 weeks of vaccination**, and 18 of which were fatal:

- **62 cases** of cerebral venous sinus thrombosis
- **24 cases** of splanchnic vein thrombosis

"1 case/100,000 person" according to EMA

WHO noted that, whilst concerning, the events under assessment are very rare, with low numbers reported among the **almost 200 million individuals who have received the AstraZeneca COVID-19 vaccine around the world.**



- <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>
- <https://www.astrazeneca.com/media-centre/articles/2021/update-following-mhra-and-ema-decisions-on-astrazenecas-covid-19-vaccine.html>

COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

News 20/04/2021

EMA confirms overall benefit-risk remains positive

April 20

7 million people have received the vaccine in US
8 cases of very rare cases of blood clots combined with low levels of blood platelets and sometimes bleeding, occurring **within 2 weeks of vaccination**, and 1 of which was fatal:

- **8 cases** of cerebral venous sinus thrombosis
- **2 cases** of splanchnic vein thrombosis

- <https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>
- <https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html>
- <https://www.jnj.com/johnson-johnson-covid-19-vaccine-roll-out-to-resume-in-europe-following-european-medicines-agency-ema-review-ema-confirms-overall-benefit-risk-profile-remains-positive>





2

Some relevant data
is still not available

Some key questions remain unanswered. For some of them, we will get answers soon. For some others, we need to wait more

- *When will children under 12y be vaccinated?*
- *Do we need a third dose? If so, who? And when?*
- *Will vaccines completely lose efficacy?*
- *When will we be able to go "back to normal"*
- *...*

We will soon have more information on efficacy data for children: **6 month to 11-year-old** readout from Pfizer is expected by October 2021

As of September 9, children account for 15.5% of all COVID cases in the US

CNBC

Pfizer CEO says Covid vaccine data for kids under age 5 may come in late October

So far, the Pfizer-BioNTech coronavirus vaccine has been cleared by the FDA for people as young as 12, while Moderna's and Johnson...



FDA may soon grant EUA to Pfizer and Moderna COVID-19 vaccines for children aged 5-11 years




The FDA said children that are part of the clinical trials 'should be monitored for at least two months for side effects.'

- **Pfizer** (Comirnaty) safety and efficacy data for children 5-11 expected to be submitted to FDA by October, vaccine **to be available before end of year**
- **Moderna** to have data on vaccine efficacy in children by **early winter**
- **Johnson & Johnson** currently only approved for **18 years and older**

Sources:

<https://www.cnn.com/2021/09/14/pfizers-covid-vaccine-data-for-kids-under-age-5-may-come-in-late-october-ceo-says-.html>
<https://www.firstpost.com/health/fda-may-soon-grant-eua-to-pfizer-and-moderna-covid-19-vaccines-for-children-aged-5-11-years-9966591.html>
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>

Immunocompromised people are getting a **third dose**. Some countries have also approved it for >65y, while there is a big debate about general population

	<ul style="list-style-type: none"> • Results presented to FDA on 8/26 • Results (unpublished) show x3 Ab with 3rd dose (n=306) 8m after 2nd dose • ISRAEL: 60% of 60–69-year-old have received a 3rd dose: x5-6 protection against hospitalization x10 Prevention of Infection (POI)
	<ul style="list-style-type: none"> • They are studying 3rd full dose (or half) – Results presented to FDA 9/2
	<ul style="list-style-type: none"> • 2nd dose produces x9 Ab (Ph1, n=17) 8 months after

Sinovac booster tested as protection ebbs

A third of Hong Kong residents got Sinovac's shot.

SEP 17

“There’s no doubt that protection against Covid-19 wanes in the months following vaccination; however, fully inoculated people rarely wind up severely ill from the virus. Most experts still argue that it’s still too early to boost in this country — and the WHO argues that global vaccination is a higher priority than re-upping in affluent nations.” STAT Sep 17, 2021

...and again, the debate is becoming a political one. Also, there is some controversy around the nomenclature of the dose: booster or third dose?

No EMA decision. Some countries are going ahead with 3rd dose → Based on current evidence, **there is no urgent need for the administration of booster doses of vaccines to fully vaccinated individuals in the general population**, according to a [technical report](#) issued by the [European Centre for Disease Prevention and Control \(ECDC\)](#)

“Booster doses are given to vaccinated people (i.e. people who have completed their primary vaccination) to restore protection after it has waned”

President Biden announced the roll-out of the 3rd dose on **9/20**. **CDC and FDA** announced a few weeks ago that they will start 3rd dose of Moderna and Pfizer **9/20**. However, this is under debate. Originally, they said after 6m and now they are talking **about 8m. 3rd dose approved for immunocompromised**

Three separate articles published last week in the CDC's Morbidity and Mortality Weekly Report suggest that the US does not need boosters

All three studies essentially concluded that well into the summer, the two doses did a good job of keeping people from ending up in the hospital with Covid-19. One [study](#) looked at data from 13 states and counties, [another](#) looked at data from nine states, and the [third](#) looked at data from five Veterans Affairs medical centers.



As we talk right now....

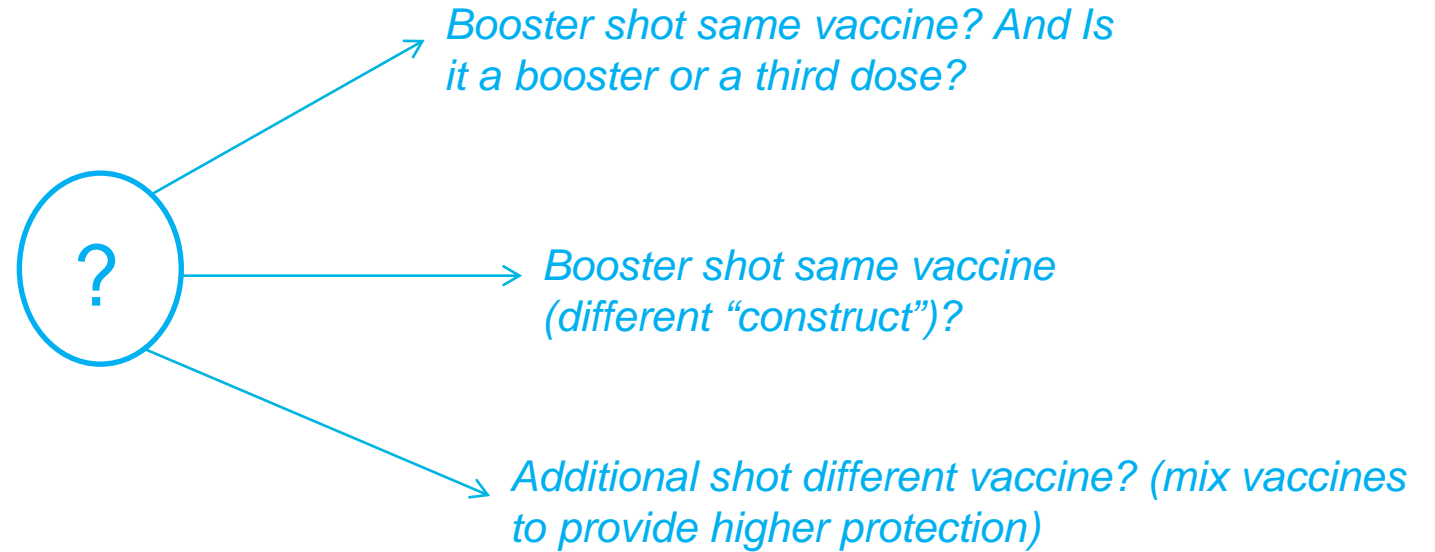
https://www.statnews.com/2021/09/13/international-review-argues-against-covid-19-vaccine-boosters/?utm_source=STAT+Newsletters&utm_campaign=b6db6ad990-RO_COPY_04&utm_medium=email&utm_term=0_8cab1d7961-b6db6ad990-152153498

More time is needed to answer how variants will continue to affect vaccine efficacy



Will vaccines protect against current and future variants?

We still don't know it: it's unlikely that protection disappears completely. However, it's becoming more and more apparent that future updates might be necessary.

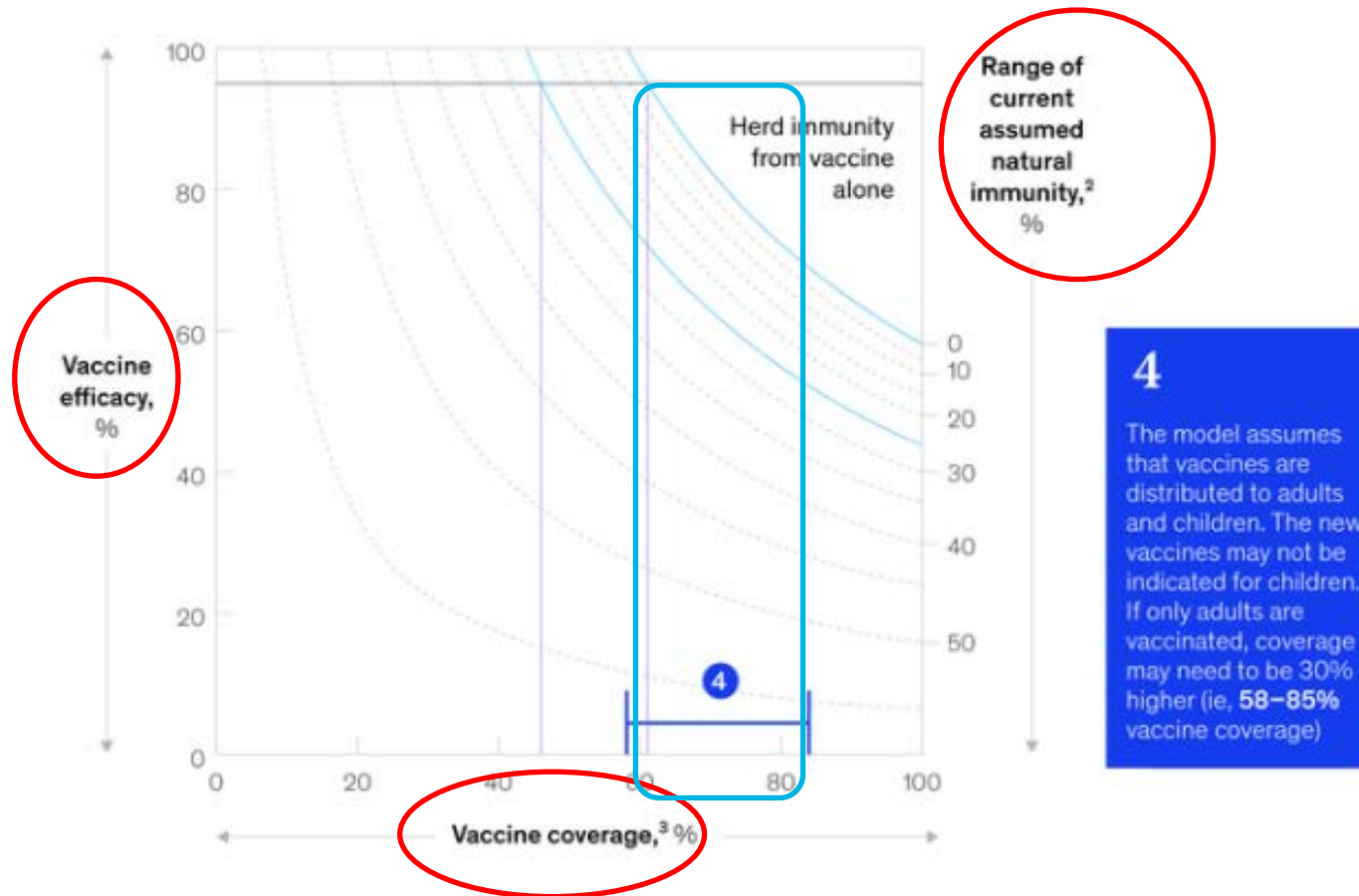


Potential reasons why COVID-19 vaccine efficacy might decrease over time:

- 1. Virus is more infectious**
- 2. Ab titers are decreasing**
- 3. More contacts (less care)**
- 4. Earliest to vaccinate were seniors**

The initial assumptions (with 95% *efficacy* and 10% of *existing immunity*, we need ~ 70% of the vaccinated population) have changed

COVID-19 immunity scenarios (Source: McKinsey)



Higher efficacy provides greater benefit to any vaccinated individual and may help encourage uptake among some segments of the population.

Higher efficacy also reduces the fraction of the population required to reach herd immunity.

Markets

Hong Kong Won't Open Up Before Vaccination Hits at Least 80%

By Felix Tam and Jinshan Hong

September 16, 2021, 9:57 PM EDT Updated on September 17, 2021, 2:11 AM EDT

Fauci: “Herd Immunity Unreachable Unless Vaccine Hesitant Get The Jab Or Get Infected”



HEALTH • CORONAVIRUS

COVID-19 will soon surpass the Spanish Flu as America's deadliest pandemic

BY LANCE LAMBERT

September 16, 2021 11:32 AM EDT

Covid Ravaged South America. Then Came a Sharp Drop in Infections.

South America was the epicenter of the Covid-19 pandemic early this year. Experts are trying to find out why new infections and deaths are falling so fast.

HEALTH • COVID-19

Israel was a vaccination poster child. Now its COVID surge shows the world what's coming next

BY DANIEL AVIS AND BLOOMBERG

September 7, 2021 9:49 AM EDT

Sources: <https://fortune.com/2021/09/16/covid-19-deadliest-pandemic-spanish-flu/>
<https://www.nytimes.com/2021/09/05/world/americas/covid-south-america-reprieve-vaccines.html>
<https://fortune.com/2021/09/07/israel-vaccination-poster-child-covid-surge-shows-world-coming-next>
<https://www.forbes.com/sites/jemimamcevoy/2021/08/24/fauci-herd-immunity-unreachable-unless-vaccine-hesitant-get-the-jab-or-get-infected/?sh=23b482d5260>

3

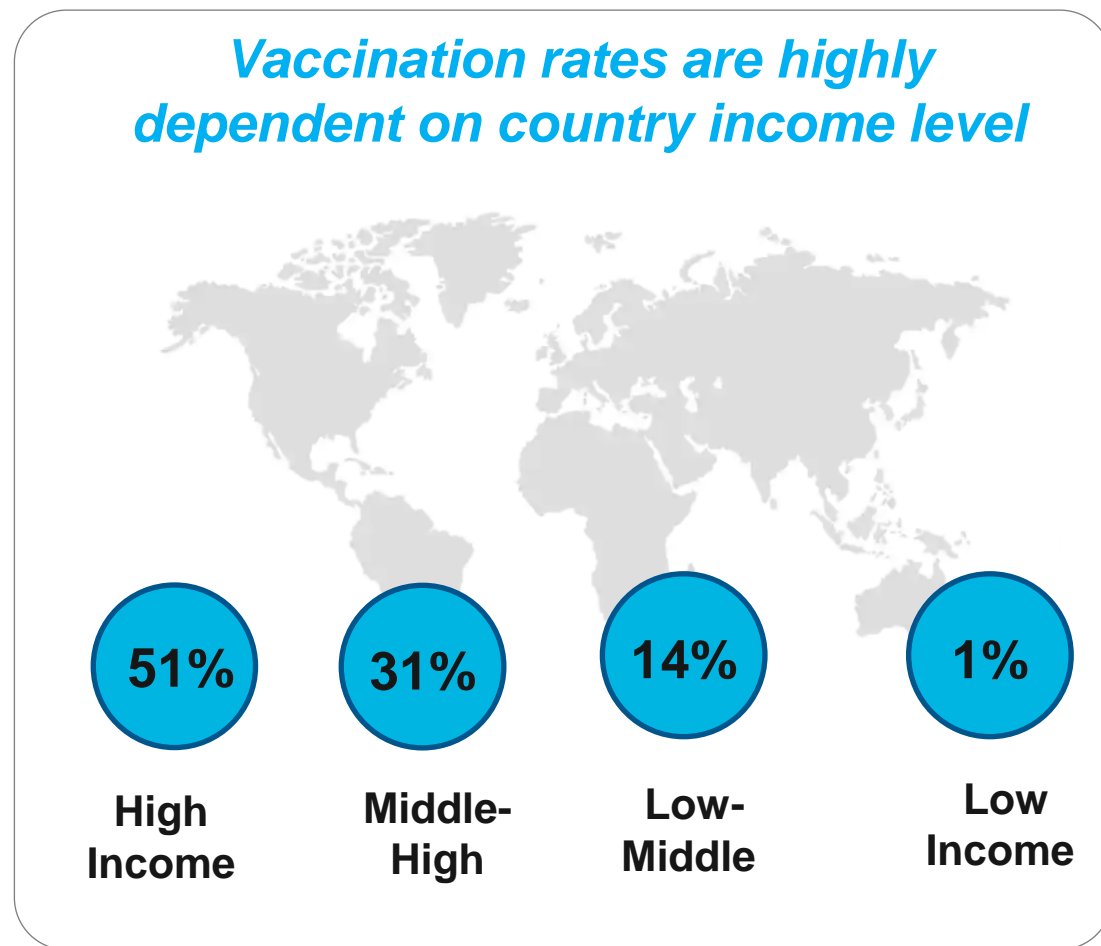
Global vaccination is a challenge
as big as developing a vaccine

An unprecedented **SUCCESS** (4 vaccines in <1y) and *an unprecedented CHALLENGE: all-ages, all-countries vaccination campaign* (7,500 million people)

Countries and regions	Doses administered ▼	Enough for % of people	% of population		Daily rate of doses administered
			given 1+ dose	fully vaccinated	
Global Total	5,832,621,485	-	-	-	30,326,612
Mainland China	2,156,938,000	77.0	78.5	69.3	4,937,857
India	766,978,042	28.0	42.2	13.5	6,180,573
EU	552,346,659	62.2	66.4	62.3	988,518
U.S.	382,294,795	59.7	63.4	54.1	787,751
Brazil	214,665,906	52.1	68.4	35.9	1,800,351
Japan	148,775,011	58.9	65.1	52.8	1,211,318
Indonesia	118,311,615	22.2	28.2	16.1	1,159,201
Germany	104,949,545	63.2	66.9	62.7	198,618
Turkey	103,584,397	62.3	62.7	49.6	547,882
Mexico	93,588,719	36.7	48.1	31.8	703,885
U.K. +	92,650,551	69.4	72.6	66.1	97,169
France	91,962,598	70.9	76.6	72.4	197,031
Russia	86,799,324	29.6	31.6	27.4	274,223
Italy	81,636,330	67.6	72.9	67.0	202,638
Pakistan	71,311,567	17.4	25.8	11.2	829,367
Spain	68,820,573	74.0	80.2	76.5	145,589
South Korea	56,145,166	54.3	67.6	40.9	777,413
Canada +	54,676,239	72.8	74.7	68.7	86,305
Argentina	47,847,207	53.2	64.2	41.8	264,524

Global Vaccination Campaign (Bloomberg, updated 16 Sept 2021)

<https://www.bbc.com/news/56100076>



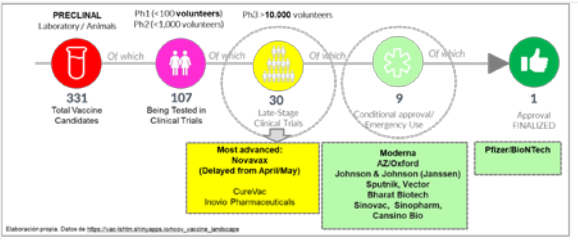
What needs to happen to go faster?

More **APPROVED** vaccines

More **AVAILABLE** doses

More **VACCINE** trust

Global funding for **LMIC**



1,500 million doses produced monthly according to PhRMA

Not only to buy doses but also to enable effective rollout campaigns

Pfizer and BioNTech ramp up COVID-19 vaccine production to 2.5 billion doses

BREAKING | Apr 29, 2021, 01:00am EDT | 1,576 views

Moderna Invests To Make Up To 3 Billion More Covid Vaccines In 2022

Pharma

Sanofi inks 3rd COVID-19 vaccine production pact, this time helping Moderna with fill and finish work

Home / News / Announcements

CEPI and the African Union join forces to boost African vaccine R&D and manufacturing

First COVID-19 COVAX vaccine doses administered in Africa

1 March 2021 | News release | Geneva / New York / Oslo | Reading time: 11 min (3107 words)



- Today, the governments of Côte d'Ivoire and Ghana began COVID-19 vaccination campaigns aimed at protecting healthcare workers.
- This week's first vaccinations happen as a further 11 million COVAX doses are expected to be delivered over the next seven days.
- Publication of the allocation of the AstraZeneca/Oxford vaccine to 142 of COVAX's participating economies, to be delivered between now and the end of May, is anticipated tomorrow.

COVAX has shipped over 279 million COVID-19 vaccines to 141 participant countries and it's still requiring significant additional funding

COVAX aims to provide around two billion doses by the end of 2021 to protect high-risk populations around the world. **However, it is far from achieving this goal.**

Forced to compete with wealthy nations for the limited number of doses coming out in 2021, COVAX has struggled to shore up sufficient supply. COVAX deliveries began in February 2021 but, shortly after, faced significant supply shortages, in part stemming from India's export restrictions.

Iraq receives first doses donated by Italy through COVAX

Canada donates doses through COVAX – Nigeria, Kenya and Niger to receive first doses

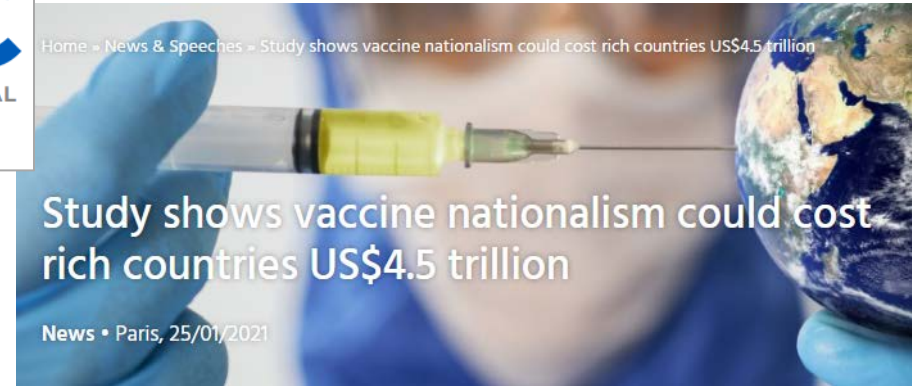
France donates 10 million doses to Africa through COVAX and AU

Global vaccination requires generosity... but *it's also the smart thing to do* as it can generate returns as high as 166x the investment

High and upper-middle income countries have purchased 71% of the 8,600 million doses purchased ⁽¹⁾

**IF RICH COUNTRIES
MONOPOLIZE COVID-19
VACCINES, IT COULD
CAUSE TWICE AS MANY
DEATHS AS
DISTRIBUTING THEM
EQUALLY**

61% of deaths could be averted if the vaccine was distributed to all countries proportional to population, while only **33% of deaths** would be averted if high-income countries got the vaccines first⁽²⁾.



\$ 27.2 billion investment by HIC/MHIC (current financial gap of COVAX) can generate returns as high as **166x the investment**.

The economic costs borne by wealthy countries in its absence range between **\$203 billion-\$5 trillion⁽³⁾**.

⁽¹⁾ Source: [Duke Global Health Innovation Center](https://launchandscalefaster.org/covid-19/vaccineprocurement) (30 MAR 2021)

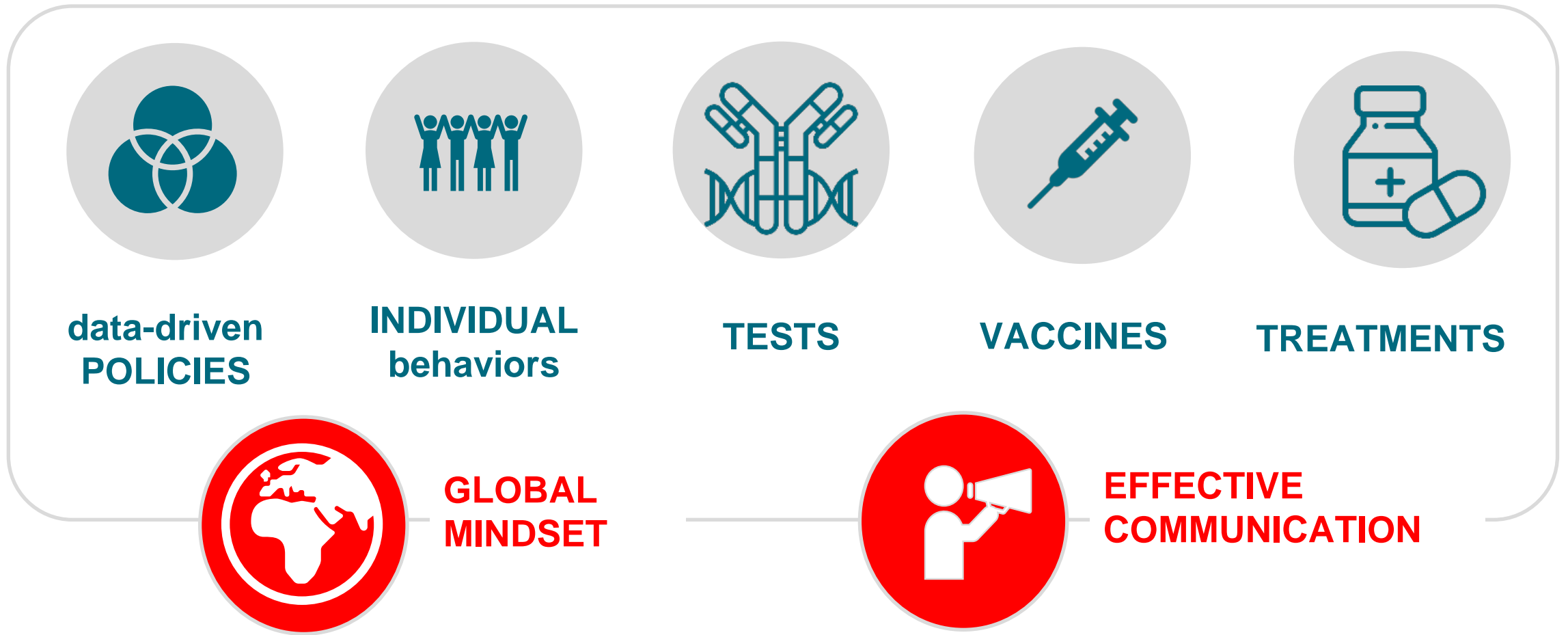
⁽²⁾ <https://launchandscalefaster.org/covid-19/vaccineprocurement>

⁽³⁾ Source: [International Chamber of Commerce](https://www.icc-wco.org/en/press-room/2021/01/study-shows-vaccine-nationalism-could-cost-rich-countries-us45-trillion) (25 JAN 2021)



In conclusion

Future forecast depends on our ability to address this pandemic together and with the *five different types of interventions needed*





#globalHEALTH
#scienceforall
#COVIDcommunication
#sciencecommunication

www.iavi.org

Linked In: Ana Cespedes

Instagram: Ana_Cespedes_Montoya