

WEBINAR

COVID-19 VACCINES AND PEOPLE WITH BLEEDING DISORDERS: SAFETY AND ACCESSIBILITY

JUNE 2, 2021



WORLD FEDERATION OF HEMOPHILIA
FÉDÉRATION MONDIALE DE L'HÉMOFILIE
FEDERACIÓN MUNDIAL DE HEMOFILIA

QUESTIONS AND TRANSLATION FOR COMPUTERS OR TABLETS

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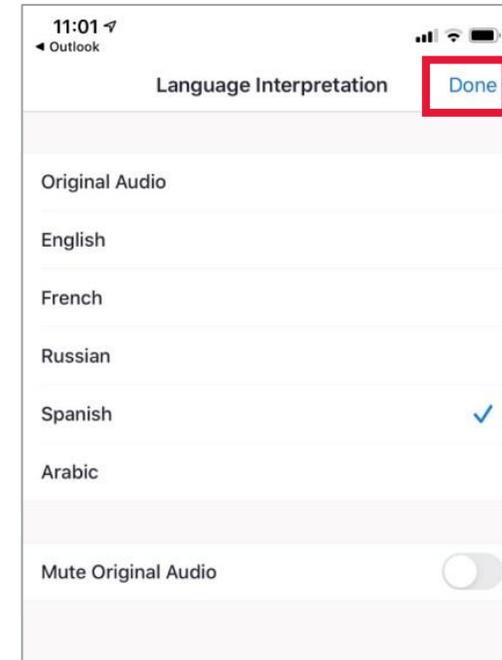
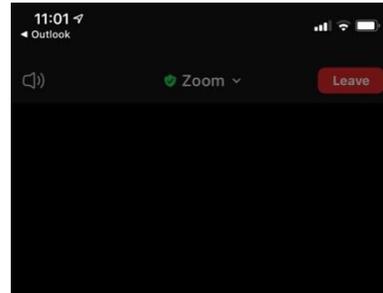
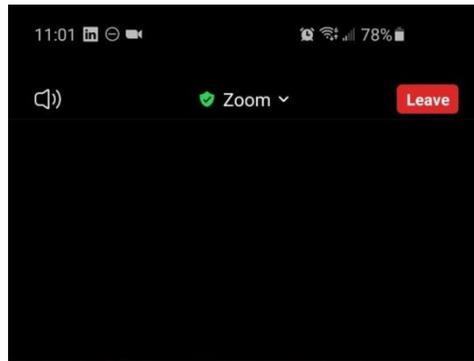


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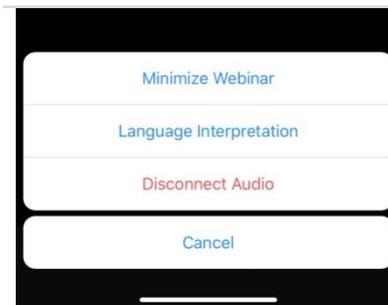
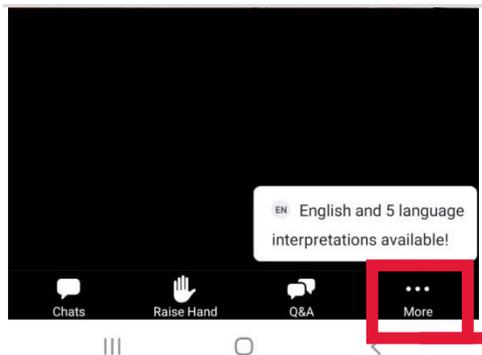


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QUESTIONS AND TRANSLATION FOR MOBILE PHONES



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AGENDA

1. Opening & welcoming remarks
2. Key issues in COVID-19 vaccines for people with bleeding disorders
3. Authorization of COVID-19 vaccines in the EU: A Regulator's Perspective
4. Authorization of COVID-19 vaccines in the US: A Regulator's Perspective
5. COVAX Update: How have low-middle income countries benefited so far?
6. Panel discussion & live Q&A

WELCOME

GLENN PIERCE, MD, PhD
WFH VICE PRESIDENT, MEDICAL



PANELISTS



Cedric Hermans, MD, PhD
WFH Medical board member



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Supply, and Access Committee chair



Peter Marks, MD, PhD
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Manuela Mura, PhD
Scientific Officer
EMA



Claudia Nannei
Senior Technical Officer
WHO

WFH COVID-19 INFORMATION

<https://www.wfh.org/en/covid-19-communications>

<https://elearning.wfh.org/>



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WFH NEWS | COMMUNITY NEWS | MEDICAL NEWS | WFH EVENTS

COVID-19 (coronavirus disease 2019) pandemic caused by SARS-CoV-2: practical recommendations for people with hemophilia

World Federation of Hemophilia - March 21, 2020
Also available in: Español, Français

MEDICAL NEWS

COVID-19 UPDATES

WFH



WEBINAR

BLEEDING DISORDERS AND COVID-19

THE FACTS AND RISKS TO PERSONS WITH BLEEDING DISORDERS

WFH Webinar: Bleeding Disorders and COVID-19

WEBINAR

Received: 22 December 2020 | Revised: 5 January 2021 | Accepted: 22 January 2021

DOI: 10.1111/hae.14271

Haemophilia  WILEY

COMMENTARY

Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders

Radoslaw Kaczmarek¹ | Magdy El Ekiaby^{1,2} | Daniel P. Hart^{1,3,4} | Cedric Hermans^{1,5} | Mike Makris^{1,6} | Declan Noone^{1,6} | Brian O'Mahony^{1,7,8} | David Page^{1,9} | Flora Peyvandji^{1,10,11} | Steven W. Pipe^{1,12,13} | Thomas Sannig^{1,6,14} | Uwe Schlenkrich^{1,15} | Mark W. Skinner^{1,16,17} | Alok Srivastava^{1,18} | Amanda Bok⁶ | Glenn F. Pierce^{1,19} | the World Federation of Hemophilia (WFH), European Association for Haemophilia, Allied Disorders (EAHAD), European Haemophilia Consortium (EHC), U.S. National Hemophilia Foundation (NHF)



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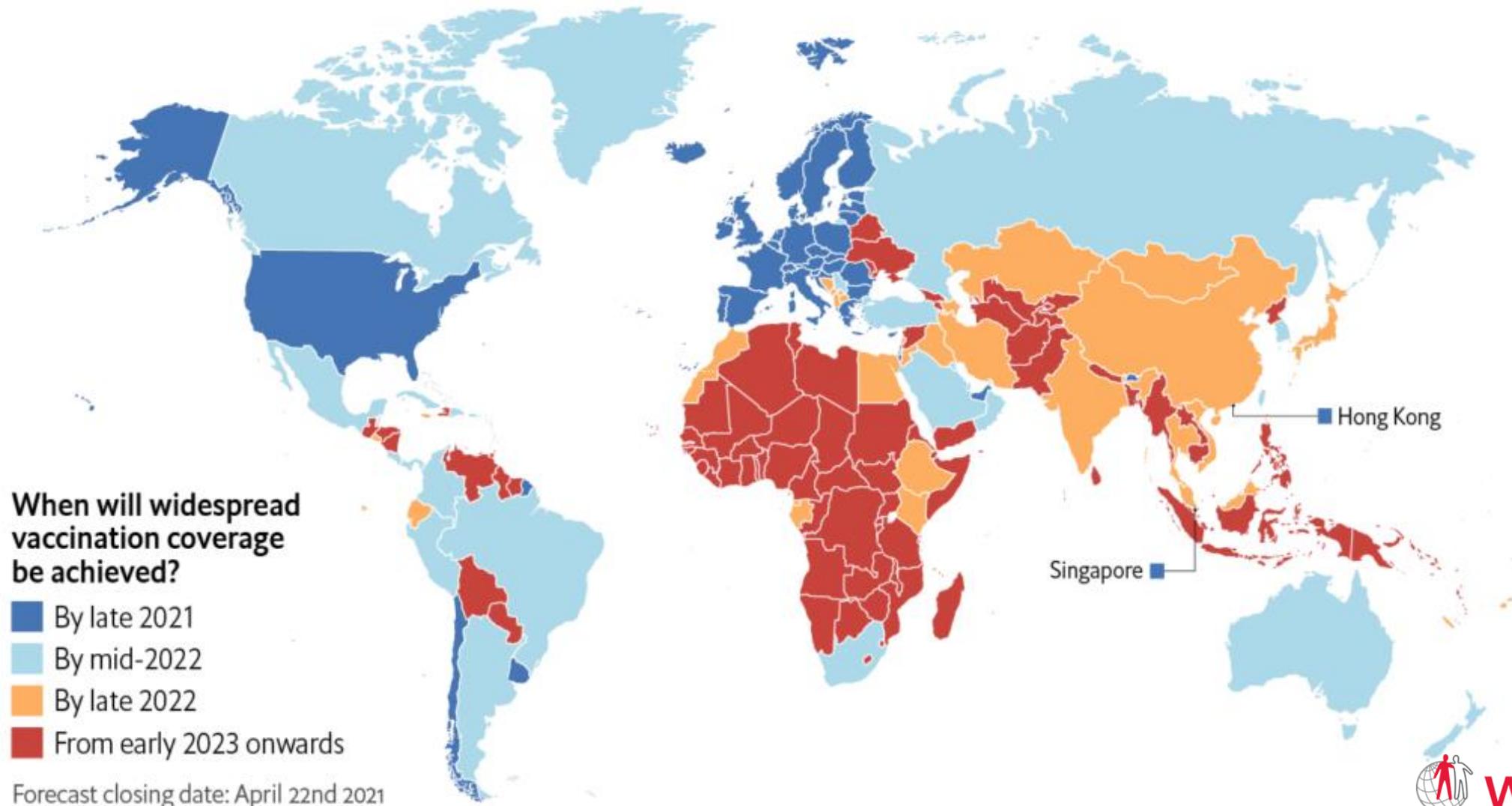
Access to Vaccines

“The contrast between rich countries and poorer ones is stark. Most developing countries will not have widespread access to the shots before 2023 at the earliest.”

- The Economist Intelligence Unit



Rich countries will get access to coronavirus vaccines earlier than others



When will widespread vaccination coverage be achieved?

- By late 2021
- By mid-2022
- By late 2022
- From early 2023 onwards

Forecast closing date: April 22nd 2021
Source: The Economist Intelligence Unit.

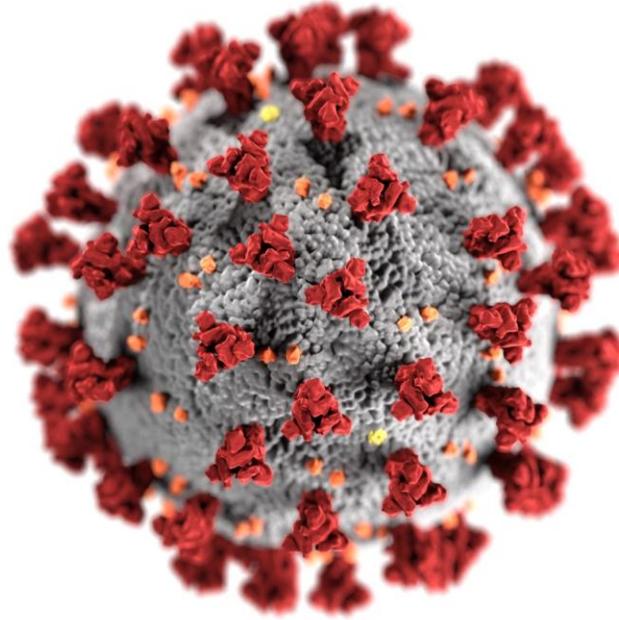
Key issues in COVID-19 vaccines for people with bleeding disorders

Cedric Hermans, MD, PhD

WFH Board member



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SARS-CoV-2 and Hemophilia

Epidemiology of COVID-19

Risk factors for exposure to the virus

Risk factors for COVID-19

Clinical presentation of COVID-19

In-hospital management of COVID-19

Impact on hemophilia care today

Modalities of vaccination

Impact on hemophilia care tomorrow

Lessons

Positive effects of the pandemic

Received: 23 March 2020 | Revised: 26 March 2020 | Accepted: 26 March 2020

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EDITORIAL

Haemophilia  WILEY

The COVID-19 pandemic: New global challenges for the haemophilia community

March 2020

Received: 15 April 2020 | Revised: 6 May 2020 | Accepted: 7 May 2020

DOI: 10.1111/hae.14045

ORIGINAL ARTICLE

Clinical haemophilia

Haemophilia  WILEY

In-hospital management of persons with haemophilia and COVID-19: Practical guidance

May 2020

Received: 15 July 2020 | Revised: 21 October 2020 | Accepted: 21 October 2020

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ORIGINAL ARTICLE

Haemophilia  WILEY

Management of COVID-19-associated coagulopathy in persons with haemophilia

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COMMENTARY

Haemophilia  WILEY

Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders

January 2021



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Received: 22 December 2020

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COMMENTARY

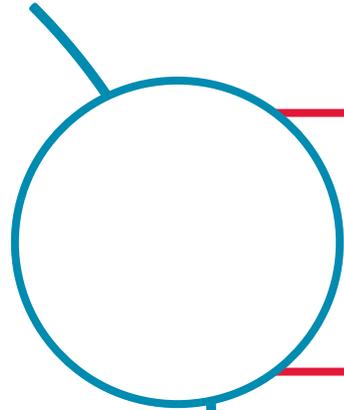
Haemophilia  WILEY

Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders

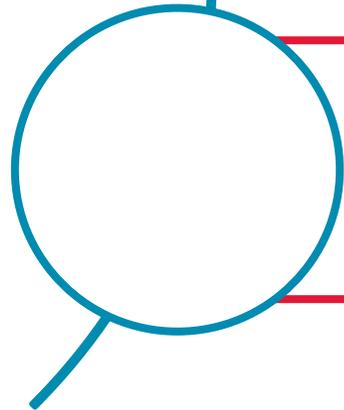


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Vaccination in PWBDs: Rationale



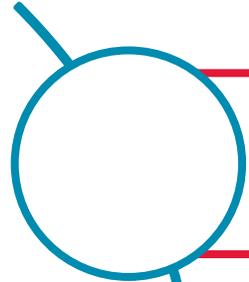
PWBDs should understand the modalities of vaccination



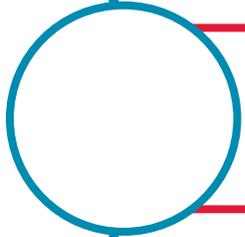
PWBDs should be vaccinated like everyone else

PWBDs: people with bleeding disorders

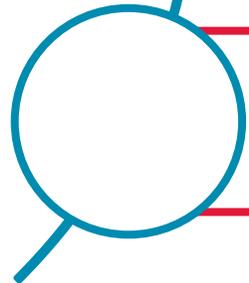
Vaccination in PWBDs: Modalities and Precautions



PWBDs = Not a priority group for vaccination



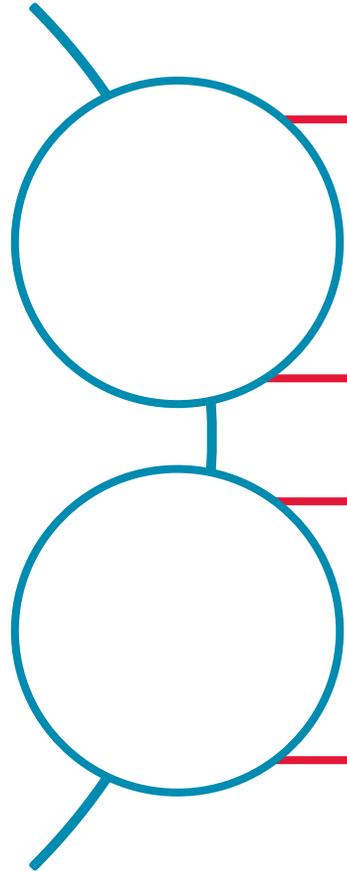
No reason to select a particular type of vaccine



The vaccine should be administered intramuscularly

PWBDs: people with bleeding disorders

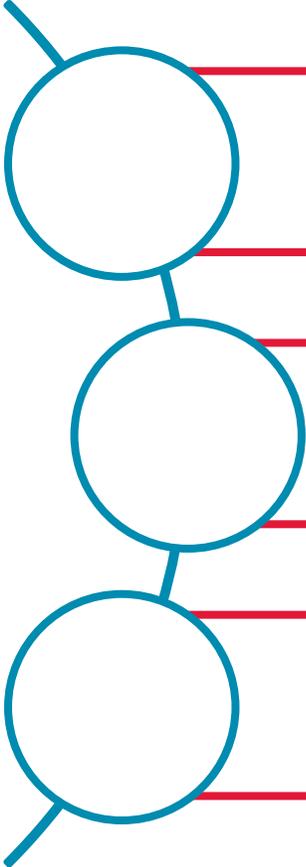
Vaccination in PWBDs: Modalities and Precautions



Hemostatic support will depend on the severity of the BD

No specific contra-indication to vaccination related to hemophilia

Vaccination in PWBDs: Modalities and Precautions



Vaccination is not contra-indicated in patients on immunosuppressive agents (e.g., cortisone...)

For PWBDs in clinical studies, vaccination should be reported to the study investigators

Initiatives to inform PWBDs and contribute to an effective vaccination programme should be encouraged

PWBDs: people with bleeding disorders

THANK YOU!



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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Safety of COVID-19 vaccines in the EU from authorisation to vaccination

Dr Manuela Mura
Scientific Officer
Office of Biological Health Threats and Vaccines Strategy, EMA

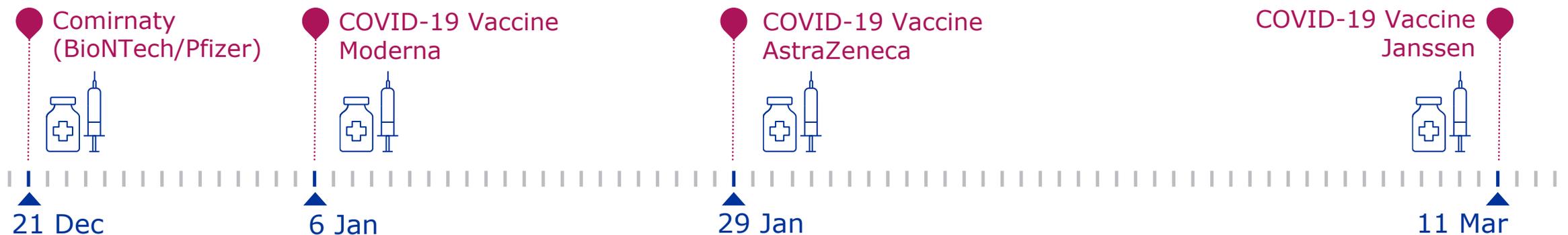
An agency of the European Union



COVID-19 vaccines approved in the EU

4 vaccines authorised in the EU

- **Comirnaty and Moderna** vaccines contain a molecule called **messenger RNA (mRNA)** with instructions for producing the spike protein from SARS-CoV-2, the virus that causes COVID-19
- The **AstraZeneca and Janssen** vaccine use a **non-replicating adenovirus** as a carrier that has been modified to produce the spike protein from SARS-CoV-2.
- The vaccines do not contain the SARS-CoV-2 virus causing COVID-19 itself and **cannot cause the disease.**



Clinical safety at time of submission

- Evaluation of the vaccines in accordance with the [Reflection paper](#) (EMA considerations on COVID-19 vaccines approval).
- For a Conditional Marketing Authorisation (CMA) a clinical safety database in the order of thousands of subjects followed up for at least 6 weeks is in principle sufficient
- Longer term follow-up is relevant for both safety and efficacy and studies should continue after reaching primary endpoint, e.g. occurrence of VAED once antibodies decay, for the remaining duration of the trials
- Rare adverse reactions occurring with a frequency of less than 1/1000 cannot likely be defined in the context of the pre-approval clinical trials and will require post-approval surveillance studies
- Long term protection and immunogenicity data post-approval will inform the need and timing of booster doses

Positive benefit/risk balance for COVID-19 vaccines

Good efficacy and good safety profile, comparable to vaccines for other diseases

- **Most common** side effects are usually **mild or moderate and temporary**.
- These include pain and tenderness at injection site, headache, tiredness, muscle pain, general feeling of being unwell, chills, fever, joint pain and nausea.
- Very large safety datasets for all vaccines up to 44,000 people allow good characterisation of uncommon adverse events (occurring in more than 1 person every 1,000 vaccinees and < 1/100)
- **Very rare but severe allergic reactions** have occurred in people receiving the vaccine (in **less than 1 in 100,000 people**)
- **Very rare events of severe thrombosis combined with thrombocytopenia** after AstraZeneca and Janssen vaccines have occurred **in around 1 in 100.000 people**, and are under investigation
- **Long term safety** is being monitored in line with the Pharmacovigilance (PhV) legislation.

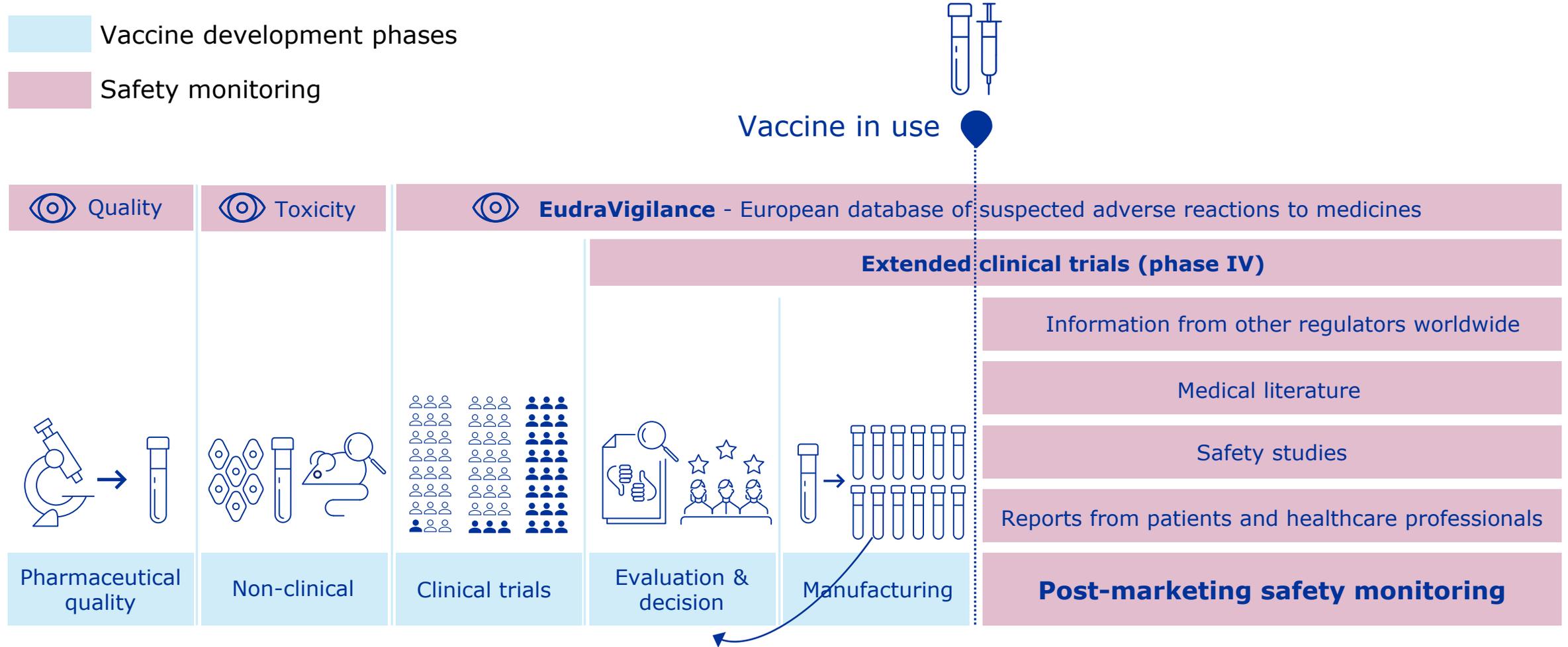
Full **scientific details and product information**:

[Comirnaty](#) | [COVID-19 Vaccine Moderna](#) | [COVID-19 Vaccine AstraZeneca](#) | [COVID-19 vaccine Janssen](#)



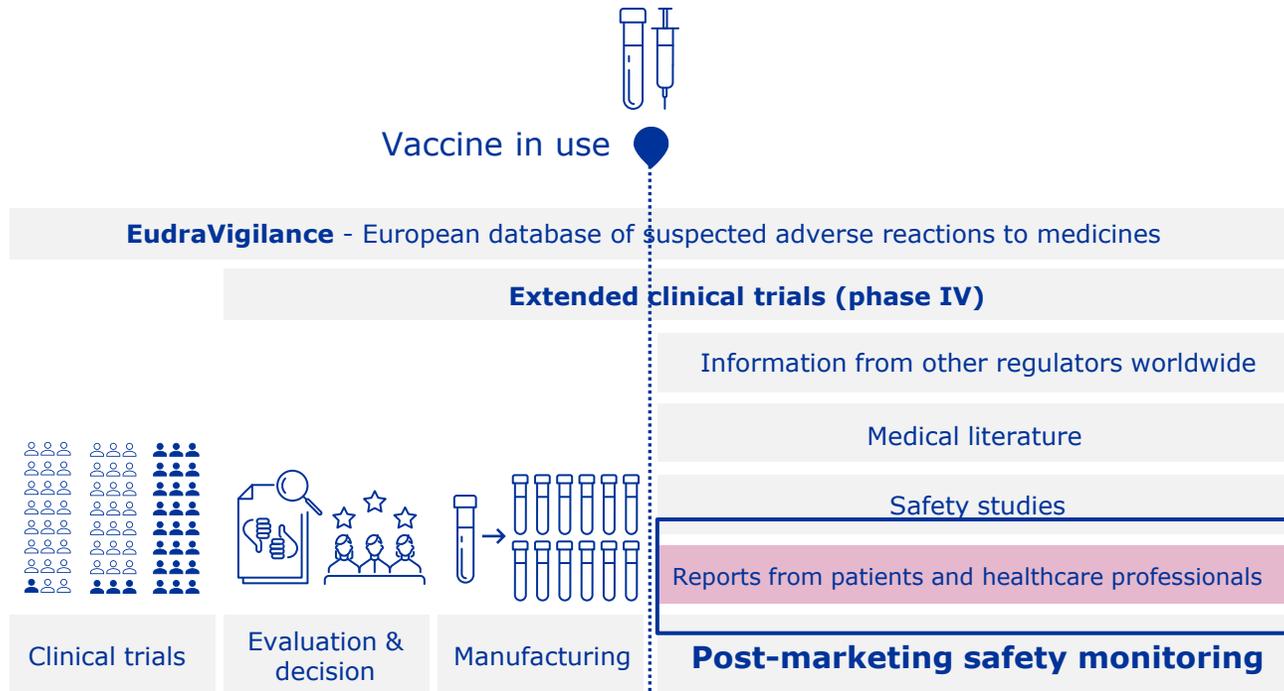
Safety monitoring of vaccines – when?

SAFETY IS STUDIED FROM THE DEVELOPMENT STAGE TO USE IN REAL LIFE



The European database of suspected adverse reactions to medicines (EudraVigilance)

<http://www.adrreports.eu/>



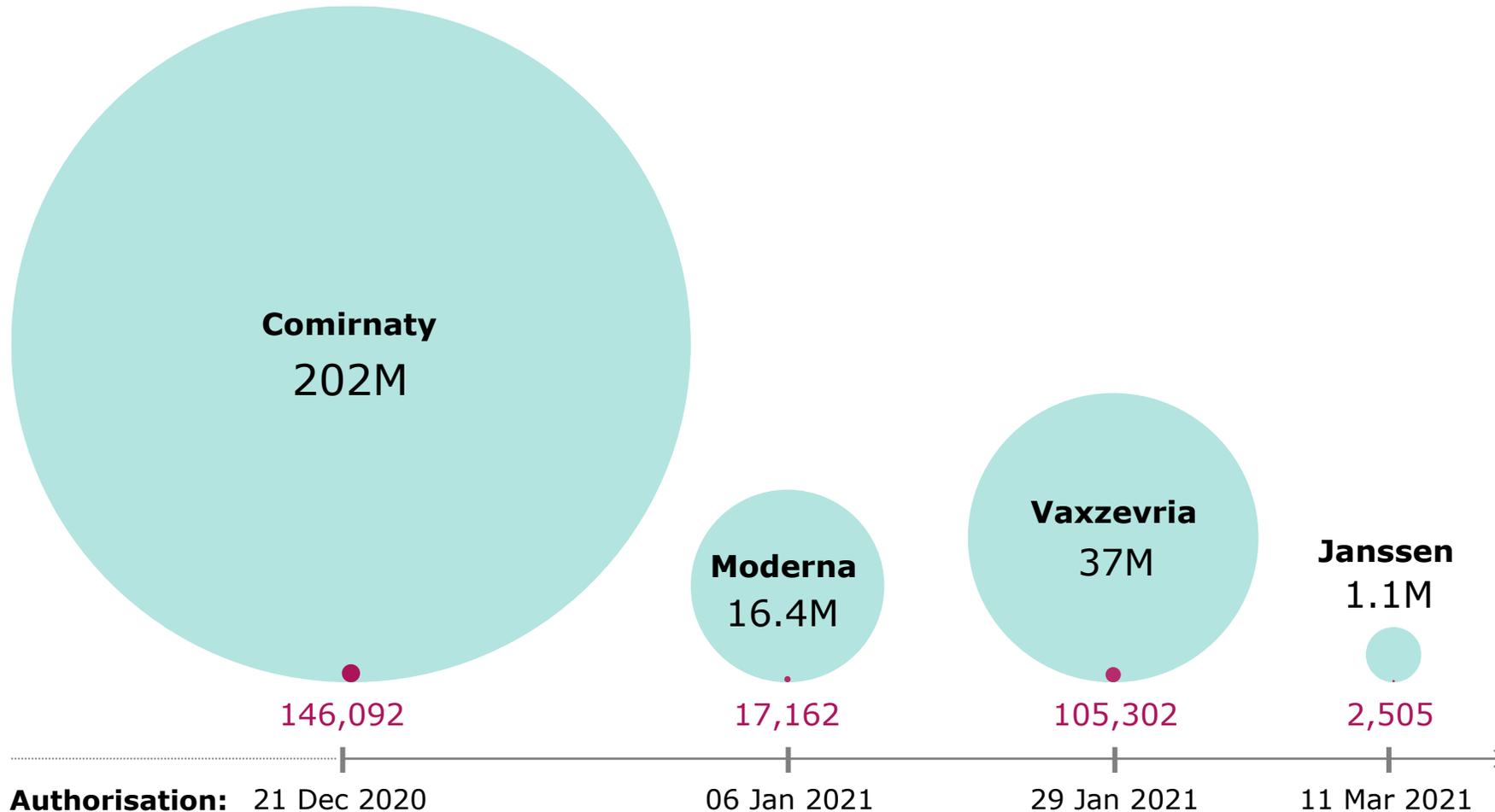
Reports from patients and healthcare professionals

Up to 25 May 2021, a total of ~502,478 worldwide cases of **suspected** side effects have been received by EudraVigilance after administration of COVID-19 vaccines

Other analyses and causality assessment are conducted to validate potential safety signals identified based on regular monitoring

Reports of suspected side effects in the context of usage

Status as of 19.05.2021 – European Economic Area (EEA)

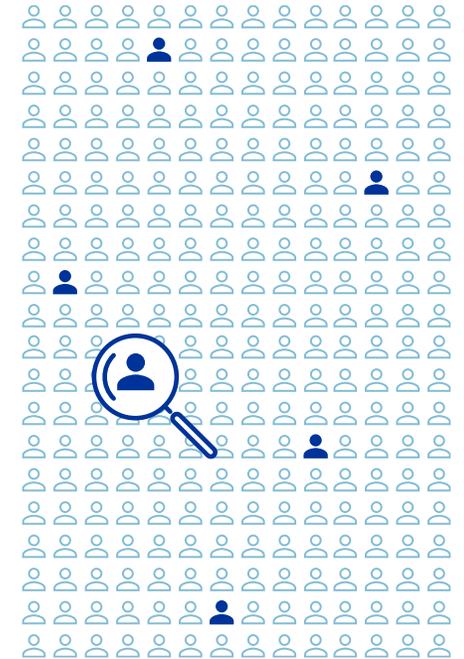


Numbers of **suspected** side effects need to be put into context of **how many** people have been vaccinated and **how long** the vaccine has been on the market

-  Vaccines administered www.ecdc.europa.eu/
-  Suspected side effects www.adrreports.eu/

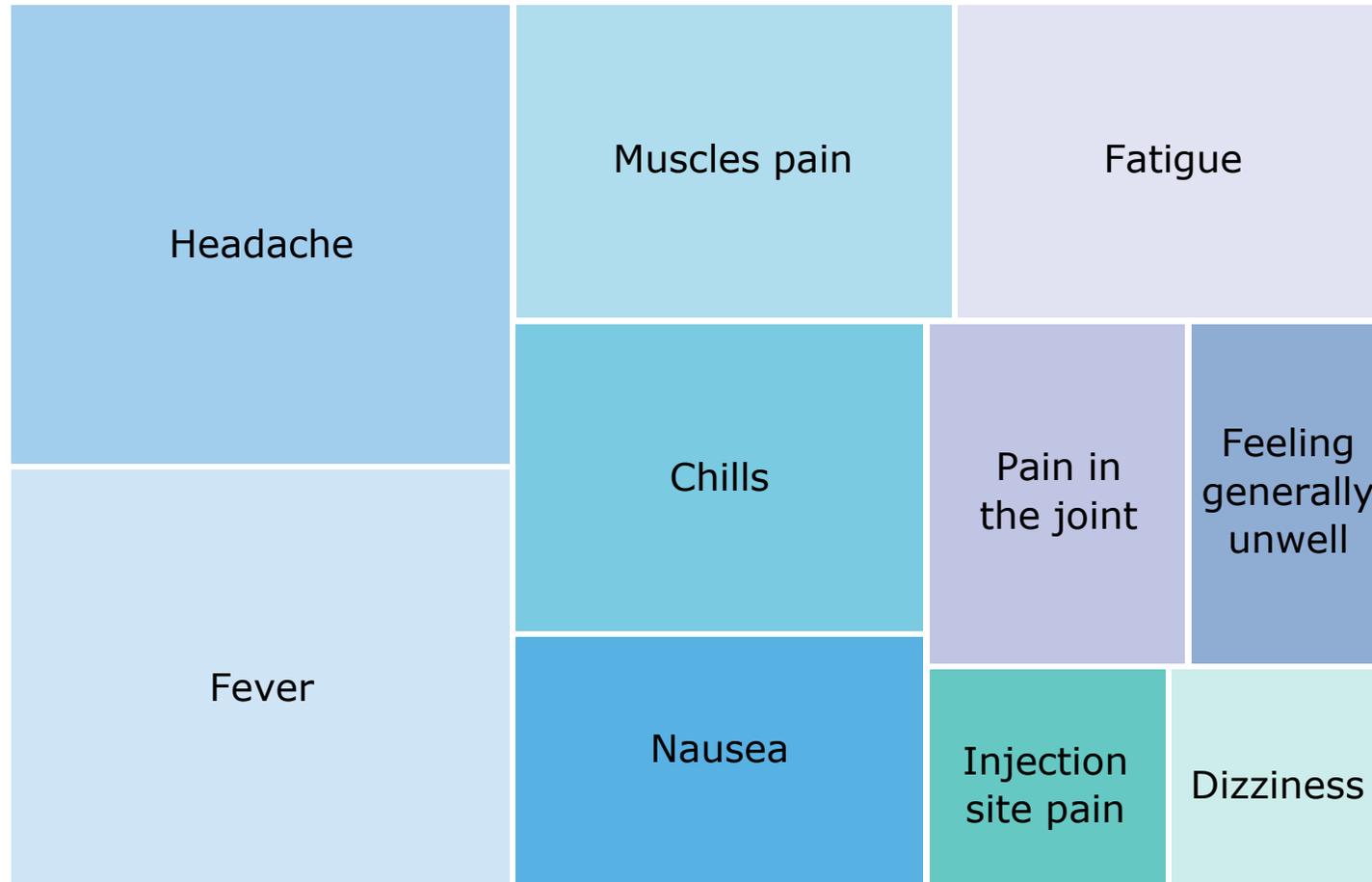
How does EMA assess if side effects could be caused by the vaccine?

- **Analysis techniques** are in place to assess whether a side effect is likely to be caused by the vaccine
- One of the main analysis used to monitor the safety of the vaccine is **observed-to-expected (OE)**
- The main aim of OE is to **contextualise the number of reports** of suspected side effects received
- When millions of people are monitored, some of them will develop illness **naturally**
- If these people are vaccinated, some of these illness would still develop naturally and **might occur in close proximity to the vaccination**
- The core idea of OE is to **estimate the expected number** of cases that would occur naturally and compare them with the number of cases actually **observed in vaccinated**



What is EudraVigilance telling us?

WHAT ARE THE MOST REPORTED SIDE EFFECTS WITH COVID-19 VACCINES SINCE THEIR APPROVAL?



The most common suspected side effects reported **are already known** and listed in the summary of product characteristics (SmPC) and the package leaflet.

HOW TO REPORT A SIDE EFFECT in EudraVigilance

- **Anyone** can report a suspected side effect to their national authority or the vaccine manufacturer
- Consult the appropriate authority from the [list of national medicines regulatory authorities in the EEA](#) for information on how to report a side effect
- All reports are sent to **EudraVigilance, the European database** of suspected side effects

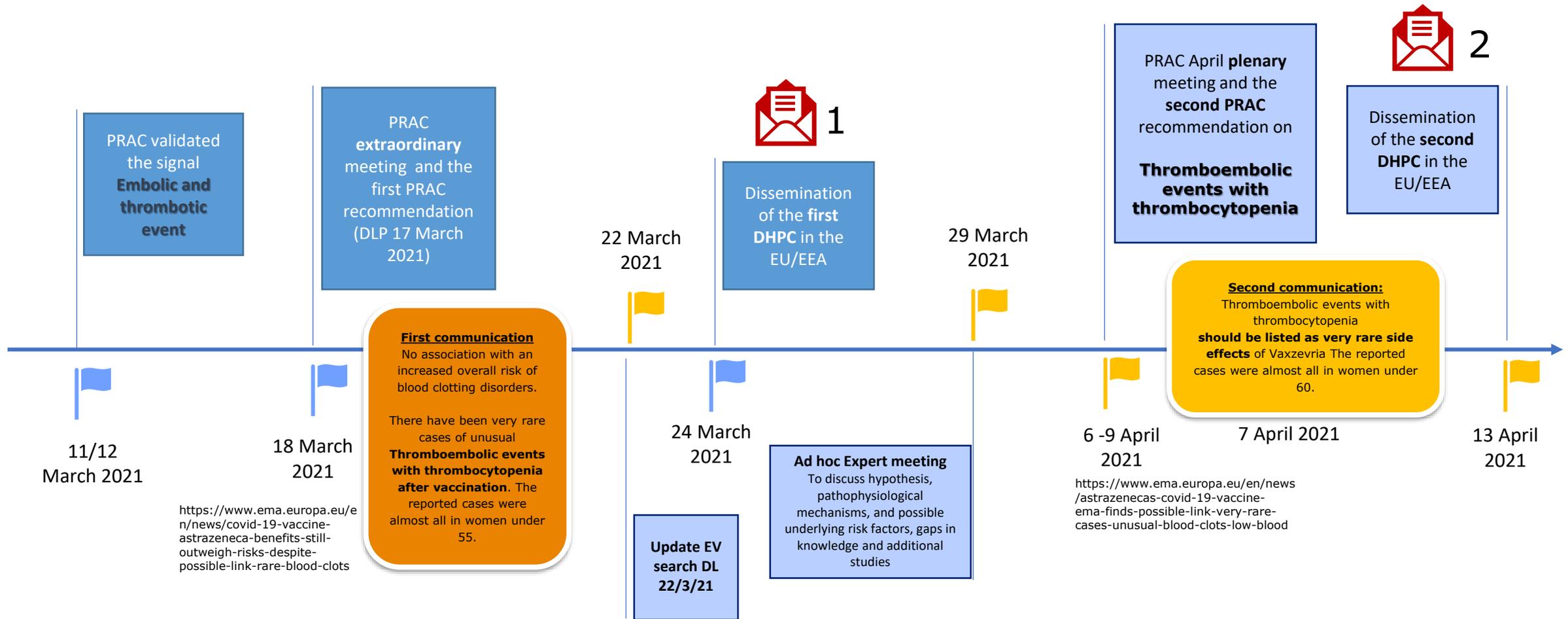


Source: [EudraVigilance](#)

Vaccines monitoring post-approval: EU PhV Plan for COVID-19

- Safety monitoring is based on legal provisions and guidance set out by the **Good PhV Practices**, includes role of vaccines manufacturers, EMA, National Authorities, Patients & Health Care Professionals.
- **Spontaneous reporting of suspected reactions to Eudravigilance**: guidance and legal requirements for reporting (quality and completeness key for causality assessment). Timely submission of reports recommended, <15days for specific events or fatal/ life threatening reactions.
- **Risk Management Plan** to conduct post-authorisation safety monitoring and studies of COVID-19 vaccines by manufacturers
- **Periodic Safety updated reports (PSURs)** submitted at 6 month intervals for the first year. **Monthly summary safety reports** include information on reported suspected reactions and sales data.
- Timely aggregated **exposure data** are essential for many PhV analyses (e.g. O/E). Member States to gather these data e.g. by national health data registers and EMA to collect and compile these data.
- **Studies on safety of vaccines** are conducted by EMA with academic organisations e.g. to define background rates of suspected AEs, or safety monitoring studies to investigate specific hypothesis like on TTS, or how history of coagulopathy and treatments might be associated with TE events after vaccination

EU regulatory network/PRAC: robust and agile system in place able to rapidly detect and minimise serious risks



Vaxzevria: table of adverse drug reactions from section 4.8 of the EU Summary of Product Characteristics (SmPC) and in the package leaflet (for the patient)

MedDRA SOC	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Common	Thrombocytopenia ^a
	Uncommon	Lymphadenopathy
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Metabolism and nutrition disorders	Uncommon	Decreased appetite
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness Somnolence
Vascular disorders	Very rare	Thrombosis with thrombocytopenia syndrome*
Gastrointestinal disorders	Very common	Nausea
	Common	Vomiting Diarrhoea
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosis Pruritus Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site tenderness Injection site pain Injection site warmth Injection site pruritus Injection site bruising ^b Fatigue Malaise Feverishness Chills
	Common	Injection site swelling Injection site erythema Fever ^c

^a In clinical trials, transient mild thrombocytopenia was commonly reported (see section 4.4).

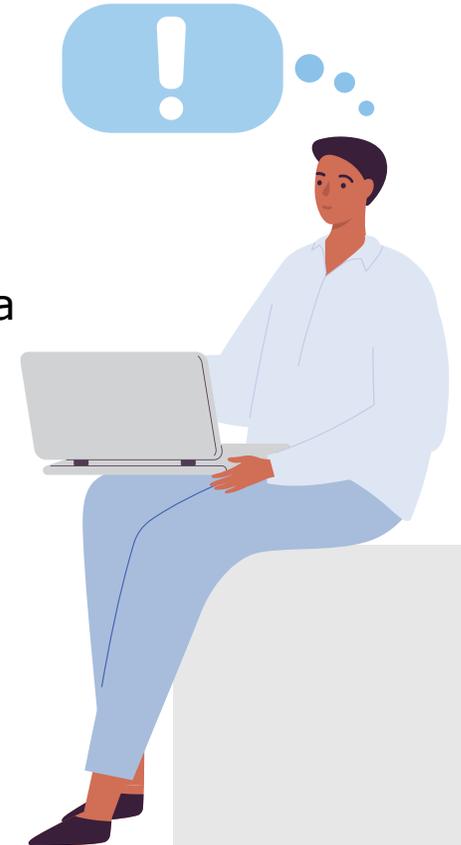
^b Injection site bruising includes injection site haematoma (uncommon)

^c Measured fever $\geq 38^{\circ}\text{C}$

*Severe and very rare cases of thrombosis with thrombocytopenia syndrome have been reported post-marketing. These included venous thrombosis such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis (see section 4.4).

Conclusions

- All approved vaccines in the EU have been shown to offer **good level of protection against COVID-19 disease and acceptable risk profile: B/R positive**
- **Most side effects are mild to moderate** in severity and are gone within a few days
- Vaccines granted conditional marketing authorisation- companies must provide more evidence to EMA under **specific obligations**, including data on long term safety and additional studies in populations not studied pre-authorisation
- **Safety monitoring** does not stop with authorisation but continues for as long as a medicine is on the market
- **Robust pharmacovigilance systems** in place to rapidly detect any safety issues and minimise serious risks to patients
- Timely exchange of information, transparency and communication are critical
- **Vaccination remains critical** to control the pandemic



Authorization of COVID-19 vaccines in the US: A Regulator's Perspective

Peter Marks, MD, PhD

WFH Webinar

June 2, 2021

Vaccine Development – Accelerating the Process

- Clear guidance on expectations from products
- Facilitate early conversations with regulators
- Integrating different phases into one clinical trial
- Manufacture large quantities of product at risk
- Use optimal path to facilitate product availability

Biologics License Application (BLA)

- Biologics are licensed under both section 351 of the Public Health Service Act and the Federal Food Drug and Cosmetic Act
- Product must be safe, pure, potent, effective
- The standard used is that there is substantial evidence of efficacy from adequate and well-controlled clinical trials

Emergency Use Authorization (EUA)

- Put in place after 9/11 to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative
- The standard used is that the product “may be effective” and its “known and potential benefits outweigh the known and potential risks”

EUA for a COVID-19 Vaccine

- Must demonstrate clear and compelling efficacy in a large well-designed phase 3 clinical trial
- Careful evaluation of quality, safety, efficacy
- Public advisory committee meeting
- Enhanced post-deployment surveillance

Advanced Candidates – May 2021

- mRNA
 - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
 - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
- Non-Replicating Viral Vector
 - Ad26.COVS.S (Janssen) – EUA granted Feb 27, 2021
 - ChAdOx1 (Astra Zeneca-Oxford)
- Protein Subunit
 - NVX-CoV2373 (Novavax)
 - MRT5500 (Sanofi-Translate Bio)



Vaccine Trial Demographics

Vaccine	Pfizer-BioNTech (2 doses 21 d apart)	Moderna (2 doses 28 d apart)	Janssen (1 dose)
Total patients	43,552	30,350	39,321
Receiving vaccine	21,768	15,180	19,630
Receiving placebo	21,784	15,170	19,691
Black/African Amer.	9.8%	9.7%	17.2%
Hispanic/Latino	26.2%	20.0%	45.1%
At least age 65	21.4%	25.3%	20.4%



Pfizer Pediatric Demographics

Characteristic	Age 12-15 Vaccine (N=1131)	Age 16-25 Vaccine (N=537)	Age 12-15 Placebo (N=1129)	Age 16-25 Placebo (N=561)
Female	49.9%	52.5%	48.2%	52.0%
Mean Age (years)	13.6	19.4	13.6	19.6
Median Age	14.0	18.0	14.0	19.0
Black	4.6%	8.8%	5.0%	8.9%
Hispanic/Latino	11.7%	20.9%	11.5%	18.7%
Comorbidity (yes)	21.9%	23.5%	21.3%	25.7%



Vaccine Efficacy in Phase 3

Primary efficacy was determined against moderate and severe/critical COVID-19

Vaccine	Pfizer-BioNTech	Moderna	Janssen
Primary efficacy (vaccinated/placebo)	95% (8/162)	94.1% (11/185)	d14 66.9% (116/348) d28 66.1% (66/193)
Young population	<u>age 16-54</u> 95.6% (5/114)	<u>age 18-64</u> 95.6% (7/156)	<u>age 18-64</u> d14 63.7% (95/260) d28 66.1% (52/152)
Older population	<u>age 55+</u> 93.7% (3/48)	<u>age 65+</u> 86.4% (5/114)	<u>age 65+</u> d14 76.3% (21/88) d28 66.2% (14/41)
Severe COVID-19	1/9	0*/30	d14 14/60; d28 5/34



Pfizer Pediatric Immune Response

Study Group	12-15 Years N=190 GMT (95% CI)	16-25 Years N=170 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

Noninferiority is declared if the lower bound of the 2-sided 95% CI for the Geometric Mean Titer (GMT) Ratio is greater than 0.67

Pfizer Pediatric Efficacy

Endpoint	Vaccine 12-15 Years N=1005 Cases	Placebo 12-15 Years N=978 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	0	16	100.0 (75.3, 100.0)

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period



Vaccine Safety in Phase 3

Second dose

Reaction (2 nd injection)	Placebo*	Pfizer-BioNTech		Moderna		Janssen	
		<55	55+	<65	65+	<60	60+
Injection site pain	14%	78%	66%	90%	83%	57%	33%
Fatigue	22%	59%	50%	68%	58%	44%	30%
Headache	21%	52%	39%	63%	46%	44%	30%
Muscle pain	10%	38%	29%	61%	47%	39%	24%
Chills	4%	35%	23%	48%	31%	N/A	N/A
Joint pain	8%	21%	19%	45%	35%	N/A	N/A
Fever	0.4%	16%	11%	17%	10%	13%	3%

*Average value across all studies, all doses, all ages

Pfizer Pediatric Safety

Characteristic	Age 12-15 Placebo Dose 2 (N=1078)	Age 12-15 Vaccine Dose 2 (N=1097)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	17.9%	78.9%	77.5%
Fatigue	24.5%	66.2%	65.6%
Headache	24.4%	64.5%	60.9%
Muscle pain	8.3%	32.4%	40.8%
Chills	6.8%	41.5%	40.0%
Joint pain	4.7%	15.8%	21.9%
Fever	0.6%	19.6%	17.2%

Safety Monitoring by CDC and FDA

- Passive monitoring through the Vaccine Adverse Event Reporting System (VAERS) and the v-safe text monitoring system for COVID-19 vaccine safety
- Active monitoring through Vaccine Safety Datalink, the Clinical Immunization Safety Assessment, and large databases such as the CMS Medicare Database and Sentinel/BEST covering ≥ 100 million lives
 - Combination of claims data and EHR data
 - Monitoring about 15 safety outcomes of interest



COVID-19 Vaccine Development

- Vaccine development timelines shortened without compromising vaccine safety and efficacy standards
- Vaccine authorization or approval will follow a process that is as open to the public as possible
- The focus on the evaluation of safety and effectiveness through a transparent process is likely to improve confidence in any approved or authorized vaccine



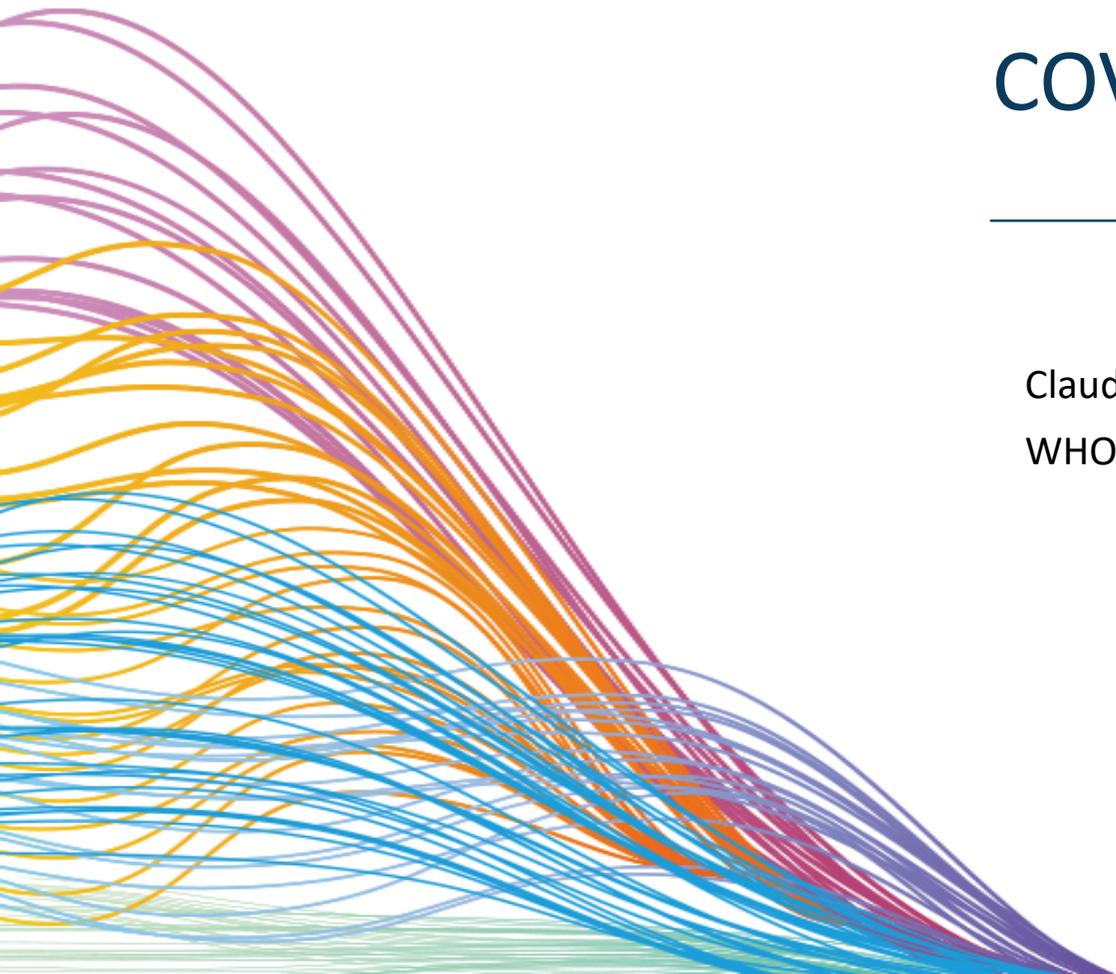
U.S. FOOD & DRUG
ADMINISTRATION

COVID-19 Vaccination & COVAX rollout

State of Vx

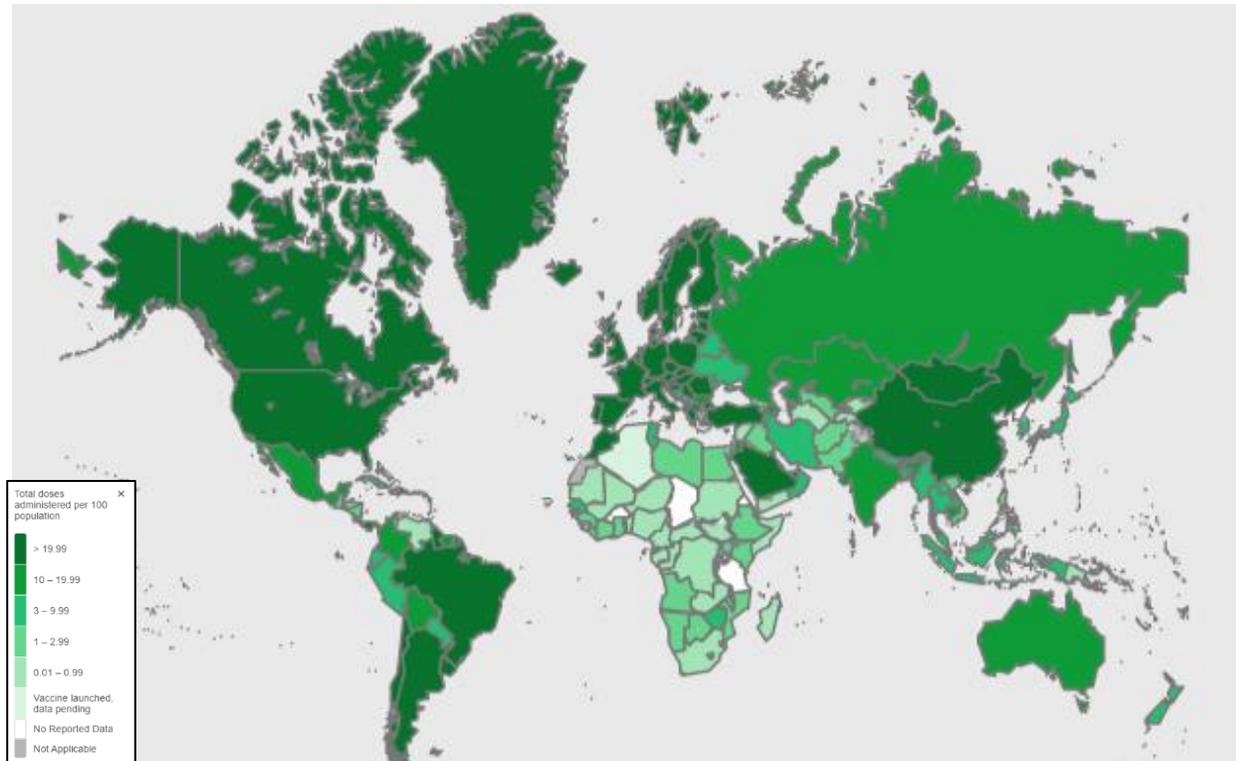
Claudia Nannei

WHO Lead of the COVAX Joint Allocation



1,870M doses of COVID-19 vaccine have been administered¹ in 211 countries, areas, territories & economies²

Total doses administered per 100 population³



1,870M vaccine doses¹
have been administered
COVAX has shipped 77.7M
doses to 127 participants⁴
Campaigns **have not yet**
started in 9 countries,
economies & territories²

Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

1. Source of data: Bloomberg; 2. Total of 220 countries, areas, territories & economies: 218 economies listed by World Bank + WHO Member states Cook Islands + Niue
3. WHO COVID-19 Dashboard at <https://covid19.who.int/>; 4. Including donations of doses through COVAX

COVAX has now shipped 77.7M doses to 127 participants

Incl. 66 LMIC/LICs; 38 participants started their first campaigns thanks to COVAX doses

- COVAX participants that received COVAX doses (incl. ones that started with others)
- Economies vaccinating only with bilateral doses or donations
- Economy not yet started vaccinating



Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

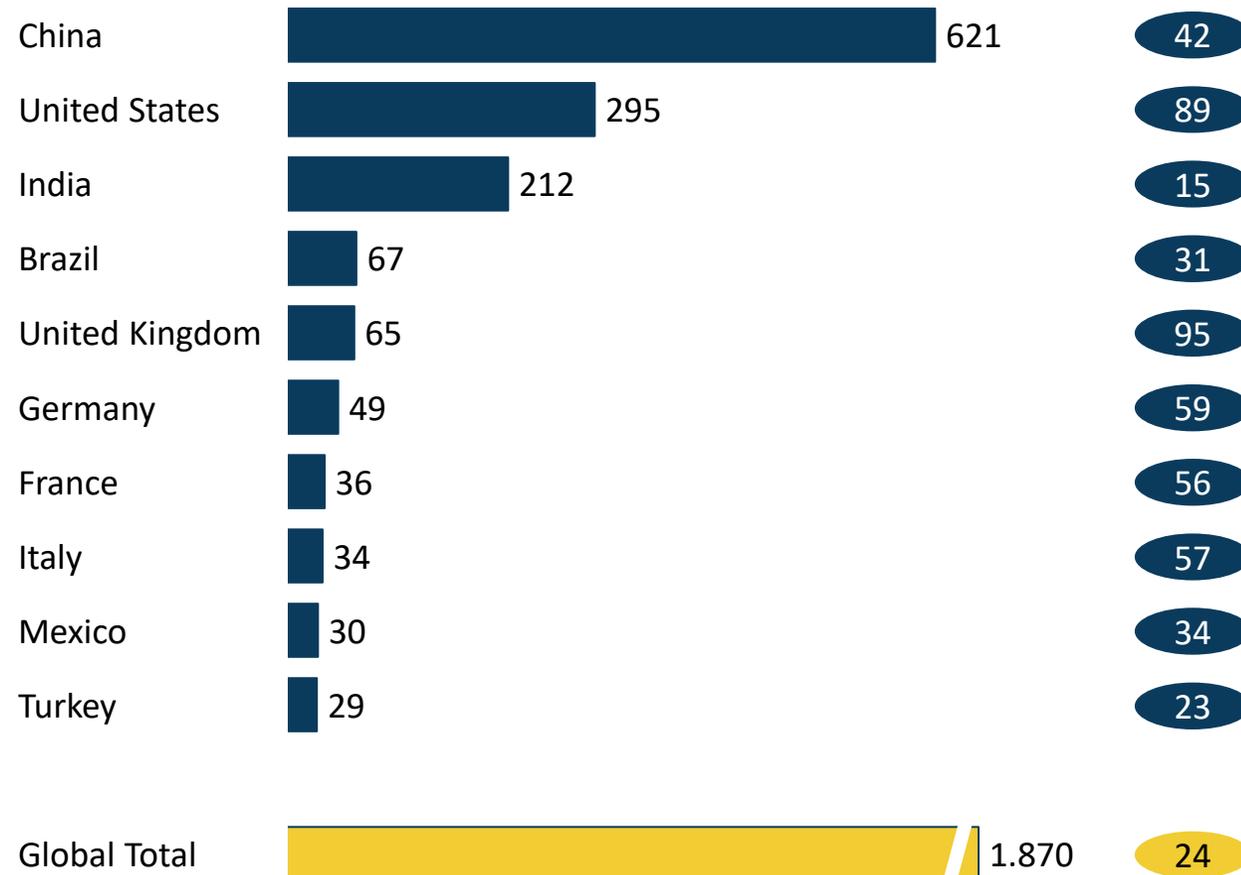
*Kosovo: All references to Kosovo should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Source: COVAX, WHO COVID-19 dashboard, Our World in Data; Government websites; Press research

10 countries administered 77% of all doses – 33% were administered by China alone

 Doses per 100 population

Top 10 countries by administered doses, M doses



Source: Bloomberg

33%

Of all doses were administered by **top 1** country (China)

77%

Of all doses were administered by **top 10** countries

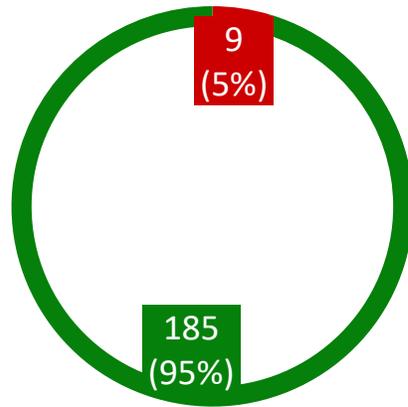
Of WHO's 194 Member States, 185 have now started COVID-19 vaccination

Status of COVID-19 vaccine roll out

■ Started ■ Not started

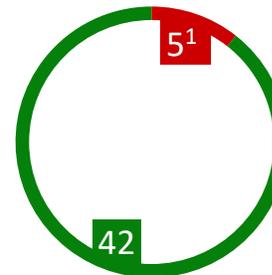
WHO Member States

N= 194



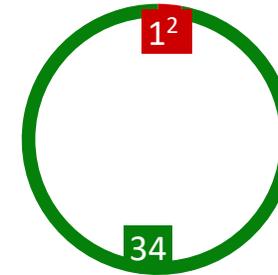
AFRO

N= 47



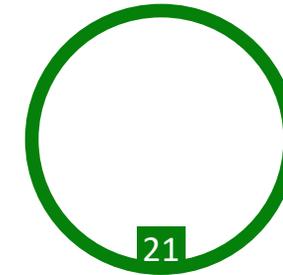
AMRO

N= 35



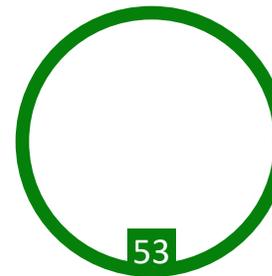
EMRO

N=21



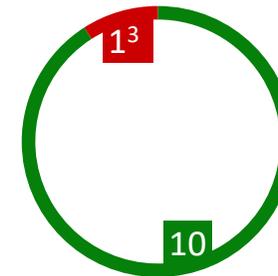
EURO

N= 53



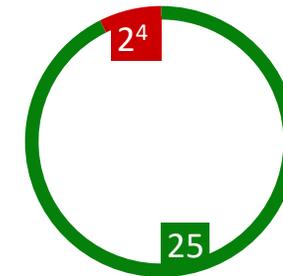
SEARO

N= 11



WPRO

N=27



- 1 Burkina Faso, Burundi, Chad, Eritrea, United Republic of Tanzania
- 2 Haiti
- 3 Democratic People's Republic of Korea
- 4 Vanuatu, Niue

State of Vaccines: rollout has started in 211 countries, areas, territories & economies

Economies classified by income level ¹	# of economies per income group	# economies where vaccination has started	% of income group where vaccination has started	Status of Vx roll out per income group	
				> 90% of economies	50 < X ≤ 70%
High income economies (HICs)	83	83	100%	70% < X ≤ 90%	≤ 50%
Upper-middle income economies (UMICs)	56	56	100%		
Lower-middle income economies (LMICs)	50	48	96%		
Low income economies (LICs)	29	23	79%		
Not classified	2	1	50%		
Total	220	211	96%		

Economies classified by income level ¹	List of economies where vaccination has started
High income economies (HICs)	Andorra, Antigua and Barbuda, Aruba, Austria, Australia, Bahamas; Bahrain, Barbados, Belgium, Bermuda, British Virgin Islands, Brunei, Canada, Cayman Islands, Channel Islands, Chile, Croatia, Curaçao, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, French Polynesia; Germany, Greece, Greenland, Gibraltar, Guam; Hungary, Hong Kong SAR, Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Macao, Malta, Mauritius, Monaco, Nauru, Netherlands, New Caledonia; New Zealand, Northern Mariana Islands; Norway, Oman, Palau; Panama, Puerto Rico; Poland, Portugal, Qatar, Romania, Saudi Arabia, San Marino, Seychelles, Singapore, Slovakia, Slovenia, South Korea, Spain, St. Kitts and Nevis, Sint Maarten (Dutch Part); St. Martin (French Part); Sweden, Switzerland, Taiwan, Trinidad and Tobago, Turks and Caicos, UAE, UK, Uruguay, USA; Virgin Islands (US)
Upper-middle income economies (UMICs)	Albania, American Samoa; Argentina, Armenia, Azerbaijan, Belarus, Belize, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, China, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, Equatorial Guinea, Fiji, Gabon, Georgia, Grenada, Guatemala, Guyana, Indonesia, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Kosovo ² , Lebanon, Libya, Malaysia, Maldives, Marshall Islands, Mexico, Montenegro, Namibia, North Macedonia, Paraguay, Peru, Russia, Serbia, South Africa, St. Lucia, St. Vincent and the Grenadines, Suriname, Thailand, Tonga, Turkey, Turkmenistan, Venezuela; Samoa; Tuvalu; Cuba
Lower-middle income economies (LMICs)	Algeria, Angola, Bangladesh, Benin, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Côte d'Ivoire, Djibouti, El Salvador, Egypt, Eswatini, Ghana, Honduras, India, Kenya, Kyrgyz Republic, Laos, Lesotho, Micronesia, Moldova, Nigeria, Mauritania, Mongolia, Morocco, Myanmar, Nepal, Nicaragua, Pakistan, Papua New Guinea, Philippines, Sao Tomé and Principe, Senegal, Solomon Islands, Sri Lanka, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vietnam, West Bank and Gaza, Zambia, Zimbabwe, Kiribati
Low income economies (LICs)	Afghanistan, Ethiopia, The Gambia, Guinea, Guinea-Bissau, Liberia, Malawi, Mali, Mozambique, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Sudan, Syrian Arab Republic, Tajikistan, Togo, Uganda; Yemen, Rep.; Congo, Dem. Rep.; Madagascar; Central African Republic
Not classified	Cook Island

1. World Bank classification (2021). Note: The term country, used interchangeably with economy, does not imply political independence but refers to any territory for which authorities report separate social or economic statistics. The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries
2. All references to Kosovo should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

COVID-19 vaccine roll-out has not yet started in 9 economies; 8 of them are LICs or LMICs

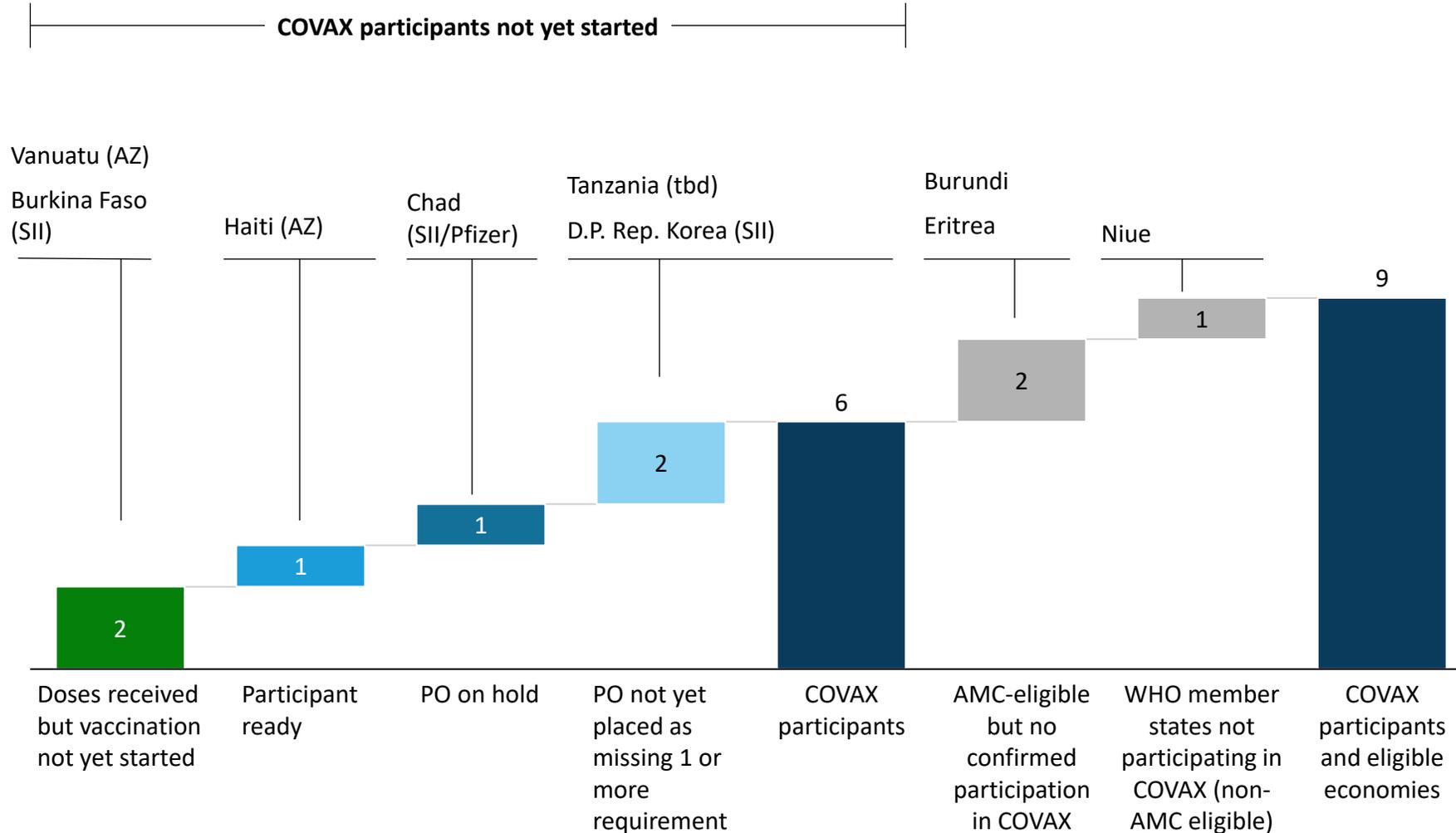
Economies classified by income level ¹	# of economies per income group	# economies where vaccination has <u>not</u> started	% of income group where vaccination has <u>not</u> started	List of economies where vaccination has <u>not</u> started
High income economies (HICs)	83	0	0%	-
Upper-middle income economies (UMICs)	56	0	0%	
Lower-middle income economies (LMICs)	50	2	4%	Tanzania; Vanuatu
Low income economies (LICs)	29	6	21%	Burkina Faso; Burundi; Chad; Eritrea; Haiti; Korea, Dem. People's Rep.
Not classified	2	1	50%	Niue
Total	220	9	4%	

Vaccination has not started in...

- ... more than 40% of economies
- ... between 25 and 40% of economies
- ... between 10 and 24% of economies
- ... less than 10% of economies

1. World Bank classification (2021). Note: The term country, used interchangeably with economy, does not imply political independence but refers to any territory for which authorities report separate social or economic statistics. The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries

Of the 9 countries yet to start, 6 are COVAX participants which require further attention to initiate vaccination

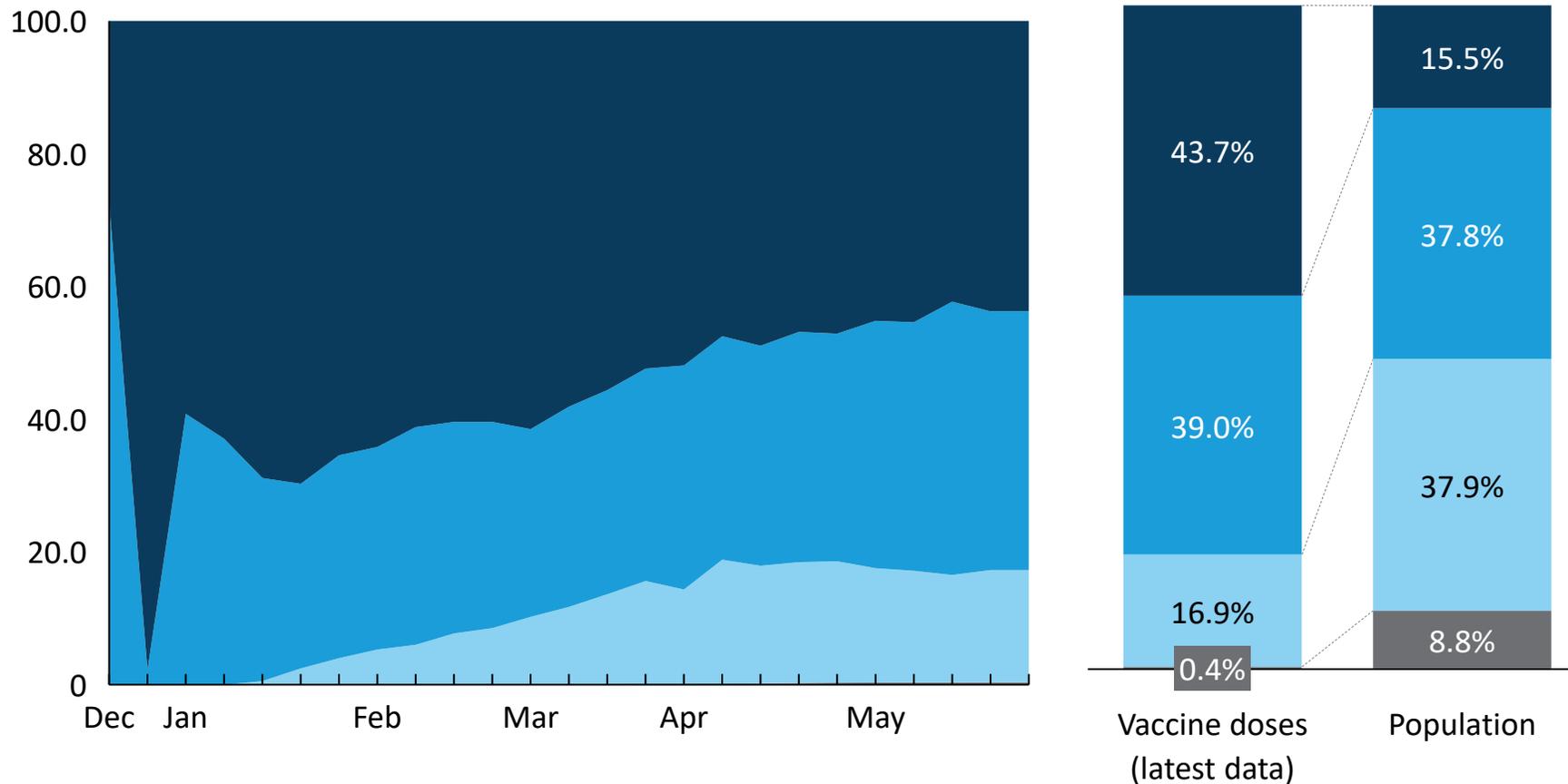


1. Cuba is developing its own two vaccine candidates with Phase III trials with >100,000 participants currently underway

17.3% of doses have been administered in LICs/LMICs while they represent 46.7% of the world's population

■ HIC ■ UMIC ■ LMIC ■ LIC

Cumulative COVID-19 doses administered by country income group, % of global total

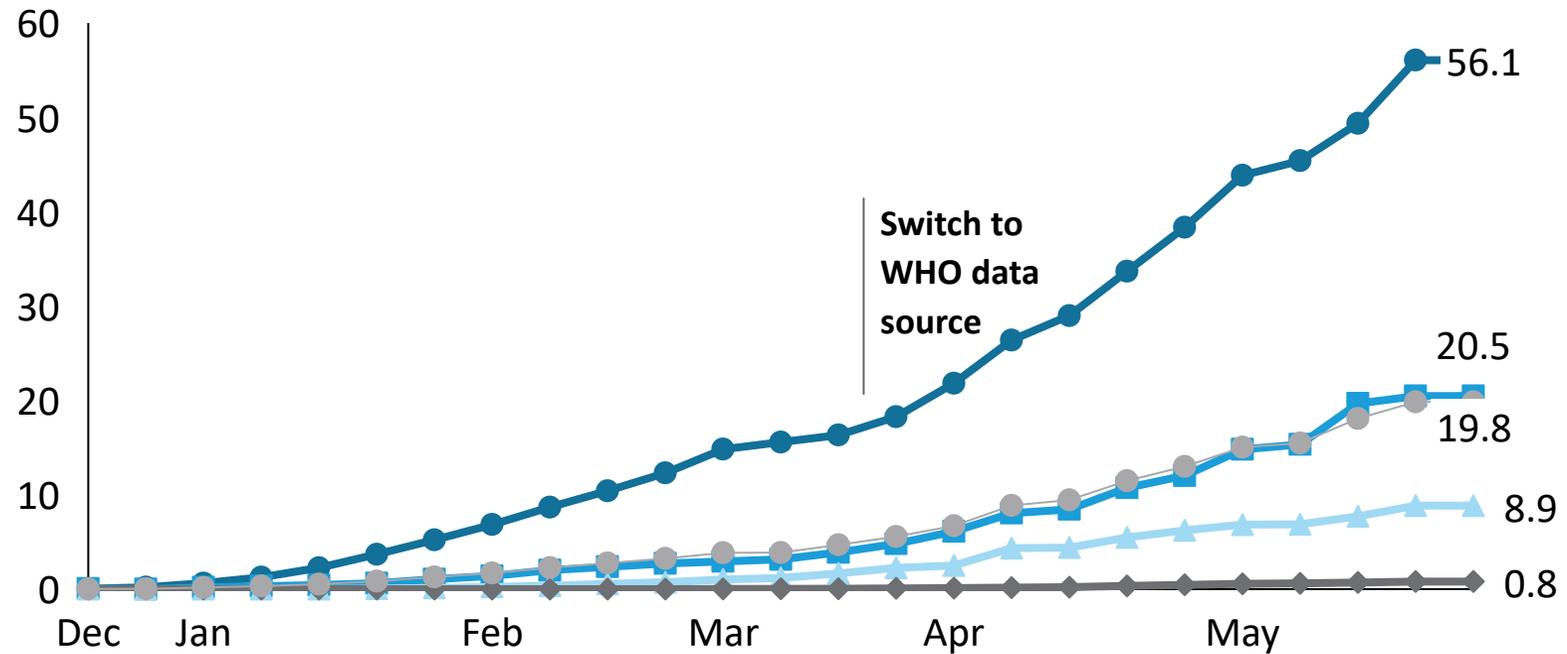


SOURCE: Our World in Data (Dec-Feb); WHO Dashboard (Mar onwards); source for income groups: World Bank.

Inequity is decreasing, but HICs have administered 69x more doses per inhabitant than LICs

● HIC ■ UMIC ▲ LMIC ◆ LIC ● Worldwide

Cumulative COVID-19 doses administered per 100 population



Ratio of HIC to LIC
0 doses in LICs

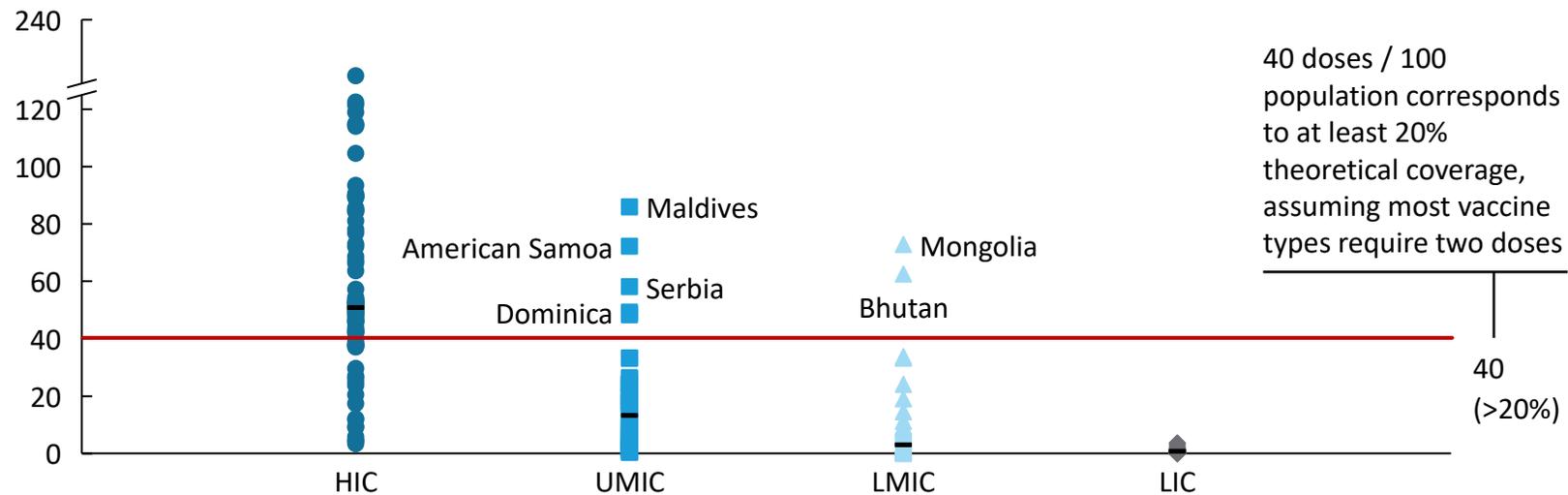
10,000x 200x 84x 69x

SOURCE: Our World in Data (Dec-Mar 7); WHO Dashboard (Mar 12 onwards); source for income groups: World Bank. Using the latest available values for each week.

Mongolia and Bhutan are the only LMIC/LIC that have achieved theoretical coverage of >20%¹

● HIC ■ UMIC ▲ LMIC ◆ LIC - Median

Cumulative COVID-19 doses administered per 100 population



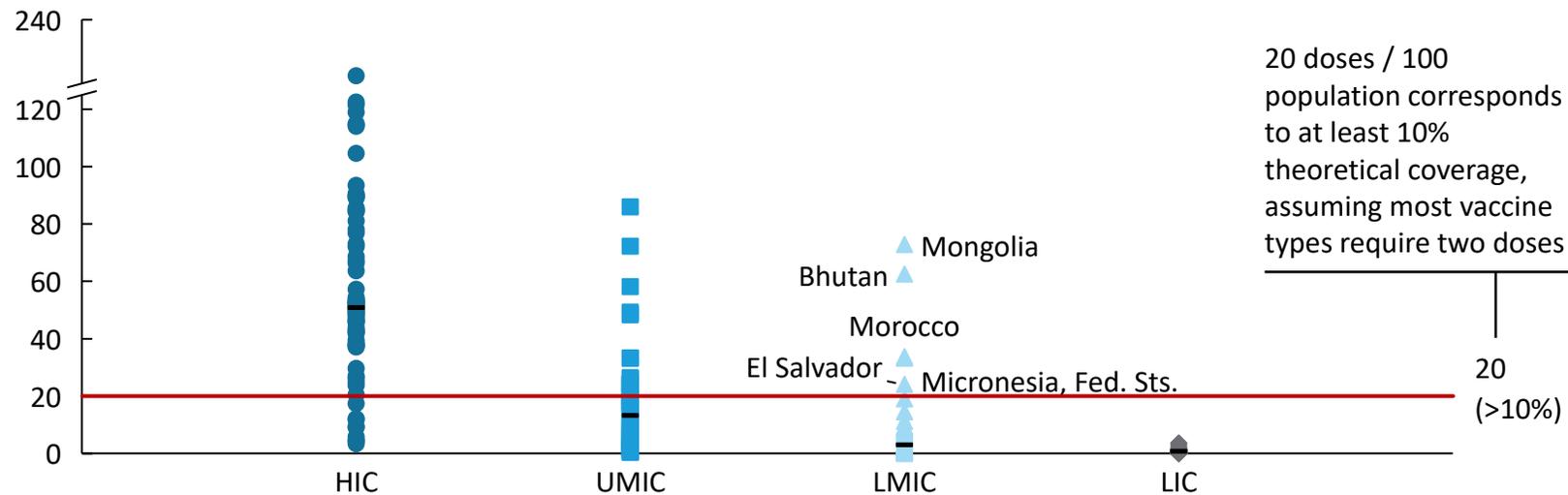
Income group	HIC	UMIC	LMIC	LIC
Population, millions	1,206	2,945	2,954	686
Population in economies above 40 d/100, millions and %	920 76.3%	8 0.3%	4 0.1%	0 0.0%
Economies above 40 d/100, # and % of total	56 67.5%	5 8.9%	2 4.0%	0 0.0%

1. As defined by 40 doses administered per 100 population (at least 20% theoretical coverage, assuming most vaccine types require two doses)

Only 5 LMIC and/or LIC countries achieved theoretical coverage of >10%¹

● HIC ■ UMIC ▲ LMIC ◆ LIC - Median

Cumulative COVID-19 doses administered per 100 population

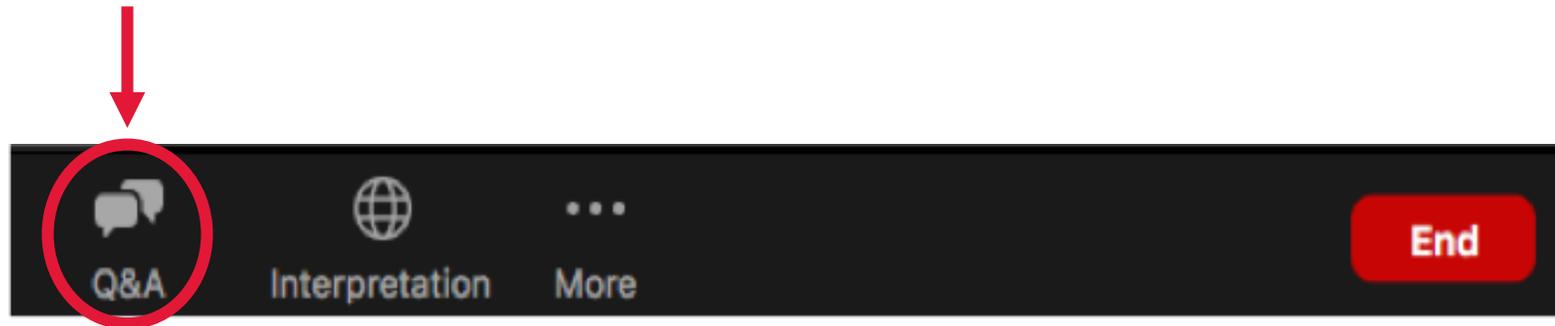


Income group	HIC	UMIC	LMIC	LIC
Population, millions	1,206	2,945	2,954	686
Population in economies above 20 d/100, millions and %	989 82.0%	1,842 62.5%	48 1.6%	0 0.0%
Economies above 20 d/100, # and % of total	68 81.9%	17 30.4%	5 10.0%	0 0.0%

1. As defined by 20 doses administered per 100 population (at least 10% theoretical coverage, assuming most vaccine types require two doses)

QUESTION & ANSWER

Please submit your questions in the Q&A box





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THANK YOU!

¡GRACIAS!

MERCI!

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