

Update on first COVID-19 vaccine efficacy results and country readiness

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Member States COVID-19 Briefing

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COVID-19 Vx landscape – 47 candidates in human clinical trials

● COVAX MoU or Sol signed¹
● CEPI agreement signed²
 First efficacy results available (Zoom next page)

Technology platform	Phase I					Phase I/II	Phase II	Phase IIb/III and III
 Viral vectors	Shenzhen GIMI aAPC	Merck / Themis TMV-083	Vaxart VXA-CoV2-1	ImmunityBio-hAd5-S-Fusion	Merck / IAVI rVSV	Shenzhen GIMI LV-SMENP-DC		CanSino Ad5-nCoV AstraZeneca ChAdOx1-S Gamaleya Gam-COVID-Vac Janssen Ad26.COV2-S
 mRNA	Walvax Biotech ARCoV					Imperial LNP-nCoVsaRNA Arcturus ARCT-021	CureVac CVnCoV	Pfizer / BioNTech BNT162 Moderna mRNA-1273
 DNA	Symvivo bacTRL-Spike					Genexine GX-19 Inovio INO-4800 Osaka / AnGes AG0301 / AG0302 Zydus Cadila ZyCoV-D		
 Protein-based	Medicago VLP	Sichuan RBD	Vaxine / Medytox COVAX-19	Medigen MVC-COV1901	Finlay FINLAY-FR-2	FBRI SRC EpiVacCorona SpyBiotech RBD-HBsAg VLP Sanofi / GSK recombinant	Anhui Zhifei RBD-Dimer	Novavax NVX-CoV2373
 Inactivated	CSL / U.Q	Covaxx UB-612	Clover SCB-2019	Adimmune AdimrSC-2f		Bharat Biotech COVAXIN Inst. of Medical Biology / CAMS RIBSP QAZCOVID-IN	Shenzhen Kangtai	Sinopharm / WIBP Sinovac / Butantan CoronaVac Sinopharm / BIBP BBIBP-CorV

Source: CEPI Vx landscape

- For Advance Purchase Commitment (APC)
- For tech transfer, scale-out and reservation fees

First efficacy results of 4 vaccine candidates are now available *(from press releases)*

Pfizer/BioNTech 
Full study results (Nov. 18)

Moderna 
Interim study results (Nov. 16)

AstraZeneca 
Interim study results (Nov. 23)

Gamaleya 
2nd Interim study results (Nov. 24)

Technology platform	mRNA	mRNA	Viral vector	Viral vector
# of trial participants	43,000	30,000	24,000	18,794
Efficacy	95% (Efficacy in elderly of >94%)	94.5% (Efficacy in elderly not reported)	70.4% combining data from 2 dosing regimens: <ul style="list-style-type: none"> • 90% for halved first dose and standard second dose • 62% efficacy for 2 full doses 	91.4% (28 days after the 1st dose & 7 days after the 2 nd dose)
# of confirmed cases	170 (162 in placebo group vs. 8 in vaccine group)	95 (90 in placebo group vs. 5 in vaccine group)	131	39 (31 in placebo group vs. 8 in vaccine group) ¹
Placebo:vaccine (randomization)	1:1	1:1	1:1	1:3
# of severe cases	10 (9 in placebo group vs. 1 in vaccine group)	11 (11 in placebo group vs. 0 in vaccine group)	No hospitalised or severe cases in anyone who received the vaccine	<i>Not available</i>
Median follow-up	> 2 months	> 2 months	<i>Not available</i>	<i>Not available</i>
Safety concerns	No serious safety concerns observed	No safety concerns	<i>Not available</i>	No unexpected adverse events

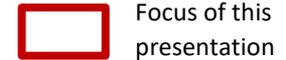
1. Ratio of the placebo group to the vaccinated group is 1 to 3

Zoom-in on products and regulatory pathway

				
Cold chain	-80°C (UCC) 2-8 °C for up to 5 days	-20°C 2-8 °C for up to 30 days	+2 to +8°C for at least 6 months	+2 to +8°C
Full analysis of efficacy target	164 cases; complete	151 cases; pending	TBD cases; pending	TBD cases; pending (78 cases for 3 rd interim analysis)
Manufacturing	Ongoing	Ongoing	Ongoing	Ongoing
Production target in 2021, # of doses ¹	1.3Bn	500M to 1Bn	3Bn	1Bn
Regulatory Reviews	<ul style="list-style-type: none"> Rolling reviews with SRAs WHO regulatory engaged 	<ul style="list-style-type: none"> Rolling reviews with SRAs WHO regulatory engaged 	<ul style="list-style-type: none"> Rolling reviews with SRAs WHO regulatory engaged 	<ul style="list-style-type: none"> WHO regulatory engaged

1. Source: [CNBC](#)

Country readiness and delivery



Critical actions

Priority decision making on:

- **Policies** for use (in-country prioritization)
- **Regulatory** approvals (e.g. WHO reliance mechanism)
- **Financing** (ensuring fiscal space, consideration of WB and other loans)
- **Indemnification & liability**

Technical & operational issues

- **Country readiness assessments (cold chain, health facility, HCW etc.)**
- **National Deployment and Vaccination Plan**
- Key bottleneck **analysis**

Global support to Policy Making for COVID-19 vaccine

SAGE Immunization

1. [The values framework for the allocation and prioritization of COVID-19 vaccination](#)
2. [The roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply](#)
(including annex on health workers)

NB: living documents as new evidence emerges.

Next major outputs:

Vaccine specific recommendations

Other documents:

[Critical Evidence Questions For COVID-19 Vaccines Policy Making](#)
[Prioritized Infectious Disease and Economic Modelling Questions](#)

See full list of documents and available translations:

www.who.int/immunization/sage/covid-19_documents/en/

Information and tools for NITAGs

- ✓ 1. Guidance document for NITAGs and national policy decision-makers on COVID-19 vaccine introduction
- ✓ 2. Infographic of the SAGE roadmap & training module
- ✓ 3. GNN monthly updates
- ✓ 4. NITAG Resource Center has inventory of existing NITAG interim recommendations
5. Sysvac database (RKI & WHO HQ) -> **December 2020**

WHO Regulatory and Safety Monitoring Coordination and Leadership

PQ/EUL

Criteria for evaluation of candidate vaccines published

Call for Expressions of Interest for candidate vaccines in Phase IIb/III, with expected regulatory approvals within 6 months

Rolling reviews of data from vaccine candidates meeting criteria

Roadmaps

Assessment pathways; WHO led global assessment involving “regional champions”; followed by facilitation for global national approval and active engagement with countries

Labelling

Working Position established; to facilitate harmonization and timely global access to candidate vaccines

Safety Monitoring

Global monitoring mechanisms coordinated by WHO; Regional and country support; guidance on requirements and methods

Critical resources to ensure country readiness

Vaccine Introduction Readiness Assessment Tool (VIRAT 2.0)

The VIRAT is the combination of 2 vaccine readiness assessments which had been developed concurrently in September 2020 by WHO/UNICEF (the VIRAT) and by the WB (the VRAF)

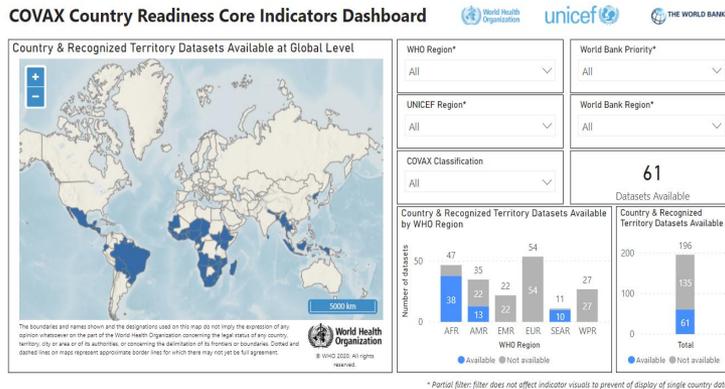
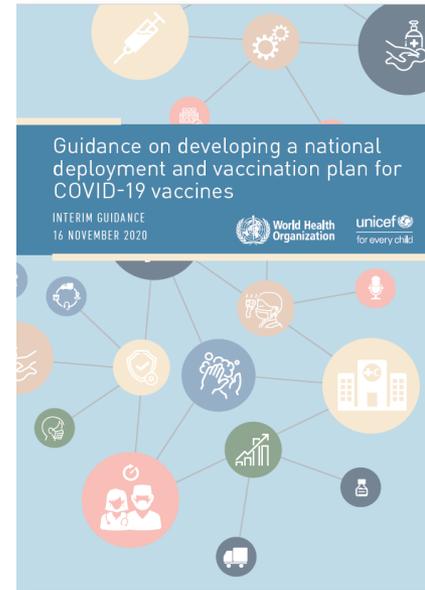


Illustration – COVAX Country Readiness & Delivery Core Indicators Dashboard

Guidance to develop a National Deployment and Vaccination Plan (NDVP)



- Published on Nov. 16th on the WHO website [here](#)
- Built upon existing documents incl. recommendations from the WHO Strategic Advisory Group of Experts (SAGE)
- Will be updated as new information becomes available

Data sharing is critical

Guidance for NDVP COVID-19 Vaccines (chapters)

-  1. Introduction
-  2. Regulatory Preparedness
-  3. Planning and Coordination
-  4. Costing and funding:
ensuring funds reach the point of delivery
-  5. Identification of Target Populations
-  6. Vaccination Delivery Strategies
-  7. Preparation of Supply Chain and Management of Health Care Waste
-  8. Human Resources Management and Training
-  9. Vaccine Acceptance and Uptake (Demand)
-  10. Vaccine Safety Monitoring Management of AEFI and Injection Safety
-  11. Immunization Monitoring Systems
-  12. COVID-19 Surveillance
-  13. Evaluation of COVID-19 vaccine introduction

Deploying vaccines requiring UCC

Higher delivery costs

Non-standard cold chain requirements will require investments in capital equipment and special equipment for handling deep-frozen shipments



Delivery of -80°C vaccines
\$0.8- \$2.38 per dose ¹
above the costs to deliver a 2-8°C product

Additional considerations of Pfizer vaccine

Non-standard vaccine volume --- syringes (0.3 mL)

Diluent

HCW training

Wastage

1. Based on COVAX analysis (ongoing)

Next steps for countries, WHO and partners

- Country readiness work is essential
- Country action on critical bottlenecks and data
- Support preparation for delivery of all vaccines with specific attention to UCC where needed
- Gavi Applications for AMC92 countries
- World Bank Applications for relevant countries

Back-up slides

Country readiness and delivery: upcoming resources

Guidance and Tools

- Operational guidance on National Vaccine Deployment Plans
- Field guide to misinformation management
- Country level monitoring guidance
- Detailed supply & logistics guide
- WHO's Maintaining essential health services: operational guidance for the COVID-19 context (June 1 update),
<https://www.who.int/publications-detail/10665-332240>
- ... and more!



The screenshot shows the AGORA platform interface. At the top left is the AGORA logo. A search bar is located at the top right. The main content area features a course card for 'Immunization Coverage Data'. The card includes a blue icon of a computer monitor with a plus sign, the course title, a brief description, and technical details such as Topic, Format, Provider, Language, and Compatibility.

AGORA

Search all activity

Immunization Coverage Data

This course will enhance staff understanding of immunization data systems and how to use data to make decisions that lead to higher immunization performance.

Advanced E-Course
UNICEF activity

Topic: Strategies, Research
Format: Online courses, Advanced e-course
Provider: UNICEF, UN & UN agencies, WHO
Language: English
Compatibility: Tablet, Agora Offline

Trainings

- Training packages for health workers and national stakeholders
- Designed with end-users in mind (modular virtual and in-person training)
- Leverage existing e-learning platforms: Agora.unicef.org and openwho.org



The screenshot shows the openwho.org website. The browser address bar displays 'openwho.org/channel/covid-19'. The website header includes the World Health Organization logo and navigation links for Home, About, Channels, Courses, and News. The main banner features the title 'Responding to COVID-19' and the subtitle 'Real-time training for the coronavirus disease outbreak', accompanied by an image of healthcare workers. Below the banner is a section titled 'About the COVID-19 Course Series' with a brief description and a 'Read less' link. At the bottom, there is a filter section for 'Filter courses by' with dropdown menus for 'Language' and 'Keyword', and a search bar.

openwho.org/channel/covid-19

World Health Organization

Responding to COVID-19

Real-time training for the coronavirus disease outbreak

About the COVID-19 Course Series

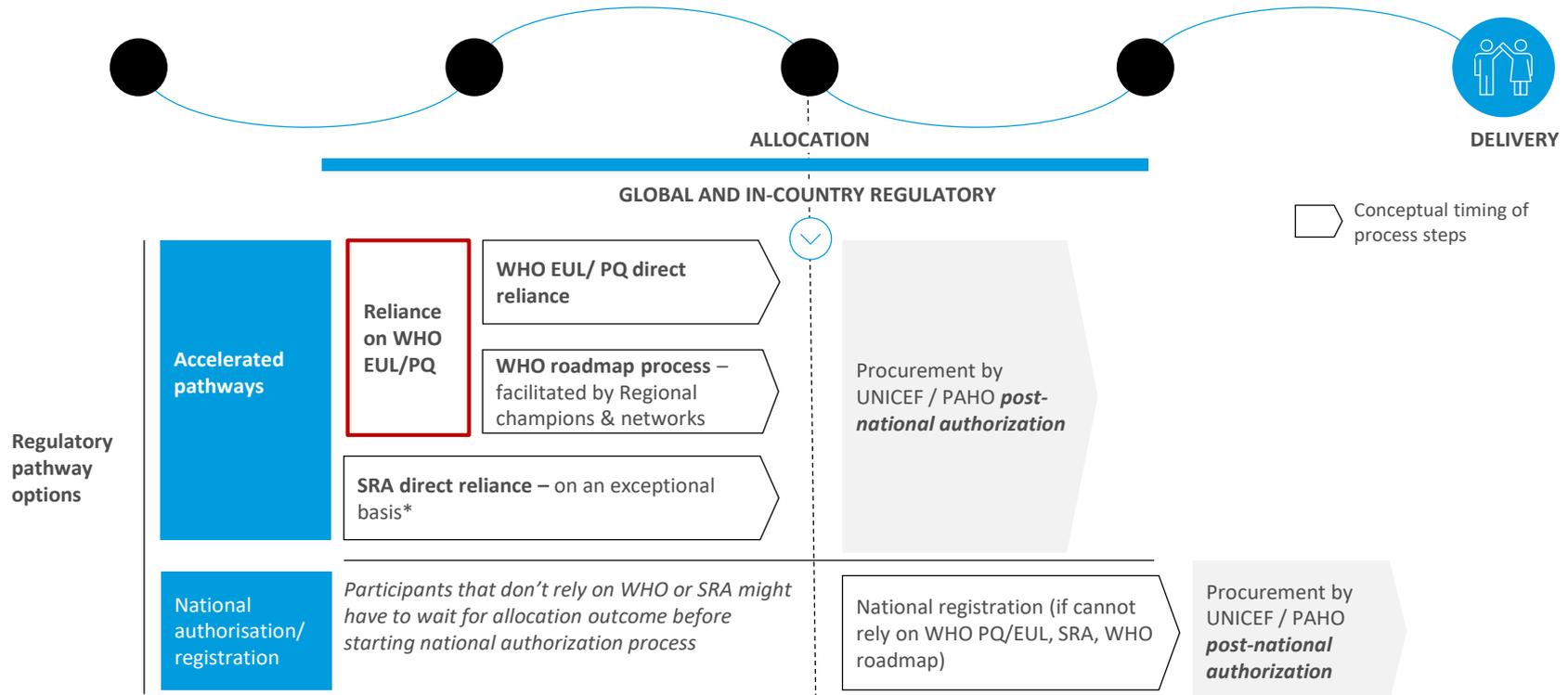
Real-time training during global emergencies is critical for effective preparedness and response. The COVID-19 channel provides learning resources for health professionals, decision-makers and the public for the outbreak of coronavirus disease (COVID-19).

As the outbreak continues to evolve, new resources will be added and existing courses will be updated to best reflect the changing context. Please visit the COVID-19 national languages channel to access the courses in additional languages.

Read less

Filter courses by Language Keyword

Accelerated regulatory pathways will minimise the time for vaccine access (COVAX Facility)



* SRA reliance to be considered on an exceptional basis, as it would not necessarily include an assessment of the programmatic suitability of vaccine candidates and data sharing could not be facilitated by WHO in that case

WHO's ongoing COVAX regulatory work

- **Alignment ongoing** (Regulatory Advisory Group, ICMRA*, regional regulators)
- **Biweekly regulatory updates, 15 regional update webinars**
- **Documents published**
 - EUL procedure (Jan), Q&A (Jul)
 - Draft consideration criteria (Sep), expected final publication 20 November
 - Expression of Interest (Eoi) (EUL/PQ) (Oct)
- **>10 dedicated company meetings** hosted prior to Eoi publication
- **Roadmap template** (Published)
- **Who working position on QR, barcodes and labelling published**
- **Safety preparedness manual**
 - PV Preparedness checklist, AESI definitions, active surveillance methods, guidance on RMPS, PSURs, data sharing platforms, reliance, work-sharing and risk communications

*ICMRA International Coalition of Medicines Regulatory Authorities

Next steps on WHO regulatory alignment activities for COVID-19 vaccines

- Continue **implementation discussions with regional networks & reference NRAs**
 - Two round tables of discussion with Regional offices for establishment of a mechanism for expedited approval in countries and monitoring performance of vaccines deployed to countries August 2020.
 - Nominations of regulatory authorities received from several regions.
 - Official communication with regulatory authorities.
 - Briefing on WHO led mechanisms to regulatory authorities and networks planned.
- Continue support for planning of **post-marketing / safety monitoring** in countries
- Continue engagement & alignment with **regulatory bodies** (e.g. ICMRA, regional regulatory networks, Reference NRAs)

Resources: Guidelines & Tools tailored to COVID-19 vaccination

Supporting countries with integrated package of guidance and tools to promote acceptance and uptake of COVID-19 vaccination Demand Planning package

- STARTS with listening to and understanding totality of health concerns of target populations, to generate social and behavioral data on the drivers of uptake and to design targeted strategies
 - **Social Behavioral Drivers Assessment (survey, interview guidelines)**
- BUILDS trust and acceptance of the vaccines through engagement of communities and civil society organizations, particularly for vulnerable target populations
 - **Risk Communication and Community Engagement Guidance**
- EQUIPS health workers with the requisite knowledge of COVID-19 vaccines as first adopters and as vaccinators, and skills for effective communication with target populations and communities
 - **Guidance tailored for health workers, FAQ**
- PREPARES countries to respond to any reports of AEFIs and have planning in place to mitigate any resulting crises of confidence.
 - **GACVS vaccine safety communication plan**
- BUILDS a supportive information environment. Guards against misinformation through integrated misinformation management linking social listening and analysis with online and offline risk communication and community engagement (RCCE) and advocacy.
 - **Field Guide to Misinformation Management**

World Bank Group financing to support COVID vaccine delivery: \$12bUS

- Options for **1) vaccine procurement** based on their specific contexts and needs:
 - **Participation in COVAX Facility**
 - **Direct purchases** by countries from vaccine manufacturers
 - **Purchase of excess** stocks from other countries
- Can also be used for :
 - **2) Health system strengthening**
 - **3) Technical assistance**
- **Loans or grant depending on country**
- **Reach: 141 countries**
- **100 countries in 100 days**
- **“One country plan” for vaccine delivery**

Ongoing collaboration between the World Bank and CRD:

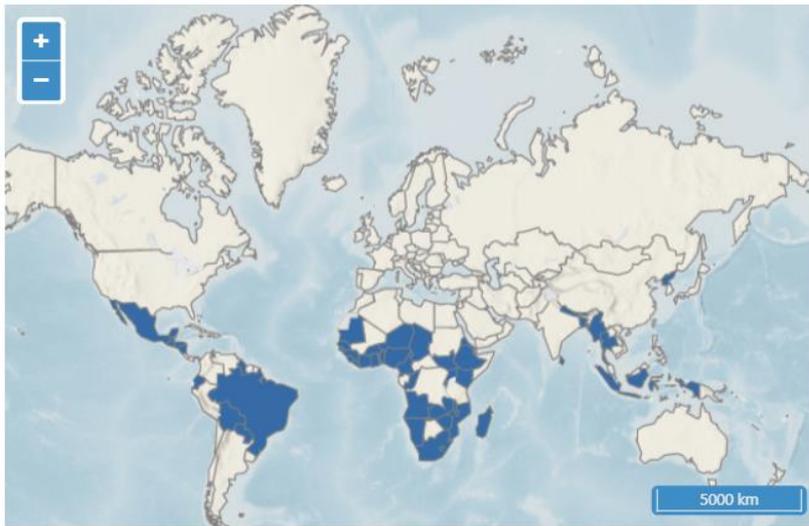
- High-level commitment to join forces
- WB sits on CRD Coordination WG and contributes to its life
- WB has committed 12b USD (going directly to countries governments) to support country procurement and health systems strengthening/preparedness
- Joint assessment of readiness and needs
- Joint application process for TA and grants
- Sharing of all data

COVAX Country Readiness and Delivery Core Indicators Dashboard (25 Nov 20)

COVAX Country Readiness Core Indicators Dashboard



Country & Recognized Territory Datasets Available at Global Level

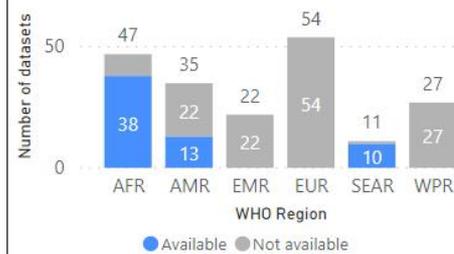


The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

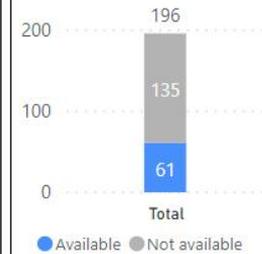


WHO Region* All	World Bank Priority* All
UNICEF Region* All	World Bank Region* All
COVAX Classification All	61 Datasets Available

Country & Recognized Territory Datasets Available by WHO Region



Country & Recognized Territory Datasets Available



* Partial filter: filter does not affect indicator visuals to prevent of display of single country data.