



## Key Messages

WHO has placed into the public domain the status of COVID-19 vaccines for which an expression of interest has been received by WHO/PQ. The information shared includes the National Regulatory Authority of record for each vaccine; whether the expression of interest has been accepted; if a pre-submission meeting has been held; if the dossier has been accepted for review; the status of the assessment; and the anticipated decision date.

## Highlights and main issues

- WHO will host global consultations to discuss:
  - an R&D agenda in response to variants of SARS-COV-2 (12 Jan 2021)
  - a 2021 research agenda for COVID-19 vaccines (15 Jan 2021)
- WHO PQ have assessed (based on available sequence information) the potential impact of the SARS-CoV-2 VOC 202012/01 (B.1.1.7) variant associated S gene mutations and deletions on the performance of the 23 molecular tests that WHO have listed for emergency use. The risk of a false negative result is assessed as low.
- Products procured and/or supplied under the COVAX Facility must be quality assured to ensure positive impact on the population that receive them and to preserve the trust that has been placed in the Facility. To achieve this, WHO has advised that the COVAX Facility should only consider products listed by WHO Emergency Use Listing (EUL) or Prequalification (PQ) or, under exceptional circumstances, products approved by a specified Stringent Regulatory Authority.
- The Pfizer/BioNTech Comirnaty COVID-19 mRNA vaccine is the first to receive emergency validation from WHO. The Emergency Use Listing opens the door for countries to expedite their own regulatory approval processes to import and administer the vaccine. It also enables UNICEF and the Pan-American Health Organization to procure the vaccine for distribution to countries in need.
- WHO's Strategic Advisory Group of Experts on Immunization (SAGE) have issued policy recommendations on how best to use the Pfizer/BioNTech vaccine. This includes a recommendation that the vaccine should be administered only in settings where resources and trained health care personnel are available to immediately manage anaphylaxis, which is estimated to occur in approximately 1 case per 100,000 doses administered.
- The WHO COVID-19 vaccine safety surveillance manual has been published and all WHO Regional Offices are supporting countries to implement safety surveillance recommended in the manual.

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## New virus variants

### **WHO Statement about the SARS-CoV-2 new variants**

The WHO Working Group on COVID-19 Animal Models (WHO-COM) is an expert group of more than 150 scientists around the world with expertise in animal models of viral diseases. Since February 2020 the group has met weekly to discuss advances, foster collaborations, share resources and reagents and avoid duplication of effort. On 22 and 29 December 2020, WHO-COM discussed current knowledge and action plans about the emerging SARS-CoV-2 variants containing multiple mutations in the viral spike protein and that are currently circulating in the UK and South Africa. The

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UK variant was identified through genomic sequencing and reported to WHO on 14 December 2020 and is referred to as SARS-CoV-2 VOC 202012/01 (B.1.1.7). The South African variant is characterized by eight lineage-defining mutations in the spike protein including three key residues in the receptor binding domain (K417N, E484K and N501Y) and is referred to as lineage 501Y.V2.

The WHO-COM agreed that setting up a mechanism to study the impact of emerging SARS-CoV-2 variants on transmission, pathogenicity and viral escape from vaccines and therapeutics is a high operational research priority.

[WHO-COM statement about the SARS-CoV-2 new variants](#) (23 Dec 2020)

[WHO Disease outbreak news on SARS-CoV-2 Variants](#) (31 Dec 2020)

## Update on the ACT-Accelerator

### COVAX

[COVAX](#), the vaccines pillar of the ACT-Accelerator, is convened by [CEPI](#), [GAVI](#) and [WHO](#), with the ambition of contracting enough volumes to equitably deliver 2 billion doses of safe, effective and quality vaccines by the end of 2021. Candidates to be included in the [COVAX Facility](#) portfolio are being selected from the COVAX R&D portfolio and other clinical candidates.

Joint News Release: [COVAX Announces additional deals to access promising COVID-19 vaccine candidates; plans global rollout starting Q1 2021](#) (18 Dec 2020)

[Principles for sharing COVID-19 vaccine doses with COVAX](#) (18 Dec 2020)

### Product eligibility under the COVAX Facility

Products procured and/or supplied under the COVAX Facility must be quality assured to ensure positive impact on the population that receive them and to preserve the trust that has been placed in the Facility. Information about these products should be available to member states to enable them to make quick decisions on their importation and/or use and facilitate their continuous monitoring and oversight.

To achieve this, WHO has advised that the COVAX Facility should only consider:

1. products listed by WHO Emergency Use Listing or Prequalification or,
2. under exceptional circumstances, products approved by a specified Stringent Regulatory Authority (SRA). The specified SRAs are [Therapeutic Goods Administration](#) (TGA, Australia); [European Medicines Agency](#) (EMA, EU); [Health Canada](#) (Canada); [Swissmedic](#) (Switzerland); [Medicines and Healthcare products Regulatory Agency](#) (UK); [U. S. Food & Drug Administration](#) (FDA, USA).

[Product eligibility under the COVAX Facility](#) (29 Dec 2020)

## Alignment of approaches by regulators

### Draft WHO Guidance for comments

#### **Evaluation of the quality, safety and efficacy of RNA-based prophylactic vaccines for infectious diseases: regulatory considerations** (comments by 31 Jan 2021)

Given the potential of mRNA vaccines as a platform technology to quickly respond to public health emergencies, such as the current COVID-19 pandemic, the need for international regulatory convergence for evaluation of mRNA vaccines is clear. The WHO [Expert Committee on Biological Standardization](#) discussed these issues at its meetings in August and December 2020 and supported the development of a document on regulatory considerations for the evaluation of mRNA vaccines, which could be updated as more scientific and clinical data became available. WHO therefore initiated activities to review scientific and regulatory issues of mRNA vaccines, set up drafting group

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and working group to develop regulatory considerations for the evaluation of mRNA vaccines.

A draft document has been [published for inviting public comments](#). This document provides scientific information and regulatory considerations on key aspects of the manufacture and quality control, nonclinical and clinical evaluation of prophylactic mRNA-based vaccines.

[Draft Guidance - Evaluation of the quality, safety and efficacy of RNA-based 6 prophylactic vaccines for infectious diseases: regulatory considerations](#) (22 Dec 2020)

Please use the [WHO Comment Form](#) to provide your comments to Dr Tiequn ZHOU, at [zhout@who.int](mailto:zhout@who.int), by **31 January 2021**.

WHO is also seeking comments on draft proposals for inclusion in *The International Pharmacopeia* on **remdesivir, remdesevir intravenous infusion and oxygen**.

Comments are requested by **28 February 2021**.

[REMDESIVIR \(REMDESIVIRUM\)](#)

[REMDESIVIR INTRAVENOUS INFUSION \(REMDESIVIRI INFUSIO INTRAVENO\)](#)

[OXYGEN \(OXYGENIUM\)](#)

## ***In vitro* diagnostics**

### **WHO EUL and listing update**

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. The following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

### **WHO EUL submissions**

Applicants are asked to submit their applications for assessment based on WHO instructions and requirements for [NAT and Ag detection RDTs](#) and [IVDs detecting antibodies to SARS-CoV-2 virus](#).

Manufacturers who are interested in an EUL submission for assays to detect SARS-CoV-2 are invited to contact [diagnostics@who.int](mailto:diagnostics@who.int), to arrange a pre-submission meeting/videoconference/phone conversation.

So far, [27 products](#) have been listed as eligible for WHO procurement among 57 expressions of interest for NAT assays, 33 for antibody detection assays and 14 for antigen detection RDTs have been received.

[The status of each EUL application](#) (05 Jan 2021)

### **Assessment of the potential impact of variant-associated mutations on EUL listed IVDs**

WHO Prequalification Diagnostic team has assessed (based on available sequence information) the potential impact of the SARS-CoV-2 VOC 202012/01 (B.1.1.7) variant associated S gene mutations and deletions on the performance of the 23 molecular tests that WHO have listed for emergency use.

Four of the 23 tests target the S gene and two are potentially impacted, either by the 69/70 deletion or by the 144 deletion. Public Health England (PHE) has demonstrated that the 69/70 deletion results in S target failure with the TaqPath COVID-19 RT-PCR kit (Thermo Fisher Scientific). Both

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assays include 2 additional SARS-CoV-2 gene targets, therefore the risk of a false negative result is assessed as low.

All 3 WHO listed antigen detection RDTs (Abbott, Panbio & SD Biosensor) detect the viral nucleocapsid protein and are therefore not impacted by genomic changes of the S gene. To what extent the 4 amino acid changes in the nucleocapsid protein of the SARS-CoV-2 VOC 202012/01 (B.1.1.7) variant influence performance of the assays cannot be predicted, as it is not known which epitope is detected by the antibodies of the test devices. However, preliminary laboratory evaluation by PHE demonstrated that test performance is not affected by the changes.

WHO Incidents and Substandard and Falsified Medicines team is following-up with manufacturers to learn if they have received feedback (complaints) from customers related to target failure / decreased target sensitivity. IVD users are encouraged to report any unusual deviation between Ct values (target failure / decreased target sensitivity) for multitarget tests. Multitarget tests for which one target is impacted by mutations/deletions can be a useful tool to monitor spread / frequency of virus variants without having to sequence each specimen e.g. the UK/PHE is utilizing the Thermo Fisher assay as a proxy to monitor trends/spread of the SARS CoV-2 VOC 202012/01.

## **IVDs listed by National Regulatory Authorities in IMDRF jurisdictions**

To help countries, WHO publishes links to emergency lists, together with contact details, on IVDs authorized for use in the International Medical Device Regulators Forum ([IMDRF](#)) jurisdictions along with other useful information on policies and guidance.

The [most recent update](#) (23 Nov 2020)

**Note: WHO does not endorse any of the lists provided by NRAs. The information is provided exclusively to assist stakeholders with identifying the links to the various lists.**

## **Therapeutics**

### **Research mapping of candidate therapeutics**

A living research mapping of candidate COVID-19 therapeutics, displaying studies per country, showing study design, disease severity in study participants, and type of treatment being studied, as well as network maps of these studies, has been made available at: <https://www.covid-nma.com/dataviz/>

### **Living synthesis of Covid-19 study results**

A list of treatment comparisons, a summary of the evidence for that comparison, and a detailed description of primary studies, including a risk of bias assessment is at: [https://covid-nma.com/living\\_data/index.php](https://covid-nma.com/living_data/index.php)

## **Convalescent plasma and blood**

### **Call for Experts - Advisory Group on Blood Regulation, Availability and Safety**

WHO has announced a call for experts for an Advisory Group on Blood Regulation, Availability and Safety. One of the functions of the Advisory Group being formed is to provide scientific assessment of current and emerging threats to the safety and availability of blood and blood products. The Advisory Group will advise on the recommended measures and actions to be taken by the Member States in preparedness for and in response to the emerging public health threats.

Nomination requested by **28 February 2021**.

[Call for Experts - Advisory Group on Blood Regulation, Availability and Safety](#)

## Vaccines

### **Pfizer/BioNTech Comirnaty COVID-19 mRNA vaccine**

#### **WHO issues its first emergency use validation for a COVID-19 vaccine**

The Pfizer/BioNTech Comirnaty COVID-19 mRNA vaccine is the first to receive emergency validation from WHO since the outbreak began a year ago. The WHO's Emergency Use Listing (EUL) opens the door for countries to expedite their own regulatory approval processes to import and administer the vaccine. It also enables UNICEF and the Pan-American Health Organization to procure the vaccine for distribution to countries in need.

Regulatory experts convened by WHO from around the world and WHO's own teams reviewed the data on the Pfizer/BioNTech vaccine's safety, efficacy and quality as part of a risk-versus-benefit analysis. The review found that the vaccine met the must-have criteria for safety and efficacy set out by WHO, and that the benefits of using the vaccine to address COVID-19 offset potential risks.

[WHO public assessment report on COVID-19 mRNA vaccine \(nucleoside modified\) submitted by Pfizer Europe MA EEIG](#) (31 Dec 2020)

[WHO recommendation COVID-19 mRNA vaccine \(nucleoside modified\) - COMIRNATY®](#) (31 Dec 2020)

#### **WHO SAGE recommendations**

WHO's Strategic Advisory Group of Experts on Immunization (SAGE) met on 5 January to review the vaccine data for the Pfizer/BioNTech vaccine and formulate policy recommendations on how best to use it. SAGE recommend the administration of two doses of this vaccine within 21 to 28 days. While acknowledging the absence of data on safety and efficacy after one dose beyond the three/four weeks studied in the clinical trials, SAGE made a provision for countries in exceptional circumstances of vaccine supply constraints and epidemiologic settings to delay the administration of the second dose for a few weeks in order to maximize the number of individuals benefiting from a first dose.

[SAGE Interim recommendations for use of the Pfizer– BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing](#) (08 Jan 2021)

#### **Updates from the Global Advisory Committee on Vaccine Safety**

Based on advice from the GACVS, WHO's SAGE recommended on 5 January that the Pfizer/BioNTech vaccine should be administered only in settings where resources and trained health care personnel are available to immediately manage anaphylaxis. Based on a global analysis of 6.8 million doses administered by 3 January 2021, and the number of anaphylaxis reports, it is estimated that approximately 1 case occurs per 100,000 doses administered.

Risk minimization and management (RMM) plans will be paramount and need to be tailored for the setting. The GACVS advised that the effectiveness of RMM plans should be monitored.

#### **US CDC publication**

On 6<sup>th</sup> January, the US CDC has published "[Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020](#)".

#### **Ultra-low temperature freezers**

WHO specifications for ultra-low temperature freezers, associated power requirements, cold boxes and vaccine carriers will be published by the end of January 2021.

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## 0.3 ml autodisable syringes

Two 0.3ml autodisable syringes have been prequalified by WHO.

[E008/079 – Kojak Selinge 0.3ml : Hindustan Syringes & Medical Devices Ltd.](#)

[E008/080 – 0.3ml AD syringe : Wuxi Yushou medical Appliances Co., Ltd.](#)

## Status of COVID-19 vaccines within WHO EUL/PQ evaluation process

WHO has placed into the public domain the status of COVID-19 vaccines for which an expression of interest has been received by WHO/PQ. The information shared includes the National Regulatory Authority (NRA) of record for each vaccine; whether the expression of interest has been accepted; if a pre-submission meeting has been held; if the dossier has been accepted for review; the status of the assessment; and the anticipated decision date.

Version 06 Jan 2021

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.		BNT162b2/COMIRNATY	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted Product in Phase I/II				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.		AZD1222	Core – EMA Non-COVAX	recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein	✓	✓	✓	In progress Core data Non-Covax. Covax data to be reviewed as EMA post approval change	Earliest by EMA Feb 2021 (non-Covax) Additional nodes in March/April for Covax
5.	SK BIO 	AZD1222	MFDS KOREA	=	✓	✓	Tentative 18 and 29 Jan 2021 (CMC for SK Bio)	Core data (non-covax) in progress	Earliest end of Feb 2021
6.		Ad26.CO2.S	EMA	recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Rolling data to EMA – Dec, Feb, April (critical data), May	Not yet started. Use abridged procedure relying on EMA	Earliest May – June 2021

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	End of Dec 2020		Earliest March
2.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	Tentative early Jan 2021		Earliest March
3.		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	Under screening – Non CTD.		
4.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
5.		Ad5-nCoV		Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested				
6.		mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	Expected in Jan 2021				Estimated end of Feb 2021
7.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	EOI Under assessment	08 Jan 2021			
8.			NMPA	No pre-submission meeting yet					
9.			EMA	No pre-submission meeting yet					

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Due to webpage uploading issues, the 28 December 2020 version of the table is currently available. Please visit the site regularly for the updated version.

<https://extranet.who.int/pqweb/vaccines/covid-19-vaccines>

## **Status of COVID-19 vaccines: country- or region-specific information** *(selected)*

WHO is aware that regulators in several countries have issued various types of authorizations to enable emergency use of specific COVID-19 vaccines. WHO can only speak about the attributes of specific products for which we have access to data which would require the product being assessed through EUL/PQ. WHO also acknowledges the regulatory reviews by specified stringent regulatory authorities (see “Product eligibility for the COVAX Facility”, above), although unless WHO has specific access to data, the Organization cannot speak to the details of the product. Nevertheless, to help stakeholders, WHO is providing the following links to emergency listings by selected other countries.

### China

Beijing Institute of Biological Products Co., Ltd (BIBP) reported on December 30 interim analysis results from phase III clinical trial for its inactivated virus COVID-19 vaccine, where the seroconversion rate was reported as 99.5% for neutralized antibody against COVID-19 virus after two dose vaccination, and vaccine efficacy to prevent disease induced by COVID-19 infection was 79.3%. Following reporting and submission with its interim report of phase III clinical trial, the above vaccine was approved by National Medical Products Administration (NMPA) for conditional marketing authorization on 31 December 2020.

[NMPA grants conditional approval for first COVID vaccine](#) (31 Dec 2020)

[Vaccine gets conditional approval for general use](#) (04 Jan 2021)

[What you need to know about China's COVID-19 vaccine](#) (05 Jan 2021)

The WHO EUL/PQ assessment of the vaccine is in progress with an anticipated decision March 2021 at the earliest.

### European Union

The European Commission granted a conditional marketing authorization to the Moderna mRNA COVID-19 vaccine on 6 January 2021. A large clinical trial showed that the vaccine was effective at preventing COVID-19 in people from 18 years of age. The trial involved around 30,000 people in total. Half received the vaccine and half placebo. Vaccine efficacy was calculated in around 28,000 people from 18 to 94 years of age who had no sign of previous infection.

The trial showed a 94.1% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (11 out of 14,134 vaccinated people got COVID-19 with symptoms) compared with people who received placebo (185 out of 14,073 people who received placebo got COVID-19 with symptoms). This means that the vaccine demonstrated a 94.1% efficacy in the trial. The trial also showed 90.9% efficacy in participants at risk of severe COVID-19, including those with chronic lung disease, heart disease, obesity, liver disease, diabetes or HIV infection. The high efficacy was also maintained across genders, racial and ethnic groups.

COVID-19 Vaccine Moderna is given as two injections into the arm, 28 days apart. The most common side effects are pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea and vomiting. These side effects were usually mild or moderate and improved within a few days after vaccination.

[CHMP summary of positive opinion for COVID-19 Vaccine Moderna](#)

[COVID-19 Vaccine Moderna - Product information](#)

[Risk management plan summary for COVID-19 Vaccine Moderna](#)

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[Prescribing information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation](#)

The WHO EUL/PQ assessment of the Moderna mRNA COVID-19 vaccine is in progress with an anticipated decision estimated at the end of February 2021.

## United Kingdom

The UK medicine licensing authority has temporarily authorized the supply for the UK (under Regulation 174 of the Human Medicine Regulations 2012) of the Covid-19 vaccine by Oxford/AstraZeneca, a recombinant chimpanzee adenovirus vector vaccine encoding the SARS-CoV-2 Spike (S) glycoprotein, in response to the spread of COVID-19, subject to specific conditions.

This approval is not a marketing authorization, and there is therefore no general authorization to place this vaccine on the market.

[MHRA Public Assessment report – Authorisation for temporary supply](#)

## India

The Drugs Controller General of India issued a restricted emergency approval for the Covid-19 recombinant chimpanzee adenovirus vector vaccine encoding the SARS-CoV-2 Spike (S) glycoprotein produced by the Serum Institute of India via technology transfer from Oxford/AstraZeneca.

The permission granted is for restricted use in an emergency situation subject to certain regulatory conditions. The clinical trial ongoing within India will continue.

[Press Statement by the Drugs Controller General of India \(DCGI\) on Restricted Emergency approval of COVID-19 virus vaccine](#) (03 Jan 2021)

The Oxford/AstraZeneca recombinant chimpanzee adenovirus vector vaccine encoding the SARS-CoV-2 Spike (S) glycoprotein is being manufactured in several nodes worldwide.

The WHO EUL/PQ assessments of the vaccine being produced in these nodes, which are under the responsibility of different NRAs, are in progress with anticipated decisions from February 2021 onwards.

**Note: WHO does not endorse any of the country-, or region-, specific information provided here. The information is provided exclusively to assist regulators and stakeholders with identifying the links to the various products.**

## **WHO COVID-19 vaccine safety surveillance manual**

The WHO COVID-19 vaccine safety surveillance manual was developed following recommendations and guidance of the Global Advisory Committee on Vaccine Safety (GACVS) members, as well as experts from around the world. The manual incorporates current and available information that is critical for all stakeholders before, during and after the introduction of COVID-19 vaccines.

All WHO Regional Offices are supporting countries to implement safety surveillance recommended in the manual.

[COVID-19 VACCINES: SAFETY SURVEILLANCE MANUAL](#) (22 Dec 2020)

- 6.1: COVID-19 vaccines: description and general safety consideration for implementation
- 6.2: Stakeholders in COVID-19 vaccine safety surveillance
- 6.3: Establishing surveillance systems in countries using COVID-19 vaccines
- 6.4: Monitoring and responding to adverse events following immunization
- 6.5: Monitoring and responding to adverse events of special interest
- 6.6: Safety data management systems, methods of post-introduction evaluation and assessing

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performance in countries using COVID-19 vaccines

- 6.7: Engaging with the pharmaceutical industry for COVID-19 vaccine safety surveillance
- 6.8: Regulatory reliance and work-sharing
- 6.9: COVID-19 vaccine safety communication

## **WHO's Science in 5 on COVID-19: variants and vaccines:**

Dr Soumya Swaminathan explains

- How concerned should we be about the new variants of SARS-CoV-2 which cause COVID-19?
- Is it unusual for viruses to change and mutate?

[WHO's Science in 5 on COVID-19: variants and vaccines](#) (07 Jan 2021)

## **Living mapping and living systematic review of COVID-19 studies**

Living mapping and living systematic reviews are available based on daily searches of the literature for candidate vaccines against COVID-19.

The tool allows vaccine comparisons where data are available as well as a table with the general characteristics of each trial. For each vaccine comparison, forest plots for all the outcomes of interest are available as well as the Summary of Findings table.

The mapping tool is available at: <https://covid-nma.com/vaccines/mapping/>

## **Landscape of candidate vaccines for SARS-CoV-2**

A landscape analysis of candidate SARS-CoV-2 vaccines is regularly published by WHO. Currently, over 230 vaccines are at some stage of development. Of these, **63 vaccine candidates are in human trial**. About 15 are in or entering phase III trials. There are several others currently in phase I/II, which will enter phase III in the coming 2 months. This is a very robust pipeline – the more candidates, the more opportunities for success (typically success rate of candidate vaccines is 10%).

The candidate vaccines are of various types – virus vaccines using live attenuated virus, viral vector vaccines, protein-based vaccines, and nucleic acid or RNA and DNA vaccines, which are completely new platforms.

A landscape analysis of candidate SARS-CoV-2 vaccines is regularly published by WHO.

[Landscape of COVID-19 candidate vaccines](#) (06 Jan 2021)

## **Research protocols, assays and reference standards**

### **WHO Policy Brief on Ethical considerations for COVID-19 vaccine trials:**

The conduct of COVID-19 vaccine trials in the context of a candidate vaccine being issued with Emergency Use Designation (EUD) raises challenging ethical questions, especially regarding the use of placebo controls and unblinding COVID-19 trial participants. Such a context requires a sensitive balancing of the interests of COVID-19 vaccine trial participants, with the need to conduct valuable and urgently needed COVID-19 vaccine research.

The WHO Access to COVID-19 Tools (ACT) Accelerator Ethics and Governance Working Group has developed a policy brief to guide ethical decision-making on COVID-19 vaccine trial unblinding and the use of active or placebo controls in the context of COVID-19 candidate vaccines attaining EUD and becoming available in settings hosting current or future COVID-19 vaccine trials.

[Emergency Use Designation of COVID-19 candidate vaccines: Ethical considerations for current and future COVID-19 placebo-controlled vaccine trials and trial unblinding](#) (18 Dec 2020)

## Substandard and falsified products

### Risk mitigation measures for the threat of falsified COVID-19 vaccines

As of 07 January, WHO is aware of some versions of falsified Covid-19 vaccines. However the incidents reported to date do not provide any cause for alarm and appropriate regulatory action has been taken. A number of these have already been the subject of media articles and reported to WHO and most are small-scale operations. There is no reason for the general public to be alarmed about falsified versions of vaccines as long as they receive products through the regulated / controlled supply chain.

Regulators and national agencies are aware of the threat of falsified COVID-19 vaccines and implementing mitigation measures to ensure supply chain integrity. It is important countries procure from safe and reliable sources that have undergone due diligence checks.

WHO works with Member States to implement prevent-detect-respond strategies to SF medical products. This covers technical and operational approaches (including a case reporting system) and a policy approach (the Member State mechanism on SF medical products).

## Medical Devices

### WHO Medical Devices Newsletter (31 Dec 2020)

The Newsletter includes updates on new documents and provides information on facility surveys, country surveys, on-line training, and short-term consultancies available at WHO.

The newsletter is available by sending an email to: [LISTSERV@listserv.who.int](mailto:LISTSERV@listserv.who.int) with the words: SUBSCRIBE WHO MEDICAL DEVICES in the body of the message.

For requests and questions, contact Adriana Velazquez at [COVID-MED-DEVICES@who.int](mailto:COVID-MED-DEVICES@who.int)

### **Interim guidance**

Medical devices:

[Priority medical devices for COVID-19 and associated technical specifications](#) (20 Nov 2020)

Personal protective equipment:

[Technical Specifications on PPE](#) (13 Nov 2020)

[On the use of masks](#)

[Use of masks for children](#)

[Rational use of personal protective equipment for coronavirus disease \(COVID-19\) and considerations during severe shortages](#) (23 Dec 2020)

[Mask use in the context of COVID-19](#) (1 Dec 2020)

IVD:

[Information about emergency use listing](#)

[Laboratory assessment](#) (23 Oct 2020)

Role of imaging diagnostics

[Role of ultrasound, chest X rays and CT scanners](#)

chapter 8 of the [Priority medical devices for COVID for the technical specifications](#)

### **Other information**

[Emergency Global Supply catalogue](#): Updated 11 November 2020.

[Nomenclature of medical devices](#)

## Upcoming events:

### **Global consultation on an R&D Agenda in response to the variants of SARS-CoV2**

On 12 January from 13:00 to 18:00 CET, WHO will host a global consultation to urgently discuss an R&D agenda in response to variants of SARS-COV-2. The key objectives will be to identify the critical research questions related to variants and agree on an approach to address this and other emerging variants.

Registration must be completed **before 11 January end-of-day in Geneva.**

Please register at [https://who.zoom.us/webinar/register/WN\\_s8p48uDITU2sthd\\_z9g40w](https://who.zoom.us/webinar/register/WN_s8p48uDITU2sthd_z9g40w)

### **Global Consultation on a 2021 R&D Agenda for COVID-19 Vaccines**

On 15<sup>th</sup> January from 13:00 to 18:00 CET, WHO will host a global consultation to discuss a 2021 research agenda for COVID-19 vaccines. The objectives will be to outline priority research questions and an agenda for 2021 that identifies science gaps for vaccines in clinical development and research needs for second generation vaccines.

Registration must be completed **before 14 January end-of-day in Geneva.**

Please register at [https://who.zoom.us/webinar/register/WN\\_lh2FuC1IQcaN1kZXmZXnew](https://who.zoom.us/webinar/register/WN_lh2FuC1IQcaN1kZXmZXnew)