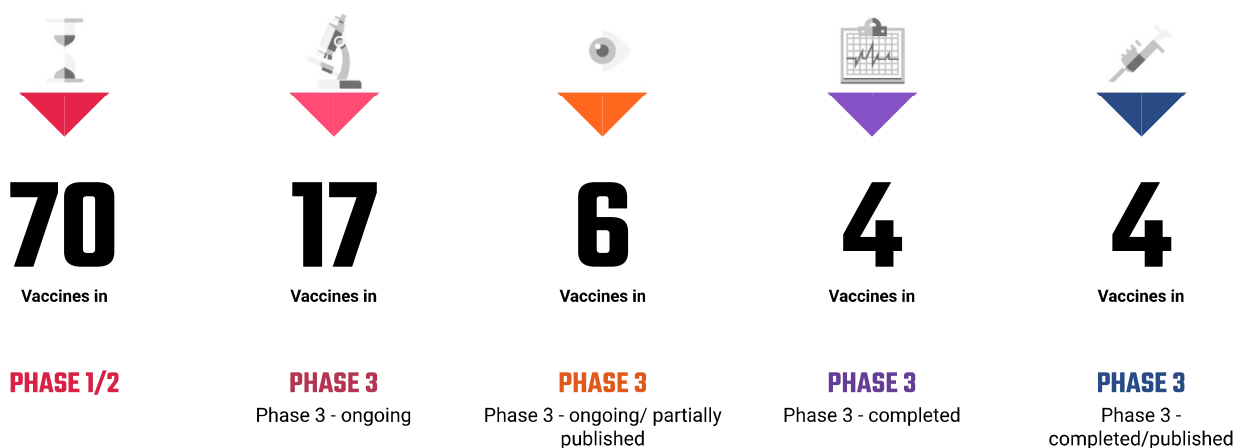


Pharmacovigilance for COVID-19 vaccines



8

Emergency use listing (EUL) /WHO

[More info](#)

21

Authorization issued by countries or regions

[More info](#)

Disclaimer: It is important to note that the data on spontaneous reports of adverse events after vaccination are just suspicious adverse events. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. **Causal associations cannot (and should not) be made using data from spontaneous reports.**

Moreover, this data is not valid for estimating the frequency of occurrence of adverse reactions in patients receiving the vaccine, nor do they allow comparisons between different vaccines. However, this data coming from spontaneous report can be useful to provide hypothesis, requiring additional epidemiological and clinical investigations to be confirmed or refuted. **Further confirmation in controlled studies is usually required.**

FILTER BY:

Phases

Country



Platform

Developer

Authorization Status

Phase 3

COVAX EUL

EU Nodex-AstraZeneca/Oxford; AstraZeneca/SK BIO; Serum Institute of India COVID-19 vaccine

Vaxzevria in Europe (formerly AZD1222 and ChAdOx1); Covishield in India

Authorization status: [EUL \(WHO\), Authorized, Registered \(marketing authorization\)](#)



Developer: AstraZeneca; Oxford University

Manufacturer: AstraZeneca/SK Bioscience Co. Ltd, Republic of Korea; Serum Institute of India Pvt. Ltd, India; AstraZeneca AB, Sweden

Platform: Viral Vector (non-replicating)

Pharmaceutical form: Solution for intramuscular injection

Phase: Phase 3 - completed/published

Doses:  Conservation:  5°C (41°F)

[More info](#)

Phase 3

COVAX EUL

Janssen COVID-19 vaccine

JNJ-78436735; Ad26.COV2-S (recombinant).

Authorization status: [EUL \(WHO\), Authorized](#)

Developer: Janssen Pharmaceutical

Manufacturer: Janssen-Cilag International NV, Belgium

Platform: Viral Vector (non-replicating)

Pharmaceutical form: Suspension for intramuscular injection

Phase: Phase 3 - completed/published

Doses:  Conservation:  -20°C (-4°F)

[More info](#)

Phase 3

COVAX EUL

Moderna COVID-19 vaccine

mRNA-1273; Elasmoran; Spikevax

Authorization status: [EUL \(WHO\), Authorized](#)

Developer: Moderna - National Institute of Allergy and Infectious Diseases (NIAID)

Manufacturer: Moderna TX, Inc., USA; Rovi Pharma Industrial Services S.A, Spain.

Platform: RNA-based vaccine

Pharmaceutical form: Dispersion for intramuscular injection

Phase: Phase 3 - completed/published

Doses:  Conservation:  -20°C (-4°F)

[More info](#)

Phase 3

COVAX EUL

Pfizer-BioNTech COVID-19 vaccine

2BNT162b2; Tozinameran; Comirnaty

Authorization status: [EUL \(WHO\), Authorized, Registered \(marketing authorization\)](#)



Developer: Pfizer/BioNTech

Manufacturer: Pfizer Europe MA EEIG

Platform: RNA-based vaccine

Pharmaceutical form: Concentrated dispersion for intramuscular injection

Phase: Phase 3 - completed/published

Doses:  Conservation:  -75°C (-103°F)

Phase 3

COVAX

Gamaleya Sputnik V; Sputnik Light COVID-19 vaccine

Sputnik V; Gam-COVID-Vac; Adeno-based (rAd26-S+rAd5-S)/ Sputnik light

Authorization status: [Authorized](#)

Developer: Gamaleya Research Institute; Health Ministry of the Russian Federation

Manufacturer: N.F. Gamaleya Ministry of Health of Rusia

Platform: Viral Vector (non-replicating)

Pharmaceutical form: Solution for intramuscular injection

Phase: Phase 3 - completed/published

Doses:  /  Conservation: 

Phase 3

EUL

Sinopharm/BIBP COVID-19 vaccine

Inactivated SARS-CoV-2-vaccine (Vero cell); BBIBP-CorV; adsorbed COVID-19 vaccine

Authorization status: [Authorized, EUL \(WHO\)](#)

Developer: Sinopharm; China National Biotec Group Co; Beijing Institute of Biological Products

Manufacturer: Beijing Institute of Biological Products Co. Ltd.

Platform: Inactivated Virus

Pharmaceutical form: Suspension for intramuscular injection

Phase: Phase 3 - ongoing/ partially published

Doses:  Conservation:  5°C (41°F)

[More info](#)[More info](#)-18°C
(-0.4°F)[More info](#)

EUL

Phase 3

Sinovac COVID-19 vaccine

CoronaVac; adsorbed COVID-19 vaccine**Authorization status:** [Authorized](#), [EUL](#) (WHO) **Developer:** Sinovac Research and Development Co, Ltd**Manufacturer:** Sinovac Life Sciences., LTD. China**Platform:** Inactivated Virus**Pharmaceutical form:** Suspension for intramuscular injection**Phase:**
Phase 3 - ongoing/ partially published**Doses:****Conservation**

5°C (41°F)

[More info](#)

Phase 3

CanSino COVID-19 vaccine

Ad5-nCoV; Convidicea; PakVac**Authorization status:** [Authorized](#) **Developer:** CanSino Biological inc; Beijing Institute of Biotechnology**Manufacturer:** CanSino Biologics Inc**Platform:** Viral Vector (non-replicating)**Pharmaceutical form:** Solution for intramuscular injection**Phase:**
Phase 3 - ongoing/ partially published**Doses:****Conservation**

5°C (41°F)

[More info](#)

COVAX

Phase 3

Novavax COVID-19 vaccine

NVX-CoV2373**Authorization status:** [Not authorized yet](#) **Developer:** Novavax**Manufacturer:** Novavax**Platform:** Protein subunit**Pharmaceutical form:** Suspension for intramuscular injection**Phase:**
Phase 3 - ongoing/ partially published**Doses:****Conservation**

5°C (41°F)

[More info](#)

Phase 3

Anhui Zhifei Longcom COVID-19 vaccine

ZF2001; ZIFIVAX; ZF-UZ-VAC 2001**Authorization status:** [Authorized](#) **Developer:** Anhui Zhifei Longcom Biopharmaceutical; Institute of Microbiology, Chinese Academy of Sciences**Manufacturer:** Anhui Zhifei Longcom Biopharmaceutical Co. Ltd.**Platform:** Protein subunit**Pharmaceutical form:** Suspension for intramuscular injection**Phase:**
Phase 3 - ongoing**Doses:****Conservation**

5°C (41°F)

[More info](#)

Phase 3

Bharat Biotech COVID-19 vaccine

BBV152; Covaxin**Authorization status:** [Authorized](#) **Developer:** Bharat Biotech International Limited**Manufacturer:** Bharat Biotech International Limited**Platform:** Inactivated Virus**Pharmaceutical form:** Suspension for intramuscular injection**Phase:**
Phase 3 - ongoing**Doses:****Conservation**

5°C (41°F)

[More info](#)

Phase 3

Sinopharm/WIBP COVID-19 vaccine

Inactivated SARS-CoV-2-vaccine (Vero cell); WIBP-CorV; adsorbed COVID-19 vaccine**Authorization status:** [Authorized](#) **Developer:** Sinopharm; China National Biotech group Co; Wuhan Institute of Biological Products**Manufacturer:** Wuhan Institute of Biological Products Co. Ltd.**Platform:** Inactivated Virus**Pharmaceutical form:** Suspension for intramuscular injection**Phase:**
Phase 3 - ongoing**Doses:****Conservation**

5°C (41°F)

[More info](#)

Phase 3

Vector Institute COVID-19 vaccine

EpiVacCorona; EpiVakKorona

Authorization status: **Authorized** 

Developer: Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "vector" (FBRI)

Manufacturer: Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "vector" (FBRI)

Platform: Protein subunit

Pharmaceutical form: Suspension for intramuscular injection

Phase:
Phase 3 - ongoing

Doses:



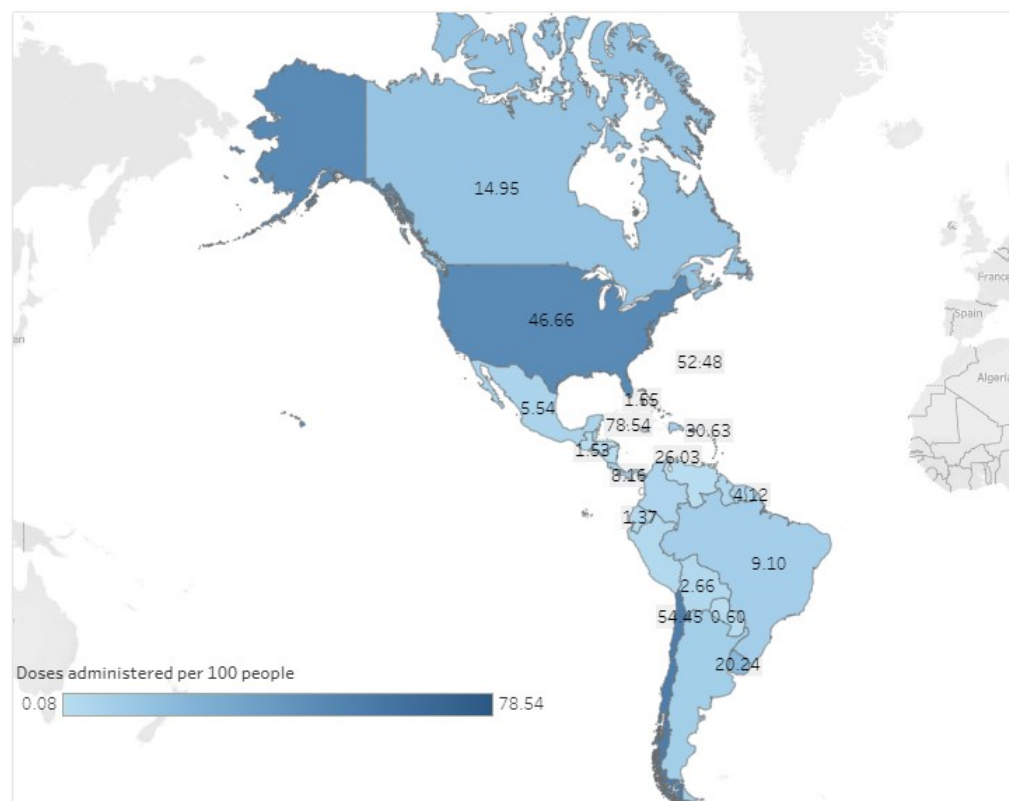
Conservation



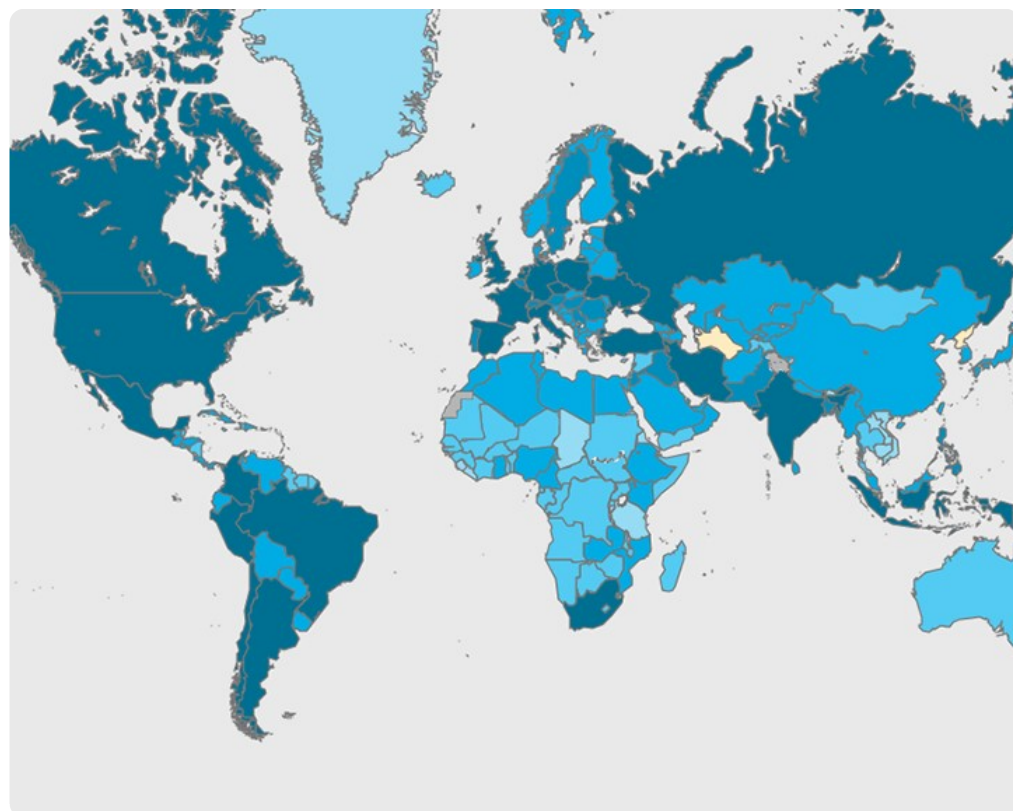
5°C (41°F)

 More info

REGIONAL VACCINATION DASHBOARD



WHO CORONAVIRUS DASHBOARD



UPDATES



The European Medicines Agency adds capillary leak syndrome as a contraindication to Janssen



OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS - 12 July 2021



AEFI and serious adverse events reported for vaccines being used in the Region of the Americas, by doses administered, as of 30 June 2021

UPDATES ON AEFI

- [☑ Periodic Update on AEFI COVID-19 Vaccine Safety - Number 16 - 10 JUNE](#)
- [☑ Periodic Update on AEFI COVID-19 Vaccine Safety - Number 17 - 17 JUNE](#)
- [☑ Periodic Update on AEFI COVID-19 Vaccine Safety - Number 18 - 30 JUNE](#)
- [☑ Periodic Update on AEFI COVID-19 Vaccine Safety - Number 19 - 12 JULY](#)

[Read more](#)

GUIDANCE AND MANUALS

- [☑ Guide for the preparation of a risk communication strategy for COVID-19 vaccines: A Resource for the countries of the Americas](#)
- [☑ COVID-19 vaccine introduction readiness assessment tool](#)
- [☑ COVID-19 vaccination: supply and logistics guidance: interim guidance](#)
- [☑ Organización Mundial de la Salud. Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines](#)
- [☑ Evidence to recommendations for COVID-19 vaccines: Evidence framework](#)

- [☐ Consultation Document for Case Definitions](#)
- [☐ Guidance for clinical case management of thrombosis with thrombocytopenia syndrome \(TTS\) following vaccination to prevent coronavirus disease \(COVID-19\)](#)
- [☐ WHO SAGE Roadmap for prioritizing uses of covid-19 vaccines in the context of limited supply Immunization](#)

[Read more](#)

DOCUMENTS

- [☐ WHO SAGE Seasonal Influenza Vaccination Recommendations during the COVID-19 Pandemic Interim guidance](#)
- [☐ Vaccination of Newborns in the Context of the COVID-19 Pandemic](#)
- [☐ The Janssen \(Johnson and Johnson\) vaccine explainer](#)

[Read more](#)

TRAININGS

- [☐ COVID-19 vaccination training for health workers](#)
- [☐ Course Signal detection and assessment \(English\)](#)
- [☐ Course AEFI reporting for VigiFlow \(English only\)](#)
- [☐ Course Orientation to national deployment and vaccination planning for COVID-19 vaccines \(English only\)](#)
- [☐ Course Introduction to pharmacovigilance \(English\)](#)
- [☐ COVID-19 vaccine-specific resources](#)
- [☐ IVI's 20th International Vaccinology Course](#)

[Read more](#)

REGULATORY RESOURCES

- [☐ Regulatory reliance principles: concept note and recommendations.](#)
- [☐ Use of decisions by other regulatory authorities to authorize emergency use of drugs and other health technologies in a pandemic \(e.g., COVID-19\). \(Spanish only\)](#)
- [☐ Operational Tool for efficient and effective lot release of SARS-CoV-2 \(Covid-19\) vaccines](#)
- [☐ Recommendations on regulatory processes and elements related to the introduction of vaccines during the COVID-19 pandemic and other emergency situations](#)
- [☐ Considerations for Regulatory Oversight of Clinical Trials in the COVID-19 Pandemic \(only Spanish\)](#)
- [☐ Risk management plans and periodic safety reports for COVID-19 vaccines. Recommendations for application, preparation, handling and evaluation \(Spanish only\)](#)
- [☐ Recommendations for the management of serious, unexpected or special interest events identified in clinical trials of vaccines against COVID-19 \(Spanish only\)](#)

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