

## COVID-19 Vaccine Update Supplement

Week of: 27<sup>th</sup> Sept. – 1<sup>st</sup> October, 2021

### I. Overview of Development and Regulatory Approvals:

- 121 candidate vaccines are in clinical development: 26 in Phase 3 trials, and 8 in Phase 4 trials – Table 1; Figure in [COVID-19 Vaccines and Therapeutics Regulatory Tracker](#) (Phases tab).
- 22 vaccines have received regulatory approvals in various countries, and 22 are at various stages of engagement with WHO for emergency use listing (EUL).
- There are 8 COVID-19 vaccines (6 different moieties) by 7 developers that have been approved by WHO for EUL to date. CARPHA-CRS has recommended all the WHO EUL COVID-19 vaccines to Member States, with updates inclusive of additional sites and monthly safety updates: Table 3.
- WHO has updated its [EUL for Pfizer-BioNTech's](#) vaccine to include persons 12-15 years, and the extended shelf-life of 9 months.
- PAHO has selected centers in Argentina, Brazil to develop COVID-19 mRNA vaccines: The Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil, and Sinergium Biotech in Argentina. This will support access to mRNA vaccines by countries in the Americas. See media release [here](#).

**Table 1: Candidate Vaccines under Clinical evaluation, by type or platform.**

Platform	Description	Phase 1	Phase 1/2	Phase 2	Phase 2/3	Phase 3	Phase 4	Total	WHO EUL
PS	Protein subunit	10	14	3	2	14	0	43	0
VVnr	Viral Vector (non-replicating)	7	5	0	2	1	3	18	4
DNA	DNA	4	4	0	2	1	0	11	0
IV	Inactivated Virus	3	2	1	1	7	2	16	2
RNA	RNA	8	4	2	2	2	3	21	2
VVr	Viral Vector (replicating)	0	0	1	1	0	0	2	0
VLP	Virus Like Particle	1	2	1	0	1	0	5	0
VVr + APC	VVr + Antigen Presenting Cell	1	0	1	0	0	0	2	0
LAV	Live Attenuated Virus	2	0	0	0	0	0	2	0
VVnr + APC	VVnr + Antigen Presenting Cell	0	1	0	0	0	0	1	0
<b>Total</b>		<b>36</b>	<b>32</b>	<b>9</b>	<b>10</b>	<b>26</b>	<b>8</b>	<b>121</b>	<b>8</b>

Source: World Health Organization. *Draft landscape of COVID-19 candidate vaccines*. WHO, Geneva, 24<sup>th</sup> September, 2021.

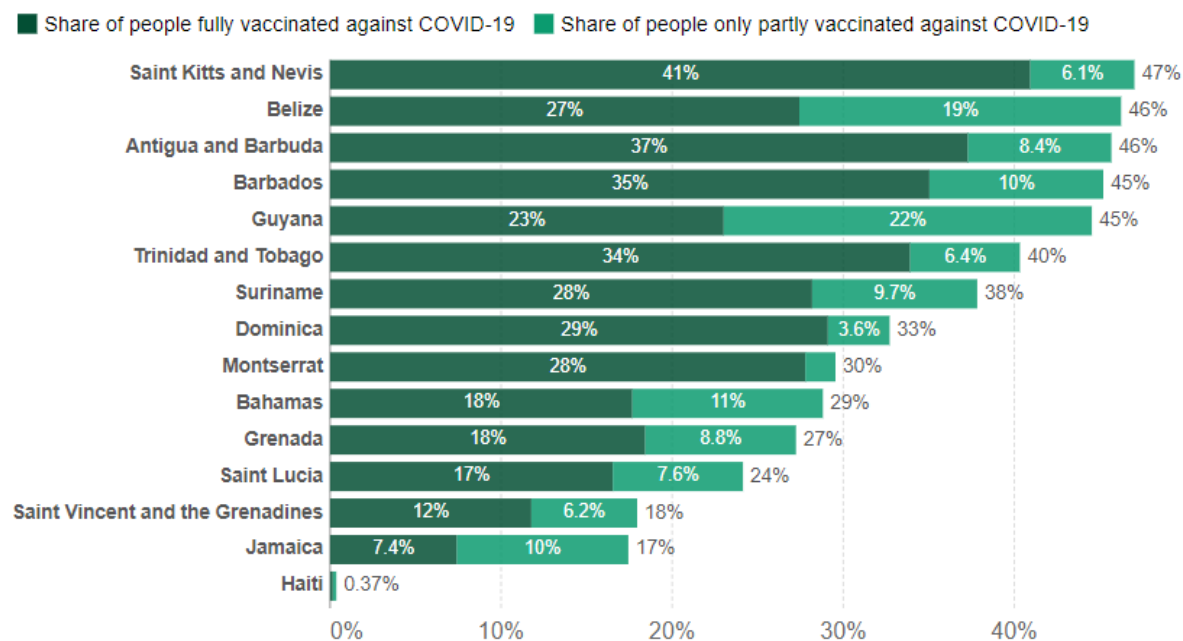
Available at: [Draft landscape of COVID-19 candidate vaccines \(who.int\)](#).

## II. Vaccine Deployment in the Caribbean

Several Caribbean countries have approved / received COVID-19 vaccines purchases and/or donations.

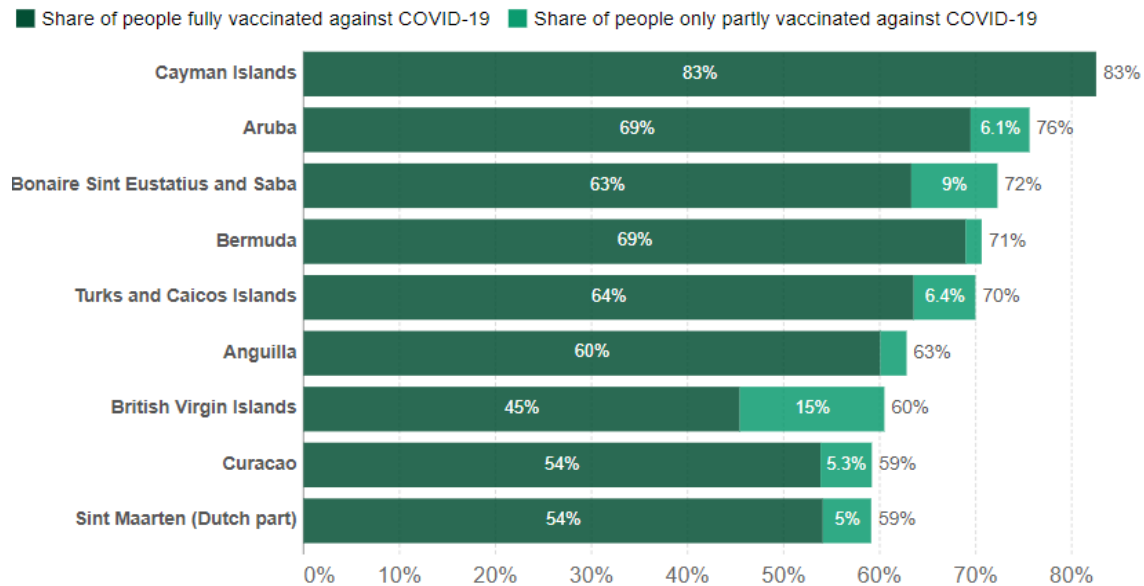
- 15 CARPHA member states have received vaccine [deliveries from COVAX](#) as of 27<sup>th</sup> September, 2021.
- Based on data collected by the Global Change Data Lab’s [Our World in Data](#) site, between 0.16% and 82.54% of persons in CARPHA Member States have been fully vaccinated (Figures 1-2). Counts may be a couple days out of date, as these are subject to data collection by OWID.
- Completed vaccination schedules, based on data from PAHO, are shown in Figure 3. Based on the PAHO Dashboard [COVID-19 Vaccination in the Americas](#) as of 24<sup>th</sup> September, 2021, among CARPHA Member States, vaccine administration (at least 1 dose) ranges from 0.5 to 167.7 doses per capita (Figure 4). Approximately **4,507,347** doses have been administered among CMS – Table 2.

**FIGURE 1: Share of People vaccinated against COVID-19 in CARICOM Member States (24<sup>th</sup> September)**



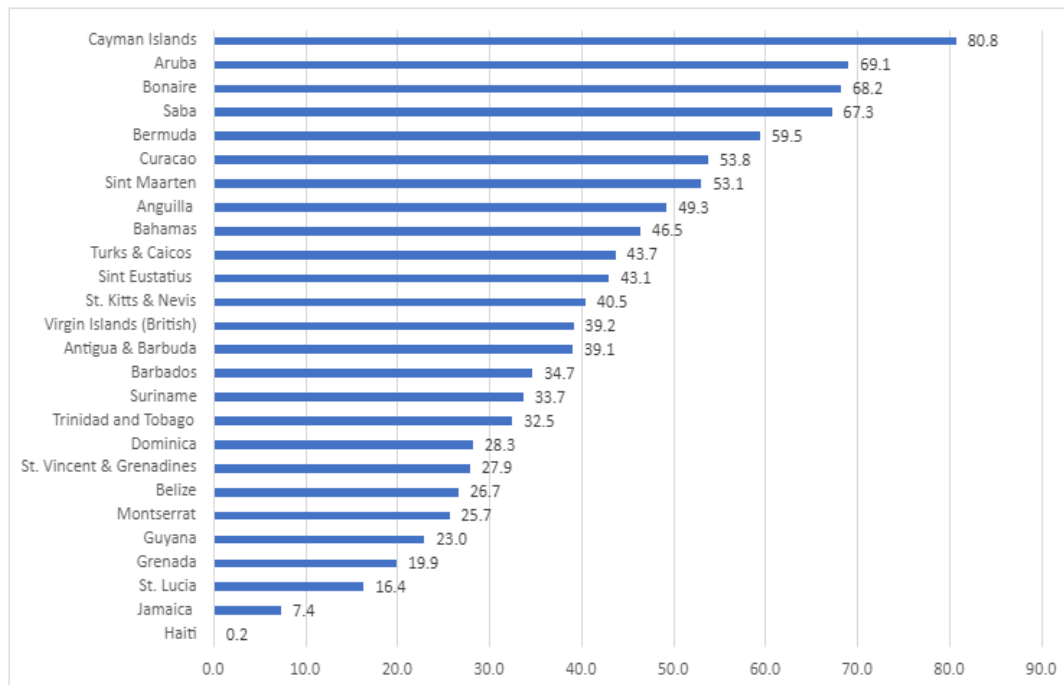
Source: Official data collated by Our World in Data. This data is only available for countries which report the breakdown of doses administered by first and second doses in absolute numbers.  
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**FIGURE 2: Share of People vaccinated against COVID-19 in CARICOM Associates / Other CARPHA Member States (24<sup>th</sup> September)**



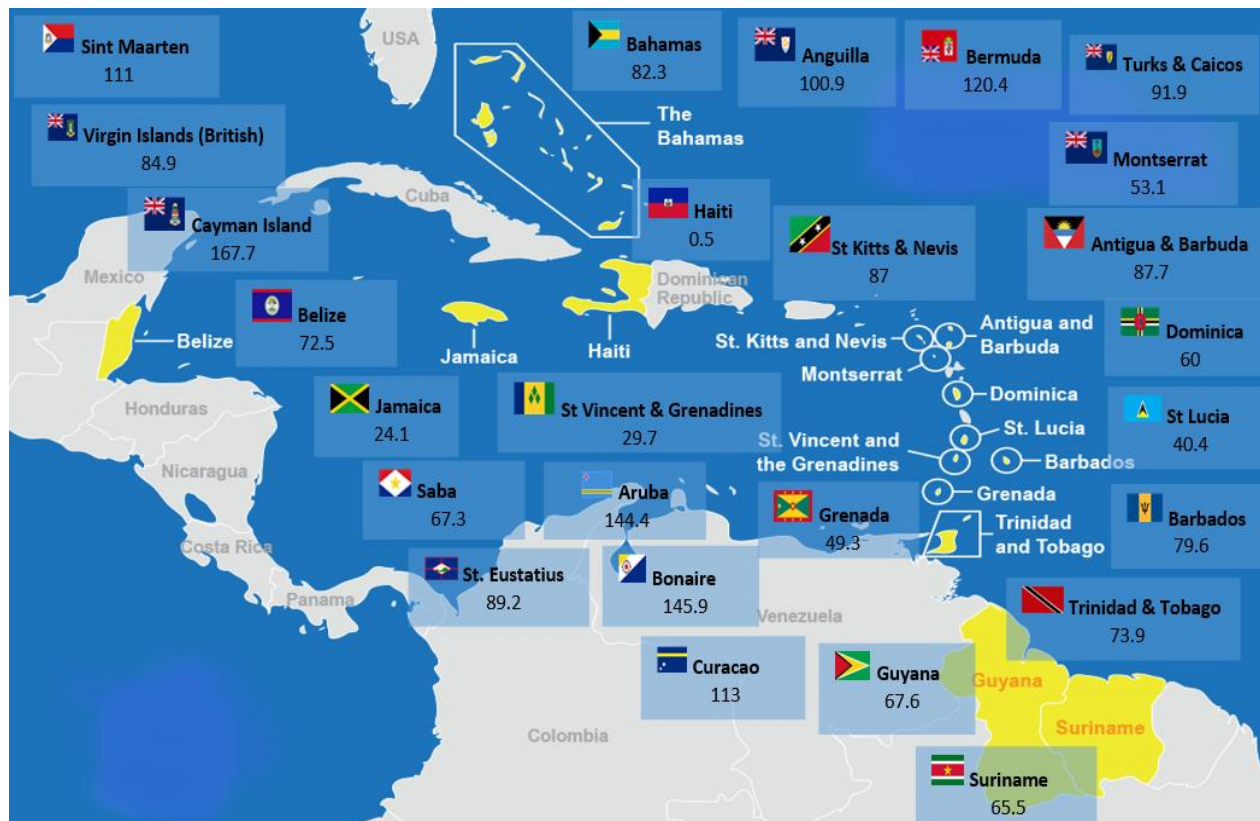
Source: Official data collated by Our World in Data. This data is only available for countries which report the breakdown of doses administered by first and second doses in absolute numbers.  
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**FIGURE 3: Completed Schedules of COVID-19 Vaccination per 100 persons, as of 24<sup>th</sup> September, 2021 (PAHO)**



Source: [PAHO COVID-19 Vaccination in the Americas Dashboard](#).

**FIGURE 4: COVID-19 Vaccine Doses Administered per 100 persons, as of 24<sup>th</sup> September, 2021**



**Note:** For vaccines that require multiple doses, each individual dose is counted. As the same person may receive more than one dose, the number of doses per 100 people can be higher than 100.

**Table 2: COVID-19 Vaccines Deployed Among CARPHA Member States as of 24<sup>th</sup> September, 2021**

Country ¥	Vaccine(s)	Number of Doses	Doses per 100 persons
<b>Anguilla</b>	AstraZeneca - Vaxzevria	18, 584	100.9
<b>Antigua &amp; Barbuda</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Gamaleya-Sputnik V; Janssen- Ad26.COV 2.5; Pfizer BioNTech – Comirnaty; SII- Covishield	86, 542	87.7
<b>Aruba</b>	Janssen- Ad26.COV 2.5; Pfizer BioNTech - Comirnaty	154, 834	144.4
<b>Bahamas</b>	AstraZeneca – Vaxzevria; Janssen- Ad26.COV 2.5; Pfizer BioNTech – Comirnaty; SII- Covishield	184, 461	82.3
<b>Barbados</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Pfizer BioNTech – Comirnaty; SII- Covishield	228, 890	79.6
<b>Bonaire</b>	Pfizer BioNTech - Comirnaty	29, 334	145.9
<b>Belize</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Janssen- Ad26.COV 2.5; Pfizer BioNTech – Comirnaty; SII- Covishield	293, 681	72.5
<b>Bermuda</b>	AstraZeneca – Vaxzevria; Pfizer BioNTech - Comirnaty	86, 676	120.4
<b>Cayman Islands</b>	Pfizer BioNTech - Comirnaty	105, 823	167.7
<b>Curacao</b>	Moderna- mRNA-1273; Pfizer BioNTech - Comirnaty	186, 229	113

Country †	Vaccine(s)	Number of Doses	Doses per 100 persons
<b>Dominica</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Pfizer BioNTech – Comirnaty; SII- Covishield	44, 624	60
<b>Grenada</b>	AstraZeneca – Vaxzevria; Pfizer BioNTech – Comirnaty; SII- Covishield	55, 663	49.3
<b>Guyana</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Gamaleya-Sputnik V; Moderna- mRNA-1273; Pfizer BioNTech – Comirnaty; SII- Covishield	533, 843	67.6
<b>Haiti</b>	Moderna- mRNA-1273; Janssen- Ad26.COV 2.5	61, 619	0.5
<b>Jamaica</b>	AstraZeneca – Vaxzevria; Janssen- Ad26.COV 2.5; Pfizer BioNTech – Comirnaty; SII- Covishield	715, 860	24.1
<b>Montserrat</b>	AstraZeneca - Vaxzevria	2, 871	53.1
<b>Saba</b>	Moderna- mRNA-1273	1, 300	67.3
<b>Sint Eustatius</b>	Janssen- Ad26.COV 2.5; Moderna- mRNA-1273	2, 800	89.2
<b>Sint Maarten</b>	AstraZeneca – Vaxzevria; Moderna- mRNA-1273; Pfizer BioNTech - Comirnaty	49, 310	111
<b>St. Kitts &amp; Nevis</b>	AstraZeneca – Vaxzevria; Pfizer BioNTech - Comirnaty; SII- Covishield	47, 098	87
<b>St. Lucia</b>	AstraZeneca – Vaxzevria; Pfizer BioNTech - Comirnaty; SII- Covishield	74, 492	40.4
<b>St. Vincent &amp; Grenadines</b>	Gamaleya - Sputnik V; AstraZeneca – Vaxzevria; Pfizer BioNTech – Comirnaty; SII- Covishield	33, 077	29.7
<b>Suriname</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Moderna- mRNA-1273; Pfizer BioNTech – Comirnaty; SII- Covishield	387, 552	65.5
<b>Trinidad &amp; Tobago</b>	AstraZeneca – Vaxzevria; Beijing CNBG – BBIBP-CorV; Janssen- Ad26.COV 2.5; Pfizer BioNTech – Comirnaty; SII- Covishield	1, 037, 412	73.9
<b>Turks and Caicos</b>	Pfizer BioNTech - Comirnaty	52, 374	91.9
<b>Virgin Islands (British)</b>	AstraZeneca – Vaxzevria; Janssen- Ad26.COV 2.5	32, 398	84.9

Source: [PAHO COVID-19 Vaccination in the Americas Dashboard](#).

*Note: For vaccines that require multiple doses, each individual dose is counted. As the same person may receive more than one dose, the number of doses per 100 people can be higher than 100.*

### III. Reports of Adverse Events Following Immunization (AEFIs) with COVID-19 vaccines to CARPHA VigiCarib

CARPHA’s Caribbean Regulatory System (CRS) assists Member States with the collection of reports of adverse events following immunization (AEFIs) (also known as Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) following use of COVID-19 vaccines.

As of 24<sup>th</sup> September, CARPHA has received **38 case reports** via its online reporting form since its launch in August: 13 were considered as ‘Serious’ including one death).

All reports were submitted to the national focal point within one business of receipt. AEFI case reports received by the CRS are unconfirmed and are subject to verification and/or investigation by local authorities.

**Table 3: COVID-19 Vaccines with Regulatory Approvals by WHO EUL Consideration**

Developers (Vaccine name)	Vaccine Platform	Dosing and Storage ¥	Authorized by	WHO Approved Drug Product site(s)	WHO EUL status and anticipated decision date:
<b>WHO EUL status – Approved</b>					
<b>Recommended by CRS</b>					
<b>Pfizer-BioNTech</b> INN: tozinameran; BNT162b2  <u>Commercial names:</u> COMIRNATY™; Pfizer-BioNTech COVID-19 vaccine	mRNA (nucleoside modified)	2 doses I.M.  -90°C to -60°C (9 mo.); 2°C to 8°C (31 days)	WHO EUL + CARPHA + 100 countries Full Market authorization by US FDA (16yrs+)	<b>Baxter Oncology GmbH</b> , Kantstraße 2, 33790 Halle/Westfalen, Germany  <b>BioNTech Manufacturing GmbH</b> , Kupferbergterrasse 17 - 19, 55116 Mainz, Germany  <b>Pfizer Manufacturing Belgium NV</b> , Rijksweg 12, 2870 Puurs, Belgium  <b>Novartis Pharma Stein AG</b> , Schaffhauserstrasse, 4332 Stein, Switzerland  <b>Mibe GmbH Arzneimittel</b> , Münchener Straße 15, 06796 Brehna, Germany  <b>Pharmacia &amp; Upjohn Company LLC</b> , 7000 Portage Road Kalamazoo, MI 49001, USA  <b>Hospira Inc., a Pfizer company</b> , 1776 Centennial Drive, McPherson, Kansas 67460, USA	<a href="#">Approved: 31st December 2020</a>  Additional sites approved: <a href="#">16th July, 2021</a>
<b>AstraZeneca-Oxford + SK Bioscience (supplier)* (AZD1222)</b>	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M. 2°C to 8°C (6 mo.)	WHO EUL + South Korea via COVAX / PAHO + CARPHA	<b>SK Bioscience</b> , 150, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea	<a href="#">Approved: 15th February</a>
<b>Serum Institute of India + AstraZeneca-Oxford University (AZD1222; Covishield™)</b>	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M. 2°C to 8°C (6 mo.)	WHO EUL + CARPHA + 45 countries	<b>Serum Institute of India Pvt. Ltd</b> , 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, (India) - 411028	<a href="#">Approved: 15th February</a>
<b>Janssen-Cilag (Johnson &amp; Johnson) (JNJ-78436735)</b>	Viral vector (non-replicating)	1 dose I.M.  -25°C to -15°C (24 mo.)  2-8°C (4.5 mo. within shelf-life)	WHO EUL + CARPHA + 66 countries	<b>Janssen Biologics B.V.</b> , Einsteinweg 101, 2333 CB Leiden, The Netherlands  <b>Janssen Pharmaceutica NV</b> , Turnhoutseweg 30, 2340 Beerse, Belgium  <b>Aspen SVP.</b> , 8B Gibaud Road, Korsten, Port Elizabeth 6020, South Africa  <b>Catalent Indiana LLC.</b> , 1300 S Patterson Drive, Bloomington. Indiana (IN) 47403, USA.  <b>Grand River Aseptic Manufacturing Inc.</b> 140 Front Ave. SW. Grand Rapids, Michigan (MI) 49504, USA.  <b>Catalent Anagni S.R.L.</b> , Fontana del Ceraso SNC, Strada Provinciale 12, Casilina 41, 03012 Anagni, Italy.	<a href="#">Approved: 12th March;</a>

Developers (Vaccine name)	Vaccine Platform	Dosing and Storage ¥	Authorized by	WHO Approved Drug Product site(s)	WHO EUL status and anticipated decision date:
<b>AstraZeneca-Oxford University</b> (AZD1222) Commercial name: VAXZEVRIA™	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M.  2°C to 8°C (6 mo.)	WHO EUL + CARPHA + 122 countries	<b>Catalent Anagni</b> , Località Fontana del Ceraso, S.P. Casilina, 41 03012, Anagni (FR), Italy  <b>CP Pharmaceuticals</b> , Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom.  <b>IDT Biologika</b> , Am Pharmapark, Dessau-Rosslau 06861, Germany  <b>SK Bioscience</b> , 150, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea  <b>Universal Farma, S.L.</b> ("Chemo"), C/Del Tejido, 2, Azogueca de Henares, Guadalajara, 19200, Spain  <b>Amylin Ohio LLC (AZ)</b> , 8814 Trade Port Drive, West Chester, OH 45071, USA	<a href="#">Approved: 16th April</a>
<b>Moderna &amp; NIAID</b> (mRNA-1273) INN: Elasmolan  <b>ModernaTX, Inc/</b> USFDA COVID-19 mRNA vaccine	mRNA-based in lipid nanoparticle (LNP)	2 doses I.M.  -25°C to -15°C (7 mo.);  2-8°C (30d) or 9-25°C (12h)	WHO EUL + CARPHA + 72 countries	<b>Rovi Pharma Industrial Services, S.A.</b> San Sebastián de los Reyes, Paseo de Europa, 50, 28703. San Sebastián de los Reyes, Madrid, Spain  <b>Baxter Pharmaceutical Solutions, LLC</b> , 927 S. Curry Pike, Bloomington, IN 47403, USA.  <b>Catalent Indiana, LLC</b> , 1300 South Patterson Drive, Bloomington, IN 47403, USA	<a href="#">Approved: 30th April</a>  Additional sites approved: <a href="#">6th August, 2021</a>
<b>Sinopharm + China National Pharmaceutical Group + Beijing Institute of Biological Products</b> (BBIBP-CorV)	Inactivated virus	2 doses I.M.  2°C to 8°C (24 mo.)	WHO EUL + CARPHA + 64 countries	<b>Beijing Institute of Biological Products Co., Ltd.</b> , kNo. 6 (East Part) and No. 9 (West Part), Boxing 2nd Road, Beijing Economic and Technological Development Area, Beijing, the People's Republic of China, 100176.	<a href="#">Approved: 7<sup>th</sup> May</a>
<b>Sinovac COVID-19 vaccine (Vero Cell [Inactivated])</b> – Commercial name: CoronaVac	Inactivated virus	2 doses I.M.  2°C to 8°C (12 mo.)	WHO EUL + CARPHA + 40 countries	<b>Sinovac Life Sciences Co., Ltd.</b> , No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China.	<a href="#">Approved: 1<sup>st</sup> June</a>
<b>AstraZeneca-Oxford University (AZD1222)/</b> TGA, Australia	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M.  2°C to 8°C (6 mo.)	WHO EUL + CARPHA + 122 countries	<b>Catalent Anagni S.R.L.</b> , Località Fontana del Ceraso S.P. Casilina, 41 03012 Anagni (FR) Italy.  <b>IDT Biologika GmbH</b> , Am Pharmapark, Dessau-Rosslau 06861 Sachsen-Anhalt, Germany.  <b>Seqirus Pty Ltd.</b> , 39-79 Poplar Road Parkville, Vic, 3052 Australia.  <b>CP Pharmaceuticals Limited</b> , Ash Road North, Wrexham Industrial Estate. Wrexham LL13 9UF, UK.	<a href="#">Approved: 9th July</a>
<b>AstraZeneca-Oxford University (AZD1222)/</b> MHLW, Japan	Recombinant ChAdOx1-S	2 doses I.M.	WHO EUL + CARPHA + 122 countries	<b>Catalent Anagni S.R.L.</b> , Contrada Fontana del Ceraso 03012. Anagni, Italy.	<a href="#">Approved: 9th July</a>



Developers (Vaccine name)	Vaccine Platform	Dosing and Storage ¥	Authorized by	WHO Approved Drug Product site(s)	WHO EUL status and anticipated decision date:
	adenoviral vector	2°C to 8°C (6 mo.)		<b>Daiichi Sankyo Biotech Co., LTD.</b> , Kitamoto Site. 6-111, Arai, Kitamoto City, Saitama, Japan.  <b>KM Biologics Co. Ltd.</b> , Koshi Production Center. 3766-1, Sakae, Koshi-shi, Kumamoto, Japan.	
<b>WHO EUL status – Pending/Not under review yet (Not eligible for CRS review)</b>					
<b>Gamaleya Research Institute &amp; Russian Health Ministry</b> (Sputnik V)	Adenovirus Viral vector (non-replicating)	2 doses I.M. 2°C to 8°C	71 countries	Not applicable	On hold, awaiting completion of rolling submission
<b>CanSino Biological Inc + Beijing Institute of Biological Products</b> (Convidicea (Ad5-nCoV))	Adenovirus; Viral vector (non-replicating)	1 dose I.M. 2°C to 8°C	9 countries	Not applicable	Rolling data started 09 August 2021
<b>NOVAVAX</b> (NVX-CoV2373)	Protein subunit	2 doses I.M. 2°C to 8°C	None to date	Not applicable	Rolling data starting in August 2021
<b>Sinopharm + China National Pharma. Group + Wuhan Institute of Biol. Products</b>	Inactivated virus	2 doses I.M. 2°C to 8°C	2 countries	Not applicable	Rolling data started 23 July 2021
<b>CureVac</b> (Zorecimeran: CVnCoV/CV07050101)	mRNA-based in lipid nanoparticle	2 doses I.M. 2°C to 8°C	None to date	Not applicable	Planned for Q4 of 2021
<b>Vector State Research Ctr of Virology and Biotech.</b> (EpiVacCorona)	Peptide vaccine	2 doses I.M. 2°C to 8°C	2 countries	Not applicable	Pending expression of interest
<b>Anhui Zhifei Longcom Biopharmaceutical, China + IMBCAMS</b> (ZF2001)	Recombinant (protein subunit)	2 or 3 Doses I.M. 2°C to 8°C	2 countries	Not applicable	Additional information requested
<b>Bharat Biotech + Indian Council of Medical Research (ICMR)</b> (Covaxin)	Whole virion inactivated	2 Doses I.M. 2°C to 8°C	9 countries	Not applicable	Rolling data started 06 July 2021
<b>Sanofi Pasteur</b> CoV2 preS dTM-AS03 vaccine	Recombinant, adjuvanted	2 Doses I.M. 2°C to 8°C	None to date	Not applicable	Rolling data started 30 July 2021
<b>Clover Biopharmaceuticals Inc. + GSK + Dynavax</b> (SCB-2019)	Protein subunit	2 doses I.M. 2°C to 8°C	None to date	Not applicable	Pre-submission meeting: Being planned



Developers (Vaccine name)	Vaccine Platform	Dosing and Storage †	Authorized by	WHO Approved Drug Product site(s)	WHO EUL status and anticipated decision date:
<b>BioCubaFarma – Cuba</b> (Soberana 01, Soberana 02 Soberana Plus, Abdala)	SARS-CoV-2 spike protein	2 doses I.M. 2°C to 8°C	None to date	Not applicable	In discussion on submission strategy and timelines
<b>Serum Institute of India + Novavax Inc.</b> NVX-CoV2373/ Covovax	Protein subunit	2 doses I.M. 2°C to 8°C	None to date	Not applicable	Rolling data starting in August 2021

† - Storage information is provided primarily for sealed vials. See product information for additional details on storage and handling.

#### References:

McGill COVID19 Vaccine Tracker. **COVID-19 Vaccines**. Updated 24<sup>th</sup> September, 2021. Available at: <https://covid19.trackvaccines.org/>.

World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 19<sup>th</sup> August 2021. WHO, Geneva, 2020. Available at: <https://www.who.int/teams/regulation-prequalification/eul/covid-19>.

World Health Organization. **Draft landscape of COVID-19 candidate vaccines**. WHO, Geneva, 24<sup>th</sup> September 2021. Available at: [Draft landscape of COVID-19 candidate vaccines \(who.int\)](https://www.who.int/teams/regulation-prequalification/eul/covid-19).

World Health Organization. **Emergency Use Listing Procedure for Vaccines**. WHO, Geneva 2021. Available at: <https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines>.